CHEMICAL SAFETY REPORT

Substance Name: dipotassium hexachloroplatinate
EC Number: 240-979-3
CAS Number: 16921-30-5
Registrant's Identity:

Table of Contents

Part A 10
1. SUMMARY OF RISK MANAGEMENT MEASURES 11
2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED 12
3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED 13
Part B 14
1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES 15
1.1. Name and other identifiers of the substance 15
1.2. Composition of the substance 16
1.3. Assessment entity information 17
1.4. Physicochemical properties 18
2. MANUFACTURE AND USES 22
2.1. Manufacture 22
2.2. Identified uses 22
3. CLASSIFICATION AND LABELLING 24
3.1. Classification and labelling according to CLP / GHS 24
4. ENVIRONMENTAL FATE PROPERTIES 31
4.1. Degradation 31
4.1.1. Abiotic degradation 31
4.1.1.1. Hydrolysis 31
4.1.1.2. Phototransformation/photolysis 31
4.1.1.2.1. Phototransformation in air 31
4.1.1.2.2. Phototransformation in water 31
4.1.1.2.3. Phototransformation in soil 31
4.1.2. Biodegradation 31
4.1.2.1. Biodegradation in water 31
4.1.2.1.1. Screening tests 31
4.1.2.1.2. Simulation tests (water and sediments) 32
4.1.2.1.3. Summary and discussion of biodegradation in water and sediment 32
4.1.2.2. Biodegradation in soil 32
4.2. Environmental distribution 32
4.2.1. Adsorption/desorption 32
4.2.2. Volatilisation 35
4.2.3. Distribution modelling 35
4.3. Bioaccumulation 35
4.3.1. Aquatic bioaccumulation 35
4.3.2. Terrestrial bioaccumulation 35
4.3.3. Summary and discussion of bioaccumulation 35
4.4. Secondary poisoning 35
5. HUMAN HEALTH HAZARD ASSESSMENT 36
5.1. Toxicokinetics (absorption, metabolism, distribution and elimination) 36
5.1.1. Non-human information 36
5.1.2. Human information 36
5.1.3. Summary and discussion of toxicokinetics 36
5.2. Acute toxicity 40
5.2.1. Non-human information 40
5.2.1.1. Acute toxicity: oral 40
5.2.1.2. Acute toxicity: inhalation 40
5.2.1.3. Acute toxicity: dermal 41
5.2.1.4. Acute toxicity: other routes 41
5.2.2. Human information 41
5.2.3. Summary and discussion of acute toxicity 41
5.3. Irritation 43
5.3.1. Skin 43
5.3.1.1. Non-human information 43

5.3.1.2. Human information 44
5.3.2. Eye 45
5.3.2.1. Non-human information 45
5.3.2.2. Human information 45
5.3.3. Respiratory tract 45
5.3.3.1. Non-human information 45
5.3.3.2. Human information 45
5.3.4. Summary and discussion of irritation 45
5.4. Corrosivity 47
5.4.1. Non-human information 47
5.4.2. Human information 47
5.4.3. Summary and discussion of corrosion 47
5.5. Sensitisation 48
5.5.1. Skin 48
5.5.1.1. Non-human information 48
5.5.1.2. Human information 52
5.5.2. Respiratory system 54
5.5.2.1. Non-human information 54
5.5.2.2. Human information 54
5.5.3. Summary and discussion of sensitisation 59
5.6. Repeated dose toxicity 72
5.6.1. Non-human information 72
5.6.1.1. Repeated dose toxicity: oral 72
5.6.1.2. Repeated dose toxicity: inhalation 73
5.6.1.3. Repeated dose toxicity: dermal 73
5.6.1.4. Repeated dose toxicity: other routes 73
5.6.2. Human information 74
5.6.3. Summary and discussion of repeated dose toxicity 74
5.7. Mutagenicity 75
5.7.1. Non-human information ..... **Error! Bookmark not defined.**
5.7.1.1. In vitro data ..... **Error! Bookmark not defined.**
5.7.1.2. In vivo data ..... **Error! Bookmark not defined.**
5.7.2. Human information ..... **Error! Bookmark not defined.**
5.7.3. Summary and discussion of mutagenicity ..... **Error! Bookmark not defined.**
5.8. Carcinogenicity 83
5.8.1. Non-human information 83
5.8.1.1. Carcinogenicity: oral 83
5.8.1.2. Carcinogenicity: inhalation 83
5.8.1.3. Carcinogenicity: dermal 84
5.8.1.4. Carcinogenicity: other routes 84
5.8.2. Human information 84
5.9. Toxicity for reproduction 84
5.9.1. Effects on fertility 84
5.9.1.1. Non-human information 84
5.9.1.2. Human information 85
5.9.2. Developmental toxicity 85
5.9.2.1. Non-human information 85
5.9.2.2. Human information 86
5.9.3. Summary and discussion of reproductive toxicity 86
5.10. Other effects 89
5.10.1. Non-human information 89
5.10.1.1. Neurotoxicity 89
5.10.1.2. Immunotoxicity 89
5.10.1.3. Specific investigations: other studies 89
5.10.1.4. Additional toxicological effects 89
5.10.2. Human information 89
5.11. Derivation of DNEL(s) and other hazard conclusions 89
5.11.1. Overview of typical dose descriptors for all endpoints 89
5.11.2. Selection of the DNEL(s) or other hazard conclusions for critical health effects 90
6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES 102

6.1. Explosivity 102
6.2. Flammability 102
6.3. Oxidising potential 103
7. ENVIRONMENTAL HAZARD ASSESSMENT 117
7.1. Aquatic compartment (including sediment) 117
7.1.1. Fish 117
7.1.1.1. Short-term toxicity to fish 117
7.1.1.2. Long-term toxicity to fish 118
7.1.2. Aquatic invertebrates 118
7.1.2.1. Short-term toxicity to aquatic invertebrates 118
7.1.2.2. Long-term toxicity to aquatic invertebrates 120
7.1.3. Algae and aquatic plants 120
7.1.4. Sediment organisms 124
7.1.5. Other aquatic organisms 124
7.2. Terrestrial compartment 124
7.2.1. Toxicity to soil macro-organisms 124
7.2.2. Toxicity to terrestrial plants 125
7.2.3. Toxicity to soil micro-organisms 125
7.2.4. Toxicity to other terrestrial organisms 125
7.3. Atmospheric compartment 125
7.4. Microbiological activity in sewage treatment systems 125
7.5. Non compartment specific effects relevant for the food chain (secondary poisoning) 127
7.5.1. Toxicity to birds 127
7.5.2. Toxicity to mammals 127
7.6. PNEC derivation and other hazard conclusions 127
7.6.1. PNEC derivation and other hazard conclusions 127
8. PBT AND vPvB ASSESSMENT 132
8.1. Assessment of PBT/vPvB Properties 132
8.1.1. PBT/vPvB criteria and justification 132
8.1.2. Summary and overall conclusions on PBT or vPvB properties 132
8.2. Emission characterisation 132
9. EXPOSURE ASSESSMENT (and related risk characterisation) 133
9.0. Introduction 133
9.0.1. Overview on uses 133
9.0.2. Assessment entity groups 133
9.0.3. Introduction to the assessment for the environment 133
9.0.3.1. Tonnage 133
9.0.3.2. Scope and type of assessment for the environment 134
9.0.3.3. Fate and distribution parameters 134
9.0.3.4. Comments on assessment approach for the environment 135
9.0.3.5. Scope and type of assessment for man via environment 136
9.0.4. Introduction to the assessment for workers 136
9.0.4.1. Scope and type of assessment for workers 136
9.0.4.2. Comments on assessment approach for workers 137
9.0.5. Introduction to the assessment for consumers 139
9.1. Exposure scenario 1: Manufacture - Manufacture of the substance (as such) 140
9.1.1. Env CS 1: Manufacture of the substance (as such) ES 1.1 (ERC 1) 140
9.1.1.1. Conditions of use 140
9.1.1.2. Releases 141
9.1.1.3. Exposure and risks for the environment and man via the environment 142
9.1.2. Env CS 2: Manufacture of the substance (as such) ES 1.2 (ERC 1) 142
9.1.2.1. Conditions of use 142
9.1.2.2. Releases 143
9.1.2.3. Exposure and risks for the environment and man via the environment 143
9.1.3. Worker CS 3: Raw material handling of dry/dusty materials (PROC 26) 143
9.1.3.1. Conditions of use 144
9.1.3.2. Exposure and risks for workers 144
9.1.4. Worker CS 4: Raw material handling of non to low dusty platinum substances (PROC 21) 145
9.1.4.1. Conditions of use 145

9.1.4.2. Exposure and risks for workers 146
9.1.5. Worker CS 5: Raw material handling of liquid platinum substances (PROC 8b, PROC 9) 147
9.1.5.1. Conditions of use 147
9.1.5.2. Exposure and risks for workers 148
9.1.6. Worker CS 6: Raw material handling of platinum substances in fully contained systems (PROC 1) 149
9.1.6.1. Conditions of use 149
9.1.6.2. Exposure and risks for workers 150
9.1.7. Worker CS 7: Sampling/Evaluation of solid platinum substances (PROC 15) 150
9.1.7.1. Conditions of use 151
9.1.7.2. Exposure and risks for workers 151
9.1.8. Worker CS 8: Sampling/Evaluation of liquid platinum substances (PROC 15) 152
9.1.8.1. Conditions of use 152
9.1.8.2. Exposure and risks for workers 153
9.1.9. Worker CS 9: Wet processing in fully contained systems (PROC 1) 154
9.1.9.1. Conditions of use 154
9.1.9.2. Exposure and risks for workers 155
9.1.10. Worker CS 10: Wet processing in not fully contained systems (PROC 2, PROC 3; PROC 4; PROC 5) 156
9.1.10.1. Conditions of use 156
9.1.10.2. Exposure and risks for workers 157
9.1.11. Worker CS 11: Separation/Filtration in fully contained systems (PROC 1) 158
9.1.11.1. Conditions of use 158
9.1.11.2. Exposure and risks for workers 158
9.1.12. Worker CS 12: Separation/Filtration of non to low dusty platinum substances (PROC 2, PROC 3; PROC 4) 159
9.1.12.1. Conditions of use 159
9.1.12.2. Exposure and risks for workers 160
9.1.13. Worker CS 13: Separation/Filtration of liquid platinum substances (PROC 2, PROC 3; PROC 4) 161
9.1.13.1. Conditions of use 161
9.1.13.2. Exposure and risks for workers 162
9.1.14. Worker CS 14: Washing/Drying in fully contained systems (PROC 1) 163
9.1.14.1. Conditions of use 163
9.1.14.2. Exposure and risks for workers 164
9.1.15. Worker CS 15: Washing/Drying of non to low dusty platinum substances (PROC 2, PROC 3; PROC 4) 164
9.1.15.1. Conditions of use 164
9.1.15.2. Exposure and risks for workers 165
9.1.16. Worker CS 16: Washing/Drying of liquid platinum substances (PROC 2, PROC 3) 166
9.1.16.1. Conditions of use 166
9.1.16.2. Exposure and risks for workers 167
9.1.17. Worker CS 17: Washing/Drying at elevated temperature (PROC 2, PROC 3) 168
9.1.17.1. Conditions of use 168
9.1.17.2. Exposure and risks for workers 169
9.1.18. Worker CS 18: Calcination in fully contained systems (PROC 1) 169
9.1.18.1. Conditions of use 170
9.1.18.2. Exposure and risks for workers 170
9.1.19. Worker CS 19: Milling/Grinding/Sieving (PROC 1) 171
9.1.19.1. Conditions of use 171
9.1.19.2. Exposure and risks for workers 172
9.1.20. Worker CS 20: Packaging/Filling of dry/dusty platinum substances (PROC 26) 172
9.1.20.1. Conditions of use 173
9.1.20.2. Exposure and risks for workers 173
9.1.21. Worker CS 21: Packaging/Filling of non to low dusty platinum substances (PROC 21) 174
9.1.21.1. Conditions of use 174
9.1.21.2. Exposure and risks for workers 175

9.1.22. Worker CS 22: Packaging/Filling of liquid platinum substances (PROC 8b, PROC 9) 176
9.1.22.1. Conditions of use 176
9.1.22.2. Exposure and risks for workers 177
9.1.23. Worker CS 23: Packaging/Filling in fully contained systems (PROC 1) 178
9.1.23.1. Conditions of use 178
9.1.23.2. Exposure and risks for workers 179
9.1.24. Worker CS 24: Cleaning and maintenance: vacuum cleaning (PROC 26) 179
9.1.24.1. Conditions of use 180
9.1.24.2. Exposure and risks for workers 180
9.1.25. Worker CS 25: Cleaning and maintenance: wet cleaning (PROC 8a) 181
9.1.25.1. Conditions of use 181
9.1.25.2. Exposure and risks for workers 182
9.2. Exposure scenario 2: Use at industrial sites - Use as an intermediate 184
9.2.1. Env CS 1: Use as an intermediate ES 1.1 (ERC 6a) 184
9.2.1.1. Conditions of use 184
9.2.1.2. Releases 185
9.2.1.3. Exposure and risks for the environment and man via the environment 185
9.2.2. Env CS 2: Use as an intermediate ES 1.2 (ERC 6a) 186
9.2.2.1. Conditions of use 186
9.2.2.2. Releases 186
9.2.2.3. Exposure and risks for the environment and man via the environment 187
9.2.3. Worker CS 3: Handling of medium/high dusty materials (PROC 26) 187
9.2.3.1. Conditions of use 187
9.2.3.2. Exposure and risks for workers 188
9.2.4. Worker CS 4: Handling of low dusty materials (PROC 26) 189
9.2.4.1. Conditions of use 189
9.2.4.2. Exposure and risks for workers 190
9.2.5. Worker CS 5: Handling of solutions and reaction (PROC 3, PROC 15; PROC 4; PROC 5; PROC 8b; PROC 9) 191
9.2.5.1. Conditions of use 191
9.2.5.2. Exposure and risks for workers 192
9.2.6. Worker CS 6: Fully contained process (PROC 1) 193
9.2.6.1. Conditions of use 193
9.2.6.2. Exposure and risks for workers 193
9.2.7. Worker CS 7: Reaction process (furnace operation) (PROC 22) 194
9.2.7.1. Conditions of use 194
9.2.7.2. Exposure and risks for workers 195
9.2.8. Worker CS 8: Hot powder production (PROC 27a) 196
9.2.8.1. Conditions of use 196
9.2.8.2. Exposure and risks for workers 197
9.2.9. Worker CS 9: Wet powder production (PROC 27b) 198
9.2.9.1. Conditions of use 198
9.2.9.2. Exposure and risks for workers 199
9.2.10. Worker CS 10: Wet cleaning (PROC 8a) 200
9.2.10.1. Conditions of use 200
9.2.10.2. Exposure and risks for workers 200
9.2.11. Worker CS 11: Vacuum cleaning (PROC 26) 201
9.2.11.1. Conditions of use 201
9.2.11.2. Exposure and risks for workers 202
10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE 204
10.1. Human health 204
10.1.1. Workers 204
10.1.2. Consumer 204
10.2. Environment (combined for all emission sources) 204
10.2.1. All uses (regional scale) 204
10.2.1.1. Total releases 204
10.2.2. Regional assessment 204
10.2.3. Local exposure due to all widespread uses 205
10.2.4. Local exposure due to combined uses at a site 205

Annexes 206
1. Annex: References 207
2. Annex: Information on Test Material 211
3. Annex: Mode of action / Human relevance Framework 221

List of Tables

1.1. Substance identity 15
1.2. Constituents (Dipotassium hexachloroplatinate - Registration boundary conditions) 17
1.3. Impurities (Dipotassium hexachloroplatinate - Registration boundary conditions) 17
1.4. Constituents (Dipotassium hexachloroplatinate) 17
1.5. Impurities (Dipotassium hexachloroplatinate) 17
1.6. Physicochemical properties 18
2.1. Manufacture 22
2.2. Uses at industrial sites 22
3.1. Classification and labelling according to CLP / GHS for physicochemical properties 24
3.2. Classification and labelling according to CLP / GHS for health hazards 25
3.3. Classification and labelling according to CLP / GHS for environmental hazards 25
3.4. Classification and labelling according to CLP / GHS for physicochemical properties 27
3.5. Classification and labelling according to CLP / GHS for health hazards 28
3.6. Classification and labelling according to CLP / GHS for environmental hazards 28
4.1. Studies on adsorption/desorption 32
5.1. Studies on acute toxicity after oral administration 40
5.2. Studies on skin irritation 43
5.3. Studies on eye irritation 45
5.4. Studies on skin sensitisation 48
5.5. Exposure-related observations on skin sensitisation in humans 52
5.6. Exposure-related observations on respiratory sensitisation in humans 54
5.7. Studies on repeated dose toxicity after oral administration 73
5.8. In vitro genotoxicity studies: ..... **Error! Bookmark not defined.**
5.9. Studies on fertility 84
5.10. Studies on developmental toxicity 85
5.11. Available dose-descriptor(s) per endpoint as a result of its hazard assessment 89
5.12. Hazard conclusions for workers 90
5.13. Hazard conclusions for the general population 98
6.1. Information on flammability 102
6.2. Information on oxidising potential 103
7.1. Short-term effects on fish 117
7.2. Short-term effects on aquatic invertebrates 118
7.3. Long-term effects on aquatic invertebrates 120
7.4. Effects on algae and aquatic plants 120
7.5. Effects on soil macro-organisms 124
7.6. Effects on terrestrial arthropods 125
7.7. Effects on micro-organisms 125
7.8. Hazard assessment conclusion for the environment 127
9.1. Assessment entity groups 133
9.2. Tonnage for assessment 133
9.3. Type of risk characterisation required for the environment 134
9.4. Substance key phys-chem and fate properties 134
9.5. Type of risk characterisation required for workers 136
9.6. Local releases to the environment 141
9.7. Exposure concentrations and risks for the environment and man via the environment 142
9.8. Local releases to the environment 143
9.9. Exposure concentrations and risks for the environment and man via the environment 143
9.10. Exposure concentrations and risks for workers 145
9.11. Exposure concentrations and risks for workers 146
9.12. Exposure concentrations and risks for workers 148
9.13. Exposure concentrations and risks for workers 150
9.14. Exposure concentrations and risks for workers 152
9.15. Exposure concentrations and risks for workers 153
9.16. Exposure concentrations and risks for workers 155
9.17. Exposure concentrations and risks for workers 157

9.18. Exposure concentrations and risks for workers 159
9.19. Exposure concentrations and risks for workers 160
9.20. Exposure concentrations and risks for workers 162
9.21. Exposure concentrations and risks for workers 164
9.22. Exposure concentrations and risks for workers 165
9.23. Exposure concentrations and risks for workers 167
9.24. Exposure concentrations and risks for workers 169
9.25. Exposure concentrations and risks for workers 170
9.26. Exposure concentrations and risks for workers 172
9.27. Exposure concentrations and risks for workers 174
9.28. Exposure concentrations and risks for workers 175
9.29. Exposure concentrations and risks for workers 177
9.30. Exposure concentrations and risks for workers 179
9.31. Exposure concentrations and risks for workers 180
9.32. Exposure concentrations and risks for workers 182
9.33. Local releases to the environment 185
9.34. Exposure concentrations and risks for the environment and man via the environment 185
9.35. Local releases to the environment 186
9.36. Exposure concentrations and risks for the environment and man via the environment 187
9.37. Exposure concentrations and risks for workers 188
9.38. Exposure concentrations and risks for workers 190
9.39. Exposure concentrations and risks for workers 192
9.40. Exposure concentrations and risks for workers 193
9.41. Exposure concentrations and risks for workers 195
9.42. Exposure concentrations and risks for workers 197
9.43. Exposure concentrations and risks for workers 199
9.44. Exposure concentrations and risks for workers 200
9.45. Exposure concentrations and risks for workers 202
10.1. Total releases to the environment per year from all life cycle stages 204
10.2. Predicted regional exposure concentrations (Regional PEC) and risks for the environment 205

Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

The risk management measures for all Exposure Scenarios are described in Chapters 9 and 10 of part B of this CSR.

The above part A element applies to: CSR (all uses)

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

Each EU manufacturer and importer, having decided to mandate the Lead Registrant to submit this CSR on his behalf, endorses the declaration that he implements those risk management measures described in Part B, Chapter 9+10 of this document, that are relevant to his manufacture or import and own uses. Registrants that submit their own Part A are excluded from the afore-mentioned endorsement.

The above part A element applies to: CSR (all uses)

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

Each EU manufacturer, importer and Only Representative having decided to mandate the Lead Registrant to submit this CSR on his behalf endorses the declaration that he communicates to distributors and the downstream users those risk management measures that are relevant for their uses as described in Part B, Section 9+10 of this document. Registrants that submit their own Part A are excluded from the afore-mentioned endorsement.

The above part A element applies to: CSR (all uses)

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

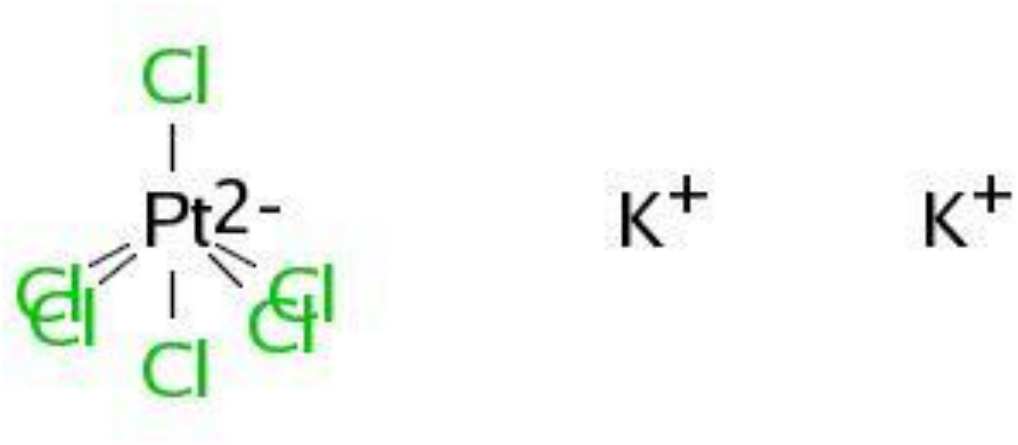
1.1. Name and other identifiers of the substance

The substance dipotassium hexachloroplatinate is a mono-constituent substance (inorganic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).
The following public name is used:

Table 1.1. Substance identity

EC number:	240-979-3
EC name:	dipotassium hexachloroplatinate
CAS number (EC inventory):	16921-30-5
CAS number:	16921-30-5
IUPAC name:	dipotassium hexachloroplatinate(2-)
Synonyms:	Platinate(2-), hexachloro-, dipotassium, (OC-6-11)- Platinate(2-), hexachloro-, dipotassium, (OC-6-11)-
Molecular formula:	Cl6Pt.2K
Molecular weight range:	485.999

Structural formula:



1.2. Composition of the substance

Overall information on composition:

Composition	Related composition(s)	Related assessment entity
Dipotassium hexachloroplatinate - Registration boundary conditions (boundary composition of the substance)		dipotassium hexachloroplatinate Pt(IV) dissolved
Dipotassium hexachloroplatinate (legal entity composition of the substance)		dipotassium hexachloroplatinate

Name: Dipotassium hexachloroplatinate - Registration boundary conditions

(boundary composition of the substance)
State/form: solid: particulate/powder

Degree of purity: >=99 - <=100 % (w/w)
Description: Mono-constituent substance

Table 1.2. Constituents (Dipotassium hexachloroplatinate - Registration boundary conditions)

Constituent	Typical concentration	Concentration range	Remarks
dipotassium hexachloroplatinate EC no.: 240-979-3	>99 % (w/w)	>=99 - <=100 % (w/w)	

Table 1.3. Impurities (Dipotassium hexachloroplatinate - Registration boundary conditions)

Constituent	Typical concentration	Concentration range	Remarks
Impurities EC no.:	<1 % (w/w)	>=0 - <=1 % (w/w)	Several minor (especially metallic, e.g. Ag, Au, Cu, Ir, Pb, Pd, Rh, Ru) impurities which do not affect the classification of the substance because of their non-hazardous nature or because they do not exceed the classification cut-off limits in the substance

Name: Dipotassium hexachloroplatinate

(legal entity composition of the substance)
State/form: solid: particulate/powder
Degree of purity: % (w/w)
Description: Mono-constituent substance

Table 1.4. Constituents (Dipotassium hexachloroplatinate)

Constituent	Typical concentration	Concentration range	Remarks
dipotassium hexachloroplatinate EC no.: 240-979-3	% (w/w)	% (w/w)	

Table 1.5. Impurities (Dipotassium hexachloroplatinate)

Constituent	Typical concentration	Concentration range	Remarks
Impurities EC no.:	% (w/w)	% (w/w)	Several minor (especially metallic, e.g. Ag, Au, Cu, Ir, Pb, Pd, Rh, Ru) impurities which do not affect the classification of the substance because of their non-hazardous nature or because they do not exceed the classification cut-off limits in the substance

1.3. Assessment entity information

Assessment entity name	Remarks

dipotassium hexachloroplatinate	Assessment entity composition: The composition(s) for this assessment entity is the one listed in section 1.2 (Composition of the Substance)
Pt(IV) dissolved	Assessment entity composition: platinum EC no.: 231-116-1 Additional information: **For this category of platinum(IV) substances, it is proposed that, in environmental media, the substances (partly) dissolve. Only the dissolved species are capable of exerting effects on organisms. The counterions dissociate from the platinum moiety / platinum complex with the formation of [Pt(OH)2]0as the dominant Pt species upon equilibrium and a free Pt-ion concentration that is vanishingly low (<<10-10M). It should be noted that this represents a chemical transformation and not a "biotransformation". The counterions do not contribute significantly to the observed effect(s), and these effects (expressed as dissolved platinum concentration) are similar for the different category members.**

1.4. Physicochemical properties

Table 1.6. Physicochemical properties

Property	Value used for CSA / Discussion	Description of key information	Assessment entity linked
Physical state	**solid at 20°C and 101.3 kPa** The CRC handbook (Lide 2008) is a peer-reviewed handbook and so can be considered reliable and suitable for use as the key study for this endpoint. At 20ºC and 1013 hPa potassium hexachloroplatinate is an inorganic solid of yellow orange cubic crystals.	At 20ºC and 1013 hPa potassium hexachloroplatinate is an inorganic solid of yellow orange cubic crystals.	Pt(IV) dissolved
Melting / freezing point	The CRC Handbook (Lide, 2008) is a peer-reviewed handbook and so can be considered reliable and suitable for use as the key study for this endpoint. Dipotassium hexachloroplatinate decomposes before it melts. The decomposition temperature is 250°C.	Dipotassium hexachloroplatinate decomposes before it melts. The decomposition temperature is 250°C.	Pt(IV) dissolved
Relative density	**3.5 at 20°C** The CRC Handbook (Lide, 2008) is a reliable peer reviewed handbook and so can be considered reliable and suitable for use as the key study	The density of potassium hexachloroplatinate is 3.5 g/cm3	Pt(IV) dissolved

	for this endpoint. The density of potassium hexachloroplatinate is 3.5g/cm3.		
Granulometry	Tremain & Atwal (2011) is a GLP compliant study following OECD guideline 110 and is considered to be suitable for use as the key study for this endpoint. The proportion of dipotassium hexachloroplatinate < 100 µm is 77.93%.	The proportion of dipotassium hexachloroplatinate <100 µm was 77.93%.	
Vapour pressure	**0Pa at 20°C** Dipotassium hexachloroplatinate is an inorganic non volatile substance. A very low value has been included for the exposure assessment.		Pt(IV) dissolved
Water solubility	**11g/L at 20°C** Gregory (2014) is a published article in peer-reviewed literature. Water solubility was measured following OECD TG 105, and the results are considered to be suitable for use as the key study for this endpoint. The water solubility of dipotassium hexachloroplatinate was determined to be 11.0 g/L. Lide (2008) is a peer-reviewed handbook and results from this handbook are considered to be suitable for use as supporting data. The solubility of potassium hexachloroplatinate is 0.77g/100g H2O at 20°C.	The water solubility of dipotassium hexachloroplatinate was determined to be 11.0 g/L.	Pt(IV) dissolved
Autoflammability / self-ignition temperature	Tremain and Atwal (2011) is a GLP compliant study following a modified N4 guideline and is considered suitable for use as the key study for this endpoint. Dipotassium hexachloroplatinate showed no signs of self-ignition or self-heating over the duration of the test.	Dipotassium hexachloroplatinate showed no signs of self-ignition or self-heating over the duration of the test.	
Flammability	**not classified**		

	Tremain and Atwal (2011) is a GLP compliant study following UN N1 method and is considered suitable for use as the key study for this endpoint. Dipotassium hexachloroplatinate is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.	Dipotassium hexachloroplatinate is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.	
Oxidising properties	**non oxidising** The oxidising properties of dipotassium hexachloroplatinate are read across from other substances with co-ordinated chloride, in the 4+ oxidation state (tetraammonium decachloro-mu-oxodiruthenate and hexachloroplatinic acid). Neither of these substances are oxidising based on GLP-compliant studies following UN method O.1 (Tremain and Atwal 2011, Walker and White 2011), there is also supplementary evidence that other metal chlorides are also not oxidizing. For example, other Group VIII transition metals such as cobalt (II) chloride, iron (II), iron(III) and nickel(II) chloride. Copper(I) chloride from the adjacent Group IB is also not classified for oxidizing properties. There is therefore no evidence that any transition metal chloride is an oxidant. Supplementary evidence also comes from the non-transition metal chlorides and there is no evidence from two centuries of industrial and academic experience that these substances are oxidants. On the basis of read-across dipotassium hexachloroplatinate is not classified as an oxidising solid.	On the basis of read-across from other substances with co-ordinated chloride, in the 4 + oxidation state (tetraammonium decachloro-mu-oxodiruthenate and hexachloroplatinic acid), dipotassium hexachloroplatinate is not considered to be oxidising.	

Data waiving

Information requirement: Boiling point

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the substance is a solid which decomposes before boiling [study scientifically not necessary / other information available]

Information requirement: Vapour pressure

Reason: other justification

Justification: see Remarks - Dipotassium hexachloroplatinate is an inorganic substance that forms a crystal lattice. Upon heating, it decomposes at 250°C. It is scientifically not plausible that dipotassium hexachloroplatinate could exist in molecular form in the gas phase due to its solid state structure. Thus, the concept of vapour pressure, i.e. the saturation pressure above a solid or liquid does not apply. Dipotassium hexachloroplatinate is soluble in water and if it dissolves, it dissolves into ions, which cannot evaporate. In consequence, the testing for vapour pressure is waived for dipotassium hexachloroplatinate, since such testing would not provide any meaningful information on the substance, nor information applicable to the assessment of environmental fate or for any further animal or environmental studies

Information requirement: Partition coefficient n-octanol/water (log value)

Reason: study technically not feasible

Justification: the study does not need to be conducted because the substance is inorganic [study technically not feasible]

Information requirement: Surface tension

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because based on structure, surface activity is not expected or cannot be predicted [study scientifically not necessary / other information available] ; the study does not need to be conducted because surface activity is not a desired property of the material [study scientifically not necessary / other information available]

Information requirement: Flash point

Reason: study technically not feasible

Justification: the study does not need to be conducted because the substance is inorganic [study technically not feasible] ; the study does not need to be conducted because the flash point is only relevant to liquids and low melting point solids [study technically not feasible]

Information requirement: Explosive properties

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties [study scientifically not necessary / other information available]

Discussion of physicochemical properties

Additional information:

Physico-chemical endpoints are completed for this substance based on reliable test data for the substance itself, handbook data and suitable data waivers.

On the basis of extreme low pH and chloride content, dipotassium hexachloroplatinate is classified as Metal corrosivity category 1 (H290).

2. MANUFACTURE AND USES

2.1. Manufacture

Table 2.1. Manufacture

	Manufacture
M-1	**Manufacture of the substance (as such)** Further description of manufacturing process: Dipotassium hexachloroplatinate is built by reaction of concentrated aqueous Dihydrogen hexachloroplatinic acid with aqueous Potassium hydroxide. Due to low solubility, K2PtCl6precipitates immediately. It's separated washed and dried. Contributing activity/technique for the environment : **- Manufacture of the substance (as such) ES 1.1 (ERC1)** **- Manufacture of the substance (as such) ES 1.2 (ERC1)** Contributing activity/technique for the workers : **- Raw material handling of dry/dusty materials (PROC 26)** **- Raw material handling of non to low dusty platinum substances (PROC 21)** **- Raw material handling of liquid platinum substances (PROC 8b ; PROC 9)** **- Raw material handling of platinum substances in fully contained systems (PROC 1)** **- Sampling/Evaluation of solid platinum substances (PROC 15)** **- Sampling/Evaluation of liquid platinum substances (PROC 15)** **- Wet processing in fully contained systems (PROC 1)** **- Wet processing in not fully contained systems (PROC 2 ; PROC 3 ; PROC 4 ; PROC 5)** **- Separation/Filtration in fully contained systems (PROC 1)** **- Separation/Filtration of non to low dusty platinum substances (PROC 2 ; PROC 3 ; PROC 4)** **- Separation/Filtration of liquid platinum substances (PROC 2 ; PROC 3 ; PROC 4)** **- Washing/Drying in fully contained systems (PROC 1)** **- Washing/Drying of non to low dusty platinum substances (PROC 2 ; PROC 3 ; PROC 4)** **- Washing/Drying of liquid platinum substances (PROC 2 ; PROC 3)** **- Washing/Drying at elevated temperature (PROC 2 ; PROC 3)** **- Calcination in fully contained systems (PROC 1)** **- Milling/Grinding/Sieving (PROC 1)** **- Packaging/Filling of dry/dusty platinum substances (PROC 26)** **- Packaging/Filling of non to low dusty platinum substances (PROC 21)** **- Packaging/Filling of liquid platinum substances (PROC 8b ; PROC 9)** **- Packaging/Filling in fully contained systems (PROC 1)** **- Cleaning and maintenance: vacuum cleaning (PROC 26)** **- Cleaning and maintenance: wet cleaning (PROC 8a)** use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Related assessment: use assessed in a joint CSR

2.2. Identified uses

No information available on identified uses.

Table 2.2. Uses at industrial sites

	Uses at industrial sites

IW-1	**Use as an intermediate** Further description of the use: Contributing activity/technique for the environment : **- Use as an intermediate ES 1.1 (ERC6a)** **- Use as an intermediate ES 1.2 (ERC6a)** Contributing activity/technique for the workers : **- Handling of medium/high dusty materials (PROC 26)** **- Handling of low dusty materials (PROC 26)** **- Handling of solutions and reaction (PROC 3 ; PROC 4 ; PROC 5 ; PROC 8b ; PROC 9 ; PROC 15)** **- Fully contained process (PROC 1)** **- Reaction process (furnace operation) (PROC 22)** **- Hot powder production (PROC 27a)** **- Wet powder production (PROC 27b)** **- Wet cleaning (PROC 8a)** **- Vacuum cleaning (PROC 26)** **Sector of end use:** SU 9: Manufacture of fine chemicals ; SU 14: Manufacture of basic metals, including alloys **Technical function of the substance:** intermediate (precursor) use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Substance supplied to that use: as such ; in a mixture Subsequent service life relevant for that use: no Related assessment: use assessed in a joint CSR

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Substance: Dipotassium hexachloroplatinate - harmonised
Implementation: EU
Related composition: Boundary Composition
The substance is classified as follows:

Table 3.1. Classification and labelling according to CLP / GHS for physicochemical properties

Hazard class	Hazard category	Hazard statement	Reason for no classification
Explosives:			data conclusive but not sufficient for classification
Desensitised explosives:			data lacking
Flammable gases and chemically unstable gases:			data conclusive but not sufficient for classification
Flammable aerosols:			data conclusive but not sufficient for classification
Oxidising gases:			data conclusive but not sufficient for classification
Gases under pressure:			data conclusive but not sufficient for classification
Flammable liquids:			data conclusive but not sufficient for classification
Flammable solids:			data conclusive but not sufficient for classification
Self-reactive substances and mixtures:			data conclusive but not sufficient for classification
Pyrophoric liquids:			data conclusive but not sufficient for classification
Pyrophoric solids:			data conclusive but not sufficient for classification
Self-heating substances and mixtures:			data conclusive but not sufficient for classification
Substances and mixtures which in contact with water emit flammable gases:			data conclusive but not sufficient for classification
Oxidising liquids:			data conclusive but not sufficient for classification
Oxidising solids:			data conclusive but not sufficient for classification
Organic peroxides:			data conclusive but not sufficient for classification

Corrosive to metals:			data lacking

Table 3.2. Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral:	Acute Tox. 3	H301: Toxic if swallowed.	
Acute toxicity - dermal:			data lacking
Acute toxicity - inhalation:			data lacking
Skin corrosion / irritation:			data lacking
Serious damage / eye irritation:	Eye Damage 1	H318: Causes serious eye damage.	
Respiratory sensitisation:	Resp. Sens. 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Skin sensitisation:	Skin Sens. 1	H317: May cause an allergic skin reaction.	
Aspiration hazard:			data lacking
Reproductive Toxicity:			data lacking
Reproductive Toxicity: Effects on or via lactation:			data lacking
Germ cell mutagenicity:			data lacking
Carcinogenicity:			data lacking
Specific target organ toxicity – single exposure:			data lacking
Specific target organ toxicity – repeated exposure:			data lacking

Table 3.3. Classification and labelling according to CLP / GHS for environmental hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Hazards to the aquatic environment (acute/short-term):			data lacking
Hazards to the aquatic environment (chronic/long-term):			data lacking
M-Factor acute:			
M-Factor chronic:			
Hazardous to the ozone layer:			data lacking

Labelling

Signal word: Danger

Hazard pictogram:

GHS05: corrosion



GHS06: skull and crossbones



GHS08: health hazard



Hazard statements:

H301: Toxic if swallowed.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements:

P101: If medical advice is needed, have product container or label at hand.

P102: Keep out of reach of children.

P103: Read carefully and follow all instructions.

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P264: Wash ... thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

P272: Contaminated work clothing should not be allowed out of the workplace.

P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

P285: In case of inadequate ventilation wear respiratory protection.

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor/…

P302+P352: IF ON SKIN: Wash with plenty of water/…

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310: Immediately call a POISON CENTER/doctor/…

P321: Specific treatment (see ... on this label).

P330: Rinse mouth.

P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor/…

P363: Wash contaminated clothing before reuse.

P405: Store locked up.

P501: Dispose of contents/container to ...

Substance: Dipotassium hexachloroplatinate - self classification
Implementation: EU
Remarks:

Self-classification - using the harmonised Annex VI classification and further available data

Related composition: Boundary Composition
The substance is classified as follows:

Table 3.4. Classification and labelling according to CLP / GHS for physicochemical properties

Hazard class	Hazard category	Hazard statement	Reason for no classification
Explosives:			data conclusive but not sufficient for classification
Desensitised explosives:			data conclusive but not sufficient for classification
Flammable gases and chemically unstable gases:			data conclusive but not sufficient for classification
Flammable aerosols:			data conclusive but not sufficient for classification
Oxidising gases:			data conclusive but not sufficient for classification
Gases under pressure:			data conclusive but not sufficient for classification
Flammable liquids:			data conclusive but not sufficient for classification
Flammable solids:			data conclusive but not sufficient for classification
Self-reactive substances and mixtures:			data conclusive but not sufficient for classification
Pyrophoric liquids:			data conclusive but not sufficient for classification
Pyrophoric solids:			data conclusive but not sufficient for classification
Self-heating substances and mixtures:			data conclusive but not sufficient for classification
Substances and mixtures which in contact with water emit flammable gases:			data conclusive but not sufficient for classification
Oxidising liquids:			data conclusive but not sufficient for classification
Oxidising solids:			data conclusive but not sufficient for classification
Organic peroxides:			data conclusive but not

			sufficient for classification
Corrosive to metals:	Met. Corr. 1	H290: May be corrosive to metals.	

Table 3.5. Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral:	Acute Tox. 3	H301: Toxic if swallowed.	
Acute toxicity - dermal:			data lacking
Acute toxicity - inhalation:			data lacking
Skin corrosion / irritation:			data conclusive but not sufficient for classification
Serious damage / eye irritation:	Eye Damage 1	H318: Causes serious eye damage.	
Respiratory sensitisation:	Resp. Sens. 1A	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Skin sensitisation:	Skin Sens. 1B	H317: May cause an allergic skin reaction.	
Aspiration hazard:			data lacking
Reproductive Toxicity:			data conclusive but not sufficient for classification
Reproductive Toxicity: Effects on or via lactation:			data lacking
Germ cell mutagenicity:			data inconclusive
Carcinogenicity:			data lacking
Specific target organ toxicity – single exposure:			data lacking
Specific target organ toxicity – repeated exposure:	STOT Rep. Exp. 1 Affected organs: Kidney	H372: Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.	

Table 3.6. Classification and labelling according to CLP / GHS for environmental hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Hazards to the aquatic environment (acute/short-term):	Aquatic Acute 1	H400: Very toxic to aquatic life.	
Hazards to the aquatic environment (chronic/long-term):	Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects.	

M-Factor acute: 10			
M-Factor chronic: 10			
Hazardous to the ozone layer:			data conclusive but not sufficient for classification

Labelling

Signal word: Danger

Hazard pictogram:

GHS05: corrosion



GHS06: skull and crossbones



GHS08: health hazard



GHS09: environment



Hazard statements:

H290: May be corrosive to metals.

H301: Toxic if swallowed.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H372: Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

Precautionary statements:

P101: If medical advice is needed, have product container or label at hand.

P102: Keep out of reach of children.

P103: Read carefully and follow all instructions.

P234: Keep only in original packaging.

P260: Do not breathe dust/fume/gas/mist/vapours/spray.

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P264: Wash ... thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

P272: Contaminated work clothing should not be allowed out of the workplace.

P273: Avoid release to the environment.

P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

P284: [In case of inadequate ventilation] wear respiratory protection.

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor/…

P302+P352: IF ON SKIN: Wash with plenty of water/…

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310: Immediately call a POISON CENTER/doctor/…

P314: Get medical advice/attention if you feel unwell.

P321: Specific treatment (see ... on this label).

P330: Rinse mouth.

P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor/…

P362+P364: Take off contaminated clothing and wash it before reuse.

P390: Absorb spillage to prevent material damage.

P391: Collect spillage.

P405: Store locked up.

P406: Store in a corrosion resistant/... container with a resistant inner liner.

P501: Dispose of contents/container to ...

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

The log Kd for water is 3.27 (stdev 0.34) and the average Kd is 1862. The log Kd for soil is 1.57 (stdev 0.46) and the average Kd is 37.2.

Additional information:

Two high quality studies have determined the partitioning of platinum between river water and suspended particulate matter. Both studies showed relatively consistent results for experiments performed in freshwaters, and similar partitioning was also observed in both estuarine and marine water in the key study (Turner et al., 2006; Cobelo-Garcia et al., 2008). A high quality study of the partitioning of platinum to two soils and one sediment provides information relevant to the soil compartment (Sako et al., 2009).

Hydrolysis and biodegradation potential have not been assessed for this substance as these endpoints are not relevant for inorganics.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

No relevant information available.

Data waiving

Information requirement: Hydrolysis

Reason: study scientifically not necessary / other information available

Justification: . - In accordance with REACH Annex XI Section 1 testing does not appear to be scientifically necessary because this method is used on organic substances to measure the decomposition or degradation of a chemical reacting with water. For inorganics this type of method is not appropriate.

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

No relevant information available.

4.1.1.2.2. Phototransformation in water

No relevant information available.

4.1.1.2.3. Phototransformation in soil

No relevant information available.

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Screening tests

No relevant information available.

Data waiving

Information requirement: Biodegradation in water: screening test

Reason: study technically not feasible

Justification: the study does not need to be conducted because the substance is inorganic [study technically not feasible]

4.1.2.1.2. Simulation tests (water and sediments)

No relevant information available.

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

No relevant information available.

4.1.2.2. Biodegradation in soil

No relevant information available.

4.2. Environmental distribution

4.2.1. Adsorption/desorption

The studies on adsorption/desorption are summarised in the following table:

Table 4.1. Studies on adsorption/desorption

Method	Results	Remarks
adsorption / desorption, other - Determination of sediment Kd values batch equilibrium method Laboratory study, no guideline followed	Adsorption coefficient: log Kd: 3.27 at 23°C (Mean for all salinities, standard deviation 0.34) log Kd: 3.45 at 23°C (Mean for freshwaters, standard deviation 0.24) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) key study experimental study **Test material** Platinum (IV), (full information in **Annex II**). **Reference** **Cobelo-Garcia A, Turner A, Millward G. 2008**
adsorption / desorption, other - Determination of sediment Kd values	Adsorption coefficient: log Kd: 3.27 at 23°C (Mean for all salinities, standard deviation 0.34) log Kd: 3.45 at 23°C (Mean for freshwaters, standard deviation 0.24) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Platinum (IV), (full information in **Annex II**).

		Reference
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH For risk assessment of metals it is not always possible to differentiate between the particular metal substances when conducting environmental monitoring and therefore exposure assessment for platinum (IV) substances is conducted based on total emissions of platinum. Multiple Kd values for each platinum substance are therefore not relevant for risk assessment and Kd values for platinum (IV) are more appropriate. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Platinum (IV) Target chemical: Dipotassium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For risk assessment purposes, total measured platinum concentrations in the environment are used in order to assess environmental exposure. The risk assessment conducted does not differentiate between platinum (IV) substances but covers all emissions of platinum (IV) substances from a site. As platinum emissions are assessed together, Kd values for platinum (IV) and not for individual platinum substances are relevant.		
adsorption / desorption, other - Determination of sediment Kd values batch equilibrium method Laboratory study, no guideline followed	Adsorption coefficient: log Kd: >3.2 - <3.6 at 20°C (Dependent on treatment of the sediment material.) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) supporting study experimental study **Test material** Pt(IV), Form: gas under pressure: refrigerated liquefied gas (full information in **Annex II**). **Reference** **Turner A, Crussell M, Millward G, Cobelo-Garcia A, Fisher A 2006**
adsorption / desorption, other - Determination of sediment Kd values	Adsorption coefficient: log Kd: >3.2 - <3.6 at 20°C (Dependent on treatment of the sediment material.) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Pt(IV), Form: gas under pressure: refrigerated liquefied gas (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH For risk assessment of metals it is not always possible to differentiate between the particular metal substances when conducting environmental monitoring and therefore exposure assessment for platinum (IV) substances is conducted based on total emissions of platinum. Multiple Kd values for each platinum substance are therefore not relevant for risk assessment and Kd values for platinum (IV) are more appropriate. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Platinum (IV) Target chemical: Dipotassium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For risk assessment purposes, total measured platinum concentrations in the environment are used in order to assess environmental exposure. The risk assessment		

conducted does not differentiate between platinum (IV) substances but covers all emissions of platinum (IV) substances from a site. As platinum emissions are assessed together, Kd values for platinum (IV) and not for individual platinum substances are relevant.		
adsorption / desorption, other - Determination of soil Kd values batch equilibrium method Laboratory study, no guideline followed	Adsorption coefficient: log Kd: 1.57 at 25°C (Overall mean, standard deviation 0.46) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) supporting study experimental study **Test material** Platinum (IV), (full information in **Annex II**). **Reference** **Sako A, Lopes L, Roychoudhury A 2009**
adsorption / desorption, other - Determination of soil Kd values	Adsorption coefficient: log Kd: 1.57 at 25°C (Overall mean, standard deviation 0.46) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Platinum (IV), (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH For risk assessment of metals it is not always possible to differentiate between the particular metal substances when conducting environmental monitoring and therefore exposure assessment for platinum (IV) substances is conducted based on total emissions of platinum. Multiple Kd values for each platinum substance are therefore not relevant for risk assessment and Kd values for platinum (IV) are more appropriate. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Platinum (IV) Target chemical: Dipotassium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For risk assessment purposes, total measured platinum concentrations in the environment are used in order to assess environmental exposure. The risk assessment conducted does not differentiate between platinum (IV) substances but covers all emissions of platinum (IV) substances from a site. As platinum emissions are assessed together, Kd values for platinum (IV) and not for individual platinum substances are relevant.		

Discussion

The following information is taken into account for any environmental exposure assessment:

The log Kd for water is 3.27 (stdev 0.34) and the average Kd is 1862. The log Kd for soil is 1.57 (stdev 0.46) and the average Kd is 37.2.

For the exposure assessment the log Kd value from the suspended solids was used in case no value was available.

Value used for CSA:
Koc at 20°C:
Other adsorption coefficients:

log Kp (solids-water in suspended matter) : 3.27

log Kp (solids-water in soil) : 1.57

log Kp (solids-water in sediment) : 3.27

log Kp (solids-water in raw sewage sludge) : 3.27

log Kp (solids-water in settled sewage sludge) : 3.27

log Kp (solids-water in activated sewage sludge) : 3.27

log Kp (solids-water in effluent sewage sludge) : 3.27

Assessment entity linked:
Pt(IV) dissolved. View the assessment entity table in chapter 1.3 **here**

Additional information:

Two high quality studies have determined the partitioning of platinum between river water and suspended particulate matter. Both studies showed relatively consistent results for experiments performed in freshwaters, and similar partitioning was also observed in both estuarine and marine water in the key study (Turner et al., 2006; Cobelo-Garcia et al., 2008). A high quality study of the partitioning of platinum to two soils and one sediment provides information relevant to the soil compartment (Sako et al., 2009).

Average partition coefficients have been derived in cases where multiple partition coefficients are available for the same type of system (e.g. partitioning to suspended particulate matter in surface waters). The average values have been derived by calculating the log values of the individual partition coefficients (Kd). Following log transformation the mean and standard deviation are calculated to define an “average” partition coefficient and its associated standard deviation, assuming a log-normal distribution of Kd values. The log Kd for water is 3.27 (stdev 0.34) and the average Kd is 1862. The log Kd for soil is 1.57 (stdev 0.46) and the average Kd is 37.2.

4.2.2. Volatilisation

No relevant information available.

4.2.3. Distribution modelling

No relevant information available.

4.3. Bioaccumulation

4.3.1. Aquatic bioaccumulation

No relevant information available.

4.3.2. Terrestrial bioaccumulation

No relevant information available.

4.3.3. Summary and discussion of bioaccumulation

4.4. Secondary poisoning

Based on the available information, there is no indication of a bioaccumulation potential and, hence, secondary poisoning is not considered relevant (see CSR chapter 7.5 “PNEC derivation and other hazard conclusions)”).

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1. Non-human information

No relevant information available.

5.1.2. Human information

No relevant information available.

5.1.3. Summary and discussion of toxicokinetics

The following information is taken into account for any hazard / risk assessment:

Dipotassium hexachloroplatinate is likely to be poorly absorbed after administration by the oral route; what small proportion of the substance is taken up is likely to be rapidly excreted. Based on experimental rat data on a related soluble platinum salt, an absorption figure of 0.5% is proposed.

Although availability by the inhalation route is anticipated to be low, inhalation absorption is likely extensive based on its water soluble nature and relatively-low molecular weight, as well as limited experimental data. Based on ECHA guidance, a conservative assumption of 100% inhalation absorption is proposed.

A high dermal bioavailability is unlikely, notably based on its high water solubility as well as experimental dermal penetration data (human in vitro studies) for a closely-related surrogate. However, the potential of dipotassium hexachloroplatinate to disrupt skin barrier function, facilitating increased dermal penetration, cannot be excluded, especially considering its known corrosivity to metals and to the eyes of rabbits. A value of 20% absorption is proposed.

Once absorbed, distribution and excretion are expected to be rapid, with little or no bioaccumulation occurring, due to the water soluble nature. The potential for bioaccumulation of certain other metals and ions is recognised.

Value used for CSA:
Bioaccumulation potential: low bioaccumulation potential
Absorption rate - oral (%): 0.5
Absorption rate - dermal (%): 20
Absorption rate - inhalation (%): 100

Additional information:

Absorption

Limited data indicate that absorption of soluble Pt compounds is very low following oral exposure. Seventy-one fasted male rats were administered a dose of radiolabelled191Pt (as PtCl4) by oral gavage, to provide 25 µCi of radiation. Routes of excretion, levels of whole-body retention and organ distribution were determined. Less than 0.5% of the orally-administered dose was absorbed (Moore et al., 1975b,c). Similarly, mice given a single gavage administration of radiolabelled Pt(SO4)2 were found to have absorbed only a very small fraction of the dose (Lown et al., 1980). [The authors of this study stated that, while they did not quantify the distribution of the radiolabel, their findings were consistent with those of Moore et al.].

Absorption of platinum from the normal diet was estimated by measuring the levels of platinum in various foods (from a hypothetical diet) and comparing to the concentration of platinum in the urine of 21 individuals. From this the investigators estimated that 42-60% of the dietary platinum was absorbed. US EPA reports the authors of this study as having presented the hypothesis that the approximately 50-fold difference between this estimate and the measured oral absorption in rodents may be a reflection of the greater bioavailability of dietary sources of platinum. Further, this estimate of absorption is based on dietary estimates from a 'hypothetical diet' and that more reliable conclusions on absorption would require measurements from subjects receiving diets with known platinum concentrations (US EPA, 2009). Also, differences between the rat and human absorption figures are likely an artefact of differences in the exposures – absolute dietary Pt content is very low compared to the gavage (bolus) doses administered to the rats, and so it follows that a higher percentage of the lower dose is absorbed and was detected. Moreover, using the lowest oral absorption figure (in this case, 0.5%) results in the most health precautionary DNELs (when extrapolating from an oral exposure to both inhalation and dermal long-term systemic values). Further, ECHA guidance is clear that the preferred approach is to undertake route-to-route extrapolation within one species as the first step. Thus, when deriving DNEL values from experimental studies in the rat, it is most appropriate to use the figures obtained in the toxicokinetic study in rats. Consequently, a figure of 0.5% oral absorption has been taken forward for use in subsequent risk and exposure assessments.

Laboratory studies provide only very limited insights into the extent of absorption of platinum compounds following inhalation. When two volunteers inhaled mainly the related salt (a member of the "hexachloroplatinate(IV) compounds" category), diammonium hexachloroplatinate, at calculated mean air concentrations of 1.7 and 0.15 µg Pt/m3, respectively, urinary Pt concentrations peaked (15-100-fold increases were seen) about 10 hr later. The results indicated rapid absorption and urinary excretion, but gave no quantitative insights into the extent of absorption (Schierl et al., 1998). Urinary Pt measurements in rats following an acute inhalation of radiolabelled Pt, PtO2, PtCl4 or Pt(SO4)2 (particle diameter around 1 µm) indicated only small fractions of the administered dose were absorbed, even for the two soluble salts. Most of the radiolabel appeared in the faeces, presumably reflecting mucociliary clearance and a lack of significant absorption from the gastrointestinal tract (Moore et al., 1975a).

While it is very unlikely that dipotassium hexachloroplatinate will be available to a high extent via the lungs, ECHA guidance notes that "that if data on the starting route (oral) are available these should be used, but for the end route (inhalation), the worst case inhalation absorption should still be assumed (i.e. 100%)". Therefore, the health-precautionary figure of 100% as recommended by ECHA has been taken forward.

No substance-specific data on dermal uptake of dipotassium hexachloroplatinate were identified. The high water solubility suggests that significant dermal absorption through intact skin is unlikely. Furthermore, REACH guidance states that a reasonable default assumption is that dermal absorption will not be greater than by the oral route (ECHA, 2012) [i.e. <1% in this case]. However, two in vitro permeation studies on a related soluble platinum salt, dipotassium tetrachloroplatinate, showed a greater degree of absorption [about 5-8%] than this default process would assume. Using a K2PtCl4 solution (0.3 mg Pt/ml in synthetic sweat) and full thickness skin from six donors (three African and three Caucasian), 4.8 and 2.3%, respectively (as mean values),

diffused into the skin in 24 hr; the receptor solutions contained a further 3.4 and 0.5%, respectively (Franken et al., 2015). A slightly earlier publication reported mean skin diffusion and receptor solution percentages of 2.2% and 2.3%, respectively, in similar studies on full thickness skin from four Caucasian females (Franken et al., 2014). Apart from these studies, very little information appears to be available regarding dermal absorption of platinum compounds.

Specific expert guidance on the health risk assessment of metals states that "inorganic compounds require dissolution involving dissociation to metal cations prior to being able to penetrate skin by diffusive mechanisms" and, as such, dermal absorption might be assumed to be very low (values of 0.1 and 1.0% are suggested for dry and wet media, respectively) (ICMM, 2007). However, the potential for dipotassium hexachloroplatinate to disrupt the skin barrier (potentially facilitating a greater degree of dermal uptake) cannot be ruled out (despite a lack of classification for skin irritation).

The related salt, diammonium hexachloroplatinate, displayed evidence of skin irritation in both a non-guideline patch test (Middleton, 1978b), and a skin sensitisation study (Middleton, 1977). Irritation, manifesting as swelling of the ear, was also seen in another skin sensitisation test (using the mouse ear swelling test (MEST) method) conducted on another category member, disodium hexachloroplatinate (Schuppe et al., 1997b). Furthermore, dipotassium hexachloroplatinate was found to be immediately corrosive when instilled into the eyes of rabbits (Berthold, 1995b), and is classified for metal corrosivity.

Overall, the default values are somewhat conflicting. Absorption in the range of that indicated by oral studies (i.e. <1%), as suggested by ECHA guidance and ICMM (2007), seems to be too low when considering the in vitro studies on human skin (Franken et al., 2014, 2015). However, assuming 100% absorption – on the basis of potential skin barrier disruption – could be considered as overestimating the dermal absorption potential, particularly considering its high water solubility. With particular reference to the Franken et al. studies, and consideration of possible disruption of the skin barrier, a value of 20% dermal absorption is proposed.

Distribution/Metabolism

Once absorbed, distribution of potassium and hexachloroplatinate ions throughout the body is expected based on a relatively low molecular weight (~486 g/mol) and high water solubility.

In Moore's study (1975b), platinum was found in the liver and kidney of rats gavaged with radiolabelled-$PtCl_4$, although levels in other organs were not significantly above background. Other investigators have detected Pt in the liver, kidney, spleen, lung and testis following gavage administration (Lown et al., 1980). A range of other studies, summarised by the US EPA, concur with these findings, with the kidney clearly the most significant site of deposition. A similar pattern was observed following inhalation (US EPA, 2009).

Elimination

In rats given gavage doses of radiolabelled-platinum compounds, absorbed Pt was found to be excreted in the urine and faeces (Moore et al., 1975b). However, given that oral absorption was so low, faecal excretion of unabsorbed Pt during the first 1-2 days after administration contributed substantially to the detected levels (US EPA, 2009).

Dipotassium hexachloroplatinate is considered to have only a low potential for bioaccumulation based on its

physico-chemical properties (especially water solubility of 7700 mg/L; CRC, 2008).

Conclusion

Experimental data suggest that dipotassium hexachloroplatinate is likely to be poorly absorbed after administration by the oral route; what small proportion of the substance is taken up is likely to be rapidly excreted. Although inhalation is not anticipated to be a significant route of exposure, inhalation absorption is likely extensive based on its water soluble nature and relatively low molecular weight, as well as limited experimental data. A high dermal bioavailability is unlikely. Nevertheless, the potential of dipotassium hexachloroplatinate to disrupt skin barrier function, potentially facilitating increased dermal penetration, cannot be ruled out, especially considering its known corrosivity to metals and to the eyes of rabbits.

Absorption values of 0.5%, 100% and 20% are proposed for the oral, inhalation and dermal routes, respectively, and are considered health-precautionary for use in the calculation of DNEL values.

References not included elsewhere:

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Moore W, Jr, Malanchuk M, Crocker W, Hysell D, Cohen A and Stara JF (1975a). Whole body retention in rats of different 191Pt compounds following inhalation exposure. Environmental Health Perspectives 12, 35-39.

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5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

The results of studies on acute toxicity after oral administration are summarised in the following table:

Table 5.1. Studies on acute toxicity after oral administration

Method	Results	Remarks
rat [common species] (Wistar-Unilever (HsdCpb:Wu)) male/female oral: gavage according to OECD Guideline 401 (Acute Oral Toxicity) [before 2002] ; according to EU Method B.1 (Acute Toxicity (Oral))	LD50: 195 mg/kg bw (male/female) LD50: 184 mg/kg bw (male) LD50: 212 mg/kg bw (female)	1 (reliable without restriction) key study experimental study **Test material** dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Berthold K 1995**

5.2.1.2. Acute toxicity: inhalation

No relevant information available.

Data waiving

Information requirement: Acute toxicity after inhalation exposure

Reason: study scientifically not necessary / other information available

Justification: see 'Remark' - Particle size distribution (PSD) data, as measured by simple sieving, indicate that a significant proportion (77.9%) of dipotassium hexachloroplatinate is <100 µm (Tremain and Atwal, 2011a). However, such data, when considered in isolation, are of only limited value to an assessment of the potential for inhalation exposure. Exposure considerations provide good support for the conclusion that an acute inhalation toxicity study can be waived. Dipotassium hexachloroplatinate is classified for respiratory sensitisation (category 1A), and is allocated to the "high" hazard band (for local effects following acute and long-term inhalation exposure) on the basis that exposure should be strictly contained. Consequently, appropriate safety labelling, personal protection and RMMs/OCs are required, ensuring that the potential for inhalation exposure is strictly controlled. Hence, exposure at levels sufficient to invoke considerations of acute inhalation toxicity is not anticipated. Finally, for animal welfare reasons, conducting new in vivo toxicity tests is considered a last resort. Consequently, no testing by the inhalation route is considered justified.

5.2.1.3. Acute toxicity: dermal

No relevant information available.

Data waiving

Information requirement: Acute toxicity after dermal administration

Reason: study scientifically not necessary / other information available

Justification: see 'Remark' - No studies involving dermal application of dipotassium hexachloroplatinate are available. However, the existing in vivo skin sensitisation studies on the structurally closely-related compounds diammonium hexachloroplatinate (Dearman et al., 1998; Middleton, 1977) and disodium hexachloroplatinate hexahydrate (Schuppe et al., 1997), albeit limited in their assessment of general systemic effects, indicate a lack of acute systemic toxicity following dermal exposure. Exposure considerations provide good support for the conclusion that an acute dermal toxicity study can be waived. First, skin contact during production and/or use is expected to be very low. Second, dipotassium hexachloroplatinate is classified for skin sensitisation (category 1B) and is allocated to the "moderate" hazard band (for local effects following acute and long-term dermal exposure), so appropriate safety labelling, personal protection and RMMs/OCs are required. These will ensure that the potential for skin exposure is minimised. Further, dipotassium hexachloroplatinate is classified for respiratory sensitisation (category 1A) and the associated RMMs/OCs at the "high" hazard banding, will ensure that airborne levels are strictly controlled, thereby reducing the possibility of dermal exposure further. As such, there are sufficient available data for chemical hazard and risk assessment, classification and labelling, and risk mitigation purposes. Finally, for animal welfare reasons, conducting new in vivo toxicity tests is considered as a last resort. Consequently, in vivo testing is considered a low priority for further work.

5.2.1.4. Acute toxicity: other routes

No relevant information available.

5.2.2. Human information

No relevant information available.

5.2.3. Summary and discussion of acute toxicity

The following information is taken into account for any hazard / risk assessment:

The acute oral LD50 of potassium hexachloroplatinate was determined to be 195 mg/kg bw in rats (Berthold, 1995a).

No relevant acute dermal or inhalation toxicity data were identified.

Value used for CSA:
Acute oral toxicity:
adverse effect observed
(LD50) 195mg/kg bw
Acute dermal toxicity:
no study available
Acute inhalation toxicity:
no study available

Additional information:

No relevant acute toxicity human data were identified, or acute dose toxicity laboratory animal data with dipotassium hexachloroplatinate..

The acute toxicity of potassium hexachloroplatinate was investigated in Sprague-Dawley rats, in an OECD Test Guideline 401 study, conducted according to GLP. Animals (5/sex/group) were administered the test substance (as a suspension in 1% carboxymethylcellulose) by oral gavage at doses of 100, 215 or 464 mg/kg bw, and observed for up to 14 days. All animals died at the top dose, while 4 males and 3 females died at 215 mg/kg bw. Deaths occurred 1 to 5 days after administration. No mortality was observed in the low dose groups. Toxic effects included hypokinesia, stilted, staggered and restrained gait, tremor, diarrhoea, and sunken sides. Additionally, clonic and tonic convulsions and piloerection were detected. Individual animals showed loss of muscle tone and righting, pain and corneal reflexes, red crusted nose, or prolapse of penis. Microscopic examination of the kidneys revealed severe to very severe acute necrosis and degeneration of the proximal tubules at the highest two doses. The acute oral LD50 was determined (using probit analysis) to be 184 mg/kg bw in male rats (95% CI 85.1-357 mg/kg bw), 212 mg/kg bw in females (95% CI 105-423 mg/kg bw) and 195 mg/kg bw for both sexes combined (95% CI 142 -268 mg/kg bw) (Berthold, 1995a). Based on the results of this study, the test material should be classified for acute oral toxicity (category 3) according to EU CLP criteria (EC 1272/2008).

No acute inhalation toxicity data were identified. However, as the compound is classified for respiratory sensitisation (category 1A), the corresponding safety/protective measures will ensure that the potential for inhalation exposure is strictly controlled. Hence, exposure at levels sufficient to invoke considerations of acute inhalation toxicity is not anticipated.

Similarly, no acute dermal toxicity data were identified. However, as the compound is classified for skin sensitisation (category 1B), the corresponding safety/protective measures will ensure that the potential for skin exposure is minimised. Moreover, skin contact during production and/or use is expected to be negligible.

Justification for classification or non classification:

Based on the results of the available and reliable acute oral rat study, dipotassium hexachloroplatinate should be classified for acute oral toxicity (category 3) according to EU CLP criteria (EC 1272/2008).

No evidence of specific target organ toxicity was noted. As such, classification for STOT-SE is not considered appropriate.

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

The results of studies on skin irritation are summarised in the following table:

Table 5.2. Studies on skin irritation

Method	Results	Remarks
rabbit [common species] (New Zealand White [rabbit]) Coverage: occlusive (Backs of the rabbits were shaved (not “closely clipped” as recommended by the OECD guidelines). One site of each rabbit was abraded immediately before application of the test material, the other site remained intact.) Vehicle: unchanged (no vehicle) according to Skin irritation patch test, as described in Federal Register 1973, Vol. 38, No. 187, Section 1500: 41. 0.5 g of material was applied on a gauze pad to abraded and non-abraded skin of six albino rabbits. The site was covered with adhesive tape. The sites were examined after 24 and 72 hours for erythema and oedema.	GHS criteria not met primary dermal irritation index (PDII) 0.5 of max. 8 (Time point: 24 and 72 hrs after initial application) Reversibility: Reversibility not assessed, as observation period only 48 hrs (not up to 14 days as recommended in the OECD guidelines)	2 (reliable with restrictions) key study experimental study **Test material** Sodium hexachloroplatinate, Form: solid: crystalline (full information in **Annex II**). **Reference** **Middleton JD 1978**
rabbit [common species] (New Zealand White [rabbit]) Coverage: occlusive (Backs of the rabbits were shaved (not “closely clipped” as recommended by the OECD guidelines). One site of each rabbit was abraded immediately before application of the test material, the other site remained intact.) Vehicle: unchanged (no vehicle) according to Skin irritation patch test, as described in Federal Register 1973, Vol. 38, No. 187, Section 1500: 41. 0.5 g of material was applied on a gauze pad to abraded and non-abraded skin of six albino rabbits. The site was covered with adhesive tape. The sites were examined after 24 and 72 hours for erythema and oedema.	GHS criteria not met primary dermal irritation index (PDII) 0.5 of max. 8 (Time point: 24 and 72 hrs after initial application) Reversibility: Reversibility not assessed, as observation period only 48 hrs (not up to 14 days as recommended in the OECD guidelines)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloroplatinate, (full information in **Annex II**). **Reference** **Middleton JD 1978**
Justification for type of information: substance is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification		

report.		
rabbit [common species] (New Zealand White [rabbit]) Coverage: occlusive (Backs of the rabbits were shaved (not “closely clipped” as recommended by the OECD guidelines). One site of each rabbit was abraded immediately before application of the test material, the other site remained intact.) Vehicle: unchanged (no vehicle) according to Skin irritation patch test, as described in Federal Register 1973, Vol. 38, No. 187, Section 1500: 41. 0.5 g of material was applied on a gauze pad to abraded and non-abraded skin of six albino rabbits. The site was covered with adhesive tape. The sites were examined after 24 and 72 hours for erythema and oedema.	GHS criteria not met primary dermal irritation index (PDII) 1.3 of max. 8 (Time point: 24 and 72 hrs after initial application) Reversibility: Reversibility not assessed, as observation period only 48 hrs (not up to 14 days as recommended in the OECD guidelines)	2 (reliable with restrictions) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Middleton JD 1978**
rabbit [common species] (New Zealand White [rabbit]) Coverage: occlusive (Backs of the rabbits were shaved (not “closely clipped” as recommended by the OECD guidelines). One site of each rabbit was abraded immediately before application of the test material, the other site remained intact.) Vehicle: unchanged (no vehicle) according to Skin irritation patch test, as described in Federal Register 1973, Vol. 38, No. 187, Section 1500: 41. 0.5 g of material was applied on a gauze pad to abraded and non-abraded skin of six albino rabbits. The site was covered with adhesive tape. The sites were examined after 24 and 72 hours for erythema and oedema.	GHS criteria not met primary dermal irritation index (PDII) 1.3 of max. 8 (Time point: 24 and 72 hrs after initial application) Reversibility: Reversibility not assessed, as observation period only 48 hrs (not up to 14 days as recommended in the OECD guidelines)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloroplatinate, (full information in **Annex II**). **Reference** **Middleton JD 1978**
Justification for type of information: substance is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		

Studies with results indicating corrosivity to the skin are summarised in section 5.4 Corrosivity.

Data waiving

Information requirement: Skin Irritation

Reason: study scientifically not necessary / other information available

Justification: an in vitro skin irritation study does not need to be conducted because adequate data from an in vivo skin irritation study are available [study scientifically not necessary / other information available]

5.3.1.2. Human information

No relevant information available.

5.3.2. Eye

5.3.2.1. Non-human information

The results of studies on eye irritation are summarised in the following table:

Table 5.3. Studies on eye irritation

Method	Results	Remarks
rabbit (White Russian (Albino)) Vehicle: unchanged (no vehicle) according to OECD Guideline 405 (Acute Eye Irritation / Corrosion) ; according to EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion)	Category 1 (irreversible effects on the eye) - Migrated information Criteria used for interpretation of results: EU positive indication of irritation - Irritation index not determined because of corrosive effects	1 (reliable without restriction) key study experimental study **Test material** dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Berthold K 1995**

Data waiving

Information requirement: Eye Irritation

Reason: study scientifically not necessary / other information available

Justification: an in vitro eye irritation study does not need to be conducted because adequate data from an in vivo eye irritation study are available [study scientifically not necessary / other information available]

5.3.2.2. Human information

No relevant information available.

5.3.3. Respiratory tract

5.3.3.1. Non-human information

No relevant information available

5.3.3.2. Human information

No relevant information available.

5.3.4. Summary and discussion of irritation

The following information is taken into account for any hazard / risk assessment:

In two early US guideline studies, sodium and ammonium hexachloroplatinate (each 0.5 g) were applied (24-hr,

occluded) to the shaved abraded and intact skin of groups of six rabbits. No evidence of irritation to intact skin was observed during the observation period following application of sodium hexachloroplatinate (Middleton, 1978a). The ammonium salt induced slight but reversible indications of irritation to intact skin in three animals during the observation period (Middleton, 1978b).

In a guideline study, to GLP, potassium hexachloroplatinate produced corrosive effects following instillation into the eye of a single male rabbit (Berthold, 1995b).

No relevant respiratory tract irritation data were identified.

Value used for CSA:
Skin irritation / corrosion: adverse effect observed (irritating) Eye irritation: adverse effect observed (irreversible damage) Respiratory irritation: no study available

Additional information:

No relevant human irritation/corrosion data were identified. No in vitro skin or eye irritation studies were identified, or are required, as reliable in vivo studies are already available.

In a US Federal Register Patch Test (1973), the skin irritant potential of sodium hexachloroplatinate was assessed in six female New Zealand White rabbits. The test material (0.5 g) was applied (occluded) to the shaved abraded and intact skin for 24 hr. The sites were assessed for evidence of erythema (and eschar) formation and oedema formation immediately upon removal of the patch, and again 48 hr later. The intact skin sites displayed no evidence of erythema/oedema at either time point. Three abraded sites showed evidence of possible necrosis associated with the abrasions in the skin. A Primary Irritation Score of 0.5 (out of 8) was obtained. The study authors classified sodium hexachloroplatinate as a mild skin irritant in this test system (Middleton, 1978a).

In an analogous guideline study, involving identical conditions with ammonium hexachloroplatinate, three intact skin sites showed evidence of erythema/oedema which was observed to be reversible (or showed indications of reversibility) during the observation period. No signs of irritation were apparent on the other three intact sites. Two abraded skin sites showed evidence of possible necrosis associated with the abrasions in the skin. A Primary Irritation Score of 1.3 (out of 8) was obtained. The study authors classified ammonium hexachloroplatinate as a mild skin irritant in this test system (Middleton, 1978b).

These two studies suffered from a number of significant deviations from those recommended in the current OECD guidelines, including use of abraded skin, no moistening of test substance (a powder) to ensure good skin contact, a longer exposure period and failure to wash off any residual test material after removal of patch, observation period was insufficient to assess reversibility of effects, and skin was only examined on 2 occasions, at 0 and 48 hrs, rather than at 1, 24, 48 and 72 hrs, after patch removal. However, certain of these deviations are likely to increase the possibility of an irritant reaction, so the study can be considered as likely more sensitive than the current methodology to identify potential irritants.

Diammonium and disodium hexachloroplatinate are considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.

In an OECD Test Guideline 405 study, conducted according to GLP, potassium hexachloroplatinate (99.5 mg) was instilled into the conjunctival sac of the left eye of a single male White Russian rabbit. The other eye was untreated to serve as a control. Following instillation the eyelids were held closed by gentle finger pressure. The ocular response was assessed at 1 and 24 hr after instillation; corneal opacity, effects on the iris and conjunctival redness, chemosis and discharge were scored according to the Draize numerical scale. The treated eye as well as eye lids and nictitating membrane were assessed microscopically. Corrosive effects were noted following instillation of the test material. The cornea was opaque and the iris was not discernible through the opacity. The conjunctiva showed diffuse beefy redness and swelling with lids more than half to completely closed. Discharge moistened considerable areas around the eye. The histological findings revealed a pronounced corrosive potential. The animal was humanely killed after 24 hr and no additional animals were tested due to the severity of the symptoms. No evidence of systemic toxicity was observed (Berthold, 1995b).

As the results were based on only one rabbit, it is not possible to give a definitive interpretation according to EU CLP criteria (EC 1272/2008). However, it is considered prudent to classify the test material for serious eye damage (Category 1), as the severe effects observed are not expected to be reversible.

No respiratory tract irritation data were identified. A new study was not conducted as it is not a REACH Standard Information Requirement.

Justification for classification or non classification:

Based on the results of the available skin irritation studies (in rabbits) with the disodium and diammonium hexachloroplatinate salts, dipotassium hexachloropalladate does not require classification for skin irritation according to EU CLP criteria (EC 1272/2008).

Based on the results of the available and reliable eye irritation study in rabbits, dipotassium hexachloropalladate should be classified for eye damage (category 1), according to EU CLP criteria (EC 1272/2008).

5.4. Corrosivity

5.4.1. Non-human information

No relevant information available.

5.4.2. Human information

No relevant information available.

5.4.3. Summary and discussion of corrosion

The studies with results indicating corrosivity are discussed in section 5.3.4 Summary and discussion of irritation.

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

The results of studies on skin sensitisation are summarised in the following table:

Table 5.4. Studies on skin sensitisation

Method	Results	Remarks
guinea pig (not specified) female skin sensitisation: in vivo (non-LLNA) equivalent or similar to OECD Guideline 406 (Skin Sensitisation)	GHS criteria not met No. with positive reactions: 1st reading : 8 out of 10 (test group ; 24 h after challenge; dose: 10%) (Reading: 1st reading. . Hours after challenge: 24.0. Group: test group. Dose level: 10%. No with. + reactions: 8.0. Total no. in groups: 10.0.) No. with positive reactions: 2nd reading : 2 out of 10 (test group ; 48 h after challenge; dose: 10%) (Reading: 2nd reading. . Hours after challenge: 48.0. Group: test group. Dose level: 10%. No with. + reactions: 2.0. Total no. in groups: 10.0.) No. with positive reactions: 1st reading : 1 out of 4 (negative control ; 24 h after challenge; dose: 10%) (Reading: 1st reading. . Hours after challenge: 24.0. Group: negative control. Dose level: 10%. No with. + reactions: 1.0. Total no. in groups: 4.0.) No. with positive reactions: 2nd reading : 1 out of 4 (negative control ; 48 h after challenge; dose: 10%) (Reading: 2nd reading. . Hours after challenge: 48.0. Group: negative control. Dose level: 10%. No with. + reactions: 1.0. Total no. in groups: 4.0.) No. with positive reactions: rechallenge : 0 out of 10 (test group ; 24 h after challenge; dose: 5%) (Reading: rechallenge. . Hours after challenge: 24.0. Group: test group. Dose level: 5%. No with. + reactions: 0.0. Total no. in groups: 10.0.) No. with positive reactions: rechallenge : 0 out of 4 (negative control ; 24 h after challenge; dose: 5%) (Reading: rechallenge. . Hours after challenge: 24.0. Group: negative control. Dose level: 5%. No with. + reactions: 0.0. Total no. in groups: 4.0.)	1 (reliable without restriction) key study experimental study **Test material** Ammonium hexachloroplatinate IV, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Middleton JD 1977**

	No. with positive reactions: rechallenge : 0 out of 10 (test group ; 24 h after challenge; dose: 1%) (Reading: rechallenge. . Hours after challenge: 24.0. Group: test group. Dose level: 1%. No with. + reactions: 0.0. Total no. in groups: 10.0.) No. with positive reactions: rechallenge : 0 out of 4 (negative control ; 24 h after challenge; dose: 1%) (Reading: rechallenge. . Hours after challenge: 24.0. Group: negative control. Dose level: 1%. No with. + reactions: 0.0. Total no. in groups: 4.0.)	
guinea pig (not specified) female skin sensitisation: in vivo (non-LLNA) equivalent or similar to OECD Guideline 406 (Skin Sensitisation)	GHS criteria not met No. with positive reactions: 1st reading : 8 out of 10 (test group ; 24 h after challenge; dose: 10%) (Reading: 1st reading. . Hours after challenge: 24.0. Group: test group. Dose level: 10%. No with. + reactions: 8.0. Total no. in groups: 10.0.) No. with positive reactions: 2nd reading : 2 out of 10 (test group ; 48 h after challenge; dose: 10%) (Reading: 2nd reading. . Hours after challenge: 48.0. Group: test group. Dose level: 10%. No with. + reactions: 2.0. Total no. in groups: 10.0.) No. with positive reactions: 1st reading : 1 out of 4 (negative control ; 24 h after challenge; dose: 10%) (Reading: 1st reading. . Hours after challenge: 24.0. Group: negative control. Dose level: 10%. No with. + reactions: 1.0. Total no. in groups: 4.0.) No. with positive reactions: 2nd reading : 1 out of 4 (negative control ; 48 h after challenge; dose: 10%) (Reading: 2nd reading. . Hours after challenge: 48.0. Group: negative control. Dose level: 10%. No with. + reactions: 1.0. Total no. in groups: 4.0.) No. with positive reactions: rechallenge : 0 out of 10 (test group ; 24 h after challenge; dose: 5%) (Reading: rechallenge. . Hours after challenge: 24.0. Group: test group. Dose level: 5%. No with. + reactions: 0.0. Total no. in groups: 10.0.) No. with positive reactions: rechallenge : 0 out of 4 (negative control ; 24 h after challenge; dose: 5%) (Reading: rechallenge. . Hours	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloroplatinate, (full information in **Annex II**). **Reference** **Middleton JD 1977**

	after challenge: 24.0. Group: negative control. Dose level: 5%. No with. + reactions: 0.0. Total no. in groups: 4.0.) No. with positive reactions: rechallenge : 0 out of 10 (test group ; 24 h after challenge; dose: 1%) (Reading: rechallenge. . Hours after challenge: 24.0. Group: test group. Dose level: 1%. No with. + reactions: 0.0. Total no. in groups: 10.0.) No. with positive reactions: rechallenge : 0 out of 4 (negative control ; 24 h after challenge; dose: 1%) (Reading: rechallenge. . Hours after challenge: 24.0. Group: negative control. Dose level: 1%. No with. + reactions: 0.0. Total no. in groups: 4.0.)	
Justification for type of information: substance is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		
mouse (Balb/c [mouse]) female skin sensitisation: in vivo (LLNA) equivalent or similar to OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay) Local lymph node (auricular lymph node; ALN) assay to detect primary immune response.	Sensitising - Based on expert judgement : (caused a 23-fold increase in number of ALN (auricular lymph node) proliferating cells, and a 4 -fold increase in global ALN cell yield per animal compared to vehicle controls. This response was comparable to that seen in the positive control)	2 (reliable with restrictions) key study experimental study **Test material** Disodium hexachloroplatinate hexahydrate; Na2[PtCl6].6H2O, Form: not specified (full information in **Annex II**). **Reference** **Schuppe H-C et al. 1997**
mouse (Balb/c [mouse]) female skin sensitisation: in vivo (LLNA) equivalent or similar to OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay) Local lymph node (auricular lymph node; ALN) assay to detect primary immune response.	Sensitising - Based on expert judgement : (caused a 23-fold increase in number of ALN (auricular lymph node) proliferating cells, and a 4 -fold increase in global ALN cell yield per animal compared to vehicle controls. This response was comparable to that seen in the positive control)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloroplatinate, (full information in **Annex II**). **Reference** **Schuppe H-C et al.**

		1997
Justification for type of information: substance is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		
mouse (Balb/c [mouse]) female skin sensitisation: in vivo (LLNA) no guideline followed Similar in methodology to local lymph node assay (LLNA), but measuring cytokine production (not lymph node cell proliferation). Aim was to explore the selective activation of different cytokine profiles in comparison to those provoked by a known respiratory allergen (TMA) and a known contact allergen (DNCB).	Sensitising - Cytokine profile indicative of Th2-type immediate-type hypersensitivity : (Cytokine analyses were comparable to those seen with the respiratory allergen trimellitic anhydride (TMA) and the contact allergen 2,4 - dinitrochlorobenzene (DNCB))	2 (reliable with restrictions) key study experimental study **Test material** Ammonium hexachloroplatinate IV, Form: dissolved in DMSO (full information in **Annex II**). **Reference** **Dearman RJ et al. 1998**
mouse (Balb/c [mouse]) female skin sensitisation: in vivo (LLNA) no guideline followed Similar in methodology to local lymph node assay (LLNA), but measuring cytokine production (not lymph node cell proliferation). Aim was to explore the selective activation of different cytokine profiles in comparison to those provoked by a known respiratory allergen (TMA) and a known contact allergen (DNCB).	Sensitising - Cytokine profile indicative of Th2-type immediate-type hypersensitivity : (Cytokine analyses were comparable to those seen with the respiratory allergen trimellitic anhydride (TMA) and the contact allergen 2,4 - dinitrochlorobenzene (DNCB))	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloroplatinate, (full information in **Annex II**). **Reference** **Dearman RJ et al. 1998**
Justification for type of information: substance is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		
in vitro study mouse (Balb/c [mouse]) female skin sensitisation [deactivated phrase] - in vivo no guideline available Repeated application of test compound to one ear of mice followed by challenge on other ear. Extent of swelling on the challenged ear was used to assess skin sensitising potential.	Sensitising - Based on expert judgement	2 (reliable with restrictions) supporting study experimental study **Test material** Disodium hexachloroplatinate hexahydrate; Na2[PtCl6].6H2O, Form: not specified

		(full information in **Annex II**). **Reference** **Schuppe H-C et al. 1997**
in vitro study mouse (Balb/c [mouse]) female skin sensitisation [deactivated phrase] - in vivo no guideline available Repeated application of test compound to one ear of mice followed by challenge on other ear. Extent of swelling on the challenged ear was used to assess skin sensitising potential.	Sensitising - Based on expert judgement	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloroplatinate, (full information in **Annex II**). **Reference** **Schuppe H-C et al. 1997**
Justification for type of information: substance is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		

Data waiving

Information requirement: Skin Sensitisation

Reason: study scientifically not necessary / other information available

Justification: an in vitro skin sensitisation study does not need to be conducted because adequate data from an in vivo skin sensitisation study are available [study scientifically not necessary / other information available]

5.5.1.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 5.5. Exposure-related observations on skin sensitisation in humans

Method	Results	Remarks
Study type: survey Type of population: occupational Subjects: Workers in a catalyst production plant where different types of production activities were carried out involving solubilizing “platinum metals” in closed reactors. The resulting solutions were used to produce intermediates (dust, granules, pellets, beads) and finished products (catalysts for transport and domestic electrical appliances) through impregnation of different substrates and calcination in kilns. Additionally precious metals were refined from exhaust	Skin prick tests with platinum salts gave positive responses in 22/153 workers (14%): 8 reacted to all 3 platinum salts tested, 4 to both hexachloroplatinic acid and potassium tetrachloroplatinate, 3 to both hexachloroplatinic acid and sodium hexachloroplatinate, 7 to hexachloroplatinic acid only Of the 22 workers with positive skin prick tests to hexachloroplatinic acid, 1 also had a positive patch test; 1 further individual with a negative skin prick test to hexachloroplatinic acid had a positive patch test Of the total of 23 workers with a skin reaction to hexachloroplatinic acid,	2 (reliable with restrictions) supporting study migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** Sodium hexachloroplatinate;

catalysts after a combustion cycle. Various jobs in the plant resulted in exposure to platinum classified into 3 levels: - production of platinum salts, solution and refining (high exposure) - all other production workers (low exposure) - office workers outside the production area (no exposure) 153 employees examined 137 men, 16 women Mean age 34 years (range 21-60 years)	incidences were 0/11 (0%), 14/105 (13%) and 9/37 (24%) in the no, low and high exposure groups respectively; the adjusted prevalence odds ratio for the high exposure group (compared with the low exposure group) was 2.4 (95% confidence limits 0.8-6.9). Incidences were 7/72 (10%) and 16/70 (23%) in those employed for 0-5 and 6-30 years respectively; adjusted prevalence odds ratio 3.2 (95% CI 1.2-8.9) Clinical characteristics of the 23 workers with positive skin responses to hexachloroplatinic acid included rhinitis (n=1), asthma (n=10), urticaria (n=5) and eczema (n=2) [some subjects had more than one symptom; results not presented in relation to exposure level] “Descriptive analysis demonstrates that asthma and urticaria are more frequent in subjects allergic to Pt-salts, while rhinitis and dermatitis commonly belong to allergies of common inhalants as well as allergies to Pt-salts.”	disodium hexachloroplatinate(2-) / 16923-58-3 / 240-983-5; hexachloroplatinic acid / 16941-12-1 / 241-010-7, (full information in **Annex II**). **Reference** **Cristaudo A et al. 2005**
Study type: survey Type of population: occupational Subjects: Workers in a catalyst production plant. Production process involved preparation of platinum salt solution in a closed system, immersion of various substrates in the solution by robots in the encapsulated impregnation area, reduction in a furnace. Total population: total number of persons in cohort from which the subjects were drawn - 222 exposed subjects; 86 control subjects 10 subjects from the catalyst department (6%), 11 craftsmen with frequent jobs in the catalyst department (20%) and 30 controls (35%) refused to complete the study; 23 catalyst department subjects (14%), 9 craftsmen (17%) and 15 controls (17%) left the plant during the study; 4 catalyst department subjects (2%) had a positive response to the skin prick test with hexachloroplatinic acid at the initial assessment and were excluded from the study. Total number of subjects in study: 209 exposed subjects: 159 from the catalyst department, 50 craftsmen with frequent jobs in the catalyst department. 66 control subjects from the canteen, administration, security staff at the plant and newly-employed blue-collar workers from other departments at the plant. Participation rate: 95% of catalyst department subjects, 93% of craftsmen with frequent jobs in the catalyst department, 77% of controls. High exposure: total n=115; 104 catalyst	Conversion from negative to positive skin prick test response to hexachloroplatinic acid occurred in 13 subjects in the high exposure category and 1 subject in the persisent low exposure category (although some high exposure had also been experienced by this individual); incidence was 4.1 conversions/100 person-years; for newly-employed subjects (n=10), incidence was 5.9 conversions/100 person-years; for existing employees (n=3), incidence was 2.1 conversions/100 person-years; multivariate analysis showed strong association between skin prick test conversion and exposure category (p=0.011); also statistically significant positive association for smoking (relative risk 3.9, 95% confidence interval 1.6-9.7). Symptoms (asthma, rhinitis, conjunctivitis, dermatitis) beginning during the study occurred more frequently in the high exposure category; frequency of at least 1 of the symptoms 35/115 (33%) high exposure, 6/61 (12%) persistent low exposure, 3/61 (5%) intermittent low exposure, 4/48 (8%) no exposure No other differences in results (total IgE, FEV1, bronchial hyperresponsiveness) between exposure groups	2 (reliable with restrictions) supporting study migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** hexachloroplatinic acid / 16941-12-1 / 241-010-7, (full information in **Annex II**). **Reference** **Merget R et al 2000**

department workers, 11 craftsmen; mean age 32 years (95% confidence interval 30-34); 115/115 (100%) male; 53 smokers, 38 ex-smokers, 24 non-smokers, mean of 9 pack-years (95% CI 7-11) Persistent low exposure: total n=51; 51 catalyst department workers; mean age 32 (95% CI 29-35); 48/51 (94%) male; 16 smokers, 12 ex-smokers, 23 non-smokers, mean of 6 pack-years (95% CI 4-8) Intermittent low exposure: total n=61; 4 catalyst department workers, 38 craftsmen, 19 controls; mean age 39 years (95% CI 36-42); 60/61 males (98%); 18 smokers, 19 ex-smokers, 24 non-smokers, mean of 9 pack-years (95% CI 6-12) No exposure: total n=48; 1 craftsman, 47 controls; mean age 38 years (95% CI35-41); 41/47 males (85%); 16 smokers, 16 ex-smokers, 16 non-smokers, mean of 11 pack-years (95% CI 7-15) Atopy occurred with similar frequency in all groups		

5.5.2. Respiratory system

5.5.2.1. Non-human information

No relevant information available.

5.5.2.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 5.6. Exposure-related observations on respiratory sensitisation in humans

Method	Results	Remarks
Study type: survey Type of population: occupational Subjects: Workers in a catalyst production plant where different types of production activities were carried out involving solubilizing “platinum metals” in closed reactors. The resulting solutions were used to produce intermediates (dust, granules, pellets, beads) and finished products (catalysts for transport and domestic electrical appliances) through impregnation of different substrates and calcination in kilns. Additionally precious metals were refined from exhaust catalysts after a combustion cycle. Various jobs in the plant resulted in exposure to platinum classified into 3 levels: - production of platinum salts, solution and refining (high exposure) - all other production workers (low exposure) - office workers outside the production area	Skin prick tests with platinum salts gave positive responses in 22/153 workers (14%): 8 reacted to all 3 platinum salts tested, 4 to both hexachloroplatinic acid and potassium tetrachloroplatinate, 3 to both hexachloroplatinic acid and sodium hexachloroplatinate, 7 to hexachloroplatinic acid only Of the 22 workers with positive skin prick tests to hexachloroplatinic acid, 1 also had a positive patch test; 1 further individual with a negative skin prick test to hexachloroplatinic acid had a positive patch test Of the total of 23 workers with a skin reaction to hexachloroplatinic acid, incidences were 0/11 (0%), 14/105 (13%) and 9/37 (24%) in the no, low and high exposure groups respectively; the adjusted prevalence odds ratio for the high exposure group (compared with the low exposure group) was 2.4 (95% confidence limits 0.8-6.9). Incidences were 7/72 (10%) and 16/70	2 (reliable with restrictions) supporting study migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** Sodium hexachloroplatinate; disodium hexachloroplatinate(2-) / 16923-58-3 / 240-983-5; hexachloroplatinic acid / 16941-12-1 / 241-010-7, (full

(no exposure) 153 employees examined 137 men, 16 women Mean age 34 years (range 21-60 years)	(23%) in those employed for 0-5 and 6-30 years respectively; adjusted prevalence odds ratio 3.2 (95% CI 1.2-8.9) Clinical characteristics of the 23 workers with positive skin responses to hexachloroplatinic acid included rhinitis (n=1), asthma (n=10), urticaria (n=5) and eczema (n=2) [some subjects had more than one symptom; results not presented in relation to exposure level] “Descriptive analysis demonstrates that asthma and urticaria are more frequent in subjects allergic to Pt-salts, while rhinitis and dermatitis commonly belong to allergies of common inhalants as well as allergies to Pt-salts.”	information in **Annex II**). **Reference** **Cristaudo A et al. 2005**
Study type: survey Type of population: occupational Subjects: - Number of subjects exposed: 65 - Sex: 63 men, 2 women - Age: Mean 37.2 years (SD 10.8 years)	Work-related symptoms (conjuntivitis, rhinitis, coughing, respiratory distress) were recorded in 15/65 (23%) of workers, 11/21 (52%), 1/23 (4%) and 3/21 (14%) in the high, moderate and low exposure groups respectively (statistically significant difference between high exposure group and the other two groups p<0.01); the symptoms occurred outside work in 10 further individuals (15%); 40 workers (62%) were without symptoms. For skin prick testing, a positive response to potassium hexachloroplatinate was recorded for 12/64 workers tested (19%), 9/14 (64%) in those with work-related symptoms, 2/10 (20%) in those who experienced symptoms outside work and 1/40 (2.5%) in those without symptoms. Total IgE and platinum-specific IgE were significantly higher in those with work-related symptoms; histamine release in response to potassium hexachloroplatinate was not. In subjects with work-related symptoms, normal lung function was seen on Monday mornings, but this fell to below normal during the shift and during the working week; resistance was unchanged. For work-related symptoms (conjunctivitis, rhinitis, coughing, respiratory distress), latency time from beginning of exposure to onset: mean (+/- SD) 4.8 (+/-3.9) years (range 1-13 years). No information in paper regarding whether assessment of symptoms was made with or without knowledge of exposure group.	2 (reliable with restrictions) supporting study experimental study **Test material** Potassium hexachloroplatinate; dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Bolm-Audorff U. et al. 1992**
Study type: survey Type of population: occupational Subjects: Workers in a catalyst production plant. Production process involved preparation of platinum salt solution in a closed system, immersion of various substrates in the solution by robots in the encapsulated impregnation area, reduction	Conversion from negative to positive skin prick test response to hexachloroplatinic acid occurred in 13 subjects in the high exposure category and 1 subject in the persisent low exposure category (although some high exposure had also been experienced by this individual); incidence was 4.1 conversions/100 person-years; for	2 (reliable with restrictions) supporting study migrated information: read-across from supporting substance (structural analogue

in a furnace. Total population: total number of persons in cohort from which the subjects were drawn - 222 exposed subjects; 86 control subjects 10 subjects from the catalyst department (6%), 11 craftsmen with frequent jobs in the catalyst department (20%) and 30 controls (35%) refused to complete the study; 23 catalyst department subjects (14%), 9 craftsmen (17%) and 15 controls (17%) left the plant during the study; 4 catalyst department subjects (2%) had a positive response to the skin prick test with hexachloroplatinic acid at the initial assessment and were excluded from the study. Total number of subjects in study: 209 exposed subjects: 159 from the catalyst department, 50 craftsmen with frequent jobs in the catalyst department. 66 control subjects from the canteen, administration, security staff at the plant and newly-employed blue-collar workers from other departments at the plant. Participation rate: 95% of catalyst department subjects, 93% of craftsmen with frequent jobs in the catalyst department, 77% of controls. High exposure: total n=115; 104 catalyst department workers, 11 craftsmen; mean age 32 years (95% confidence interval 30-34); 115/115 (100%) male; 53 smokers, 38 ex-smokers, 24 non-smokers, mean of 9 pack-years (95% CI 7-11) Persistent low exposure: total n=51; 51 catalyst department workers; mean age 32 (95% CI 29-35); 48/51 (94%) male; 16 smokers, 12 ex-smokers, 23 non-smokers, mean of 6 pack-years (95% CI 4-8) Intermittent low exposure: total n=61; 4 catalyst department workers, 38 craftsmen, 19 controls; mean age 39 years (95% CI 36-42); 60/61 males (98%); 18 smokers, 19 ex-smokers, 24 non-smokers, mean of 9 pack-years (95% CI 6-12) No exposure: total n=48; 1 craftsman, 47 controls; mean age 38 years (95% CI35-41); 41/47 males (85%); 16 smokers, 16 ex-smokers, 16 non-smokers, mean of 11 pack-years (95% CI 7-15) Atopy occurred with similar frequency in all groups	newly-employed subjects (n=10), incidence was 5.9 conversions/100 person-years; for existing employees (n=3), incidence was 2.1 conversions/100 person-years; multivariate analysis showed strong association between skin prick test conversion and exposure category (p=0.011); also statistically significant positive association for smoking (relative risk 3.9, 95% confidence interval 1.6-9.7). Symptoms (asthma, rhinitis, conjunctivitis, dermatitis) beginning during the study occurred more frequently in the high exposure category; frequency of at least 1 of the symptoms 35/115 (33%) high exposure, 6/61 (12%) persistent low exposure, 3/61 (5%) intermittent low exposure, 4/48 (8%) no exposure No other differences in results (total IgE, FEV1, bronchial hyperresponsiveness) between exposure groups	or surrogate) [deactivated phrase] **Test material** hexachloroplatinic acid / 16941-12-1 / 241-010-7, (full information in **Annex II**). **Reference** **Merget R et al 2000**
Study type: survey Type of population: occupational Subjects: Total number of persons in cohort from which data were generated: 547 (in 3 process areas); sub-group of chemical processs operators (CPOs; exposed to soluble platinum for at least 50% of their work) identified within each	FULL COHORT PGM refinery (lowest exposure to airborne soluble platinum, exposure to chloroplatinates only, i.e. not TPC): 110/406 cases of sensitisation (27%); 106/270 cases (39%) in the CPO sub-group TPC lab (highest exposure to airborne soluble platinum, exposure to chloroplatinates and TPC): 5/41 cases of	2 (reliable with restrictions) supporting study experimental study **Test material** Chloroplatinates & Tetaammine

exposure group, total n=341 EXPOSURE DATA - DURATION New employees who started work between 01-Jan-1976 and 31-Dec-1995, followed up until 31-Dec-1995, were considered for inclusion the study. Criteria for inclusion: - no previous exposure to soluble platinum compounds - work gave regular exposure to soluble platinum compounds which required subjects to undergo medical surveillance - employed for long enough to have at least one medical examination (these were performed every 3 months) - CATEGORIES 3 exposure categories to airborne soluble platinum: - PGM refinery (n=406, CPOs=270); workers exposed to chloroplatinates, but not TPC; lowest Pt exposure of the 3 groups - TPC lab (n=41; CPOs=31); workers regularly exposed to TPC and chloroplatinates; highest Pt exposure of the 3 groups - Autocat (n=100; CPOs=40); exposure to TPC only; group with intermediate Pt exposure SUBJECT DESCRIPTION PGM refinery: total n=406; 373 men, 33 women; mean age 29 years (range 18-61); 199 smokers; 1 atopic TPC lab: total n=41; 40 men, 1 woman; mean age 25 years (range 17-47); 11 smokers; 0 atopic Autocat: total n=100; 85 men, 15 women; mean age 26 years (range 16-61); 33 smokers; 4 atopic A sub-group of chemical processs operators (CPOs; exposed to soluble platinum for at least 50% of their work) was identified within each exposure group, with the following characteristics: - PGM refinery: total n=270; 257 men, 13 women; mean age 30 years (range 18-59); 164 smokers; 0 atopic; - TPC lab: total n=31; 31 men, 0 women; mean age 25 years (range 17-47); 9 smokers; 0 atopic; - Autocat: total n=40; 40 men, 0 women; mean age 29 years (range 16-61); 17 smokers; 0 atopic MEDICAL SURVEILLANCE ROUTINE Enquiry about symptoms and skin prick tests every 3 months with 3 platinum salts (ammonium hexachloroplatinate up to 1994, sodium hexachloroplatinate throughout, sodium tetrachloroplatinate up to 1992, TPC from 1992 onwards) at 10 mg/ml in glycerol carbol saline or 0.9% saline; spirometry every 6 months. Positive responses (> or = to 2 mm dimaeter weal) were followed up with further testing. SUBJECT TRANSFERS 11 employees (8 CPOs) from the PMG refinery transferred to the Autocat; 1 CPO from the TPC group and 1 from the Autocat transferred to the PGM refinery.	sensitisation (12%); 5/31 cases (16%) in the CPO sub-group; probability of sensitisation was significantly less than in the PMG refinery (p<0.05), relative risk (with 95% confidence interval) reported as 0.33 (0.14-0.78). Autocat (intermediate exposure to airborne soluble platinum, exposure to TPC only): 0/100 cases of sensitisation (0%); 0/40 cases (0%) in the CPO sub-group; probability of sensitisation was significantly less than in the PMG refinery (p<0.001) and the TPC lab (p<0.05), relative risk 0.00 CPO SUB-GROUP PGM refinery, no relationship between probability of sensitisation and age at the start of employment; strong evidence of a relationship with smoking; smoking-adjusted RRs (with 95% CI) for the TPC lab and the Autocat groups, compared with the PGM refinery group, were 0.47 (0.20-1.12; not statistically signficant) and 0.00 (p<0.001) PGM refinery (lowest exposure to airborne soluble platinum, exposure to chloroplatinates only, i.e. not TPC): median time to diagnosis of sensitisation 13 months (range 1-108 months); 80/106 cases diagnosed in first 2 years of employment; 1.4 cases/100 person-months in the first 5 years of employment TPC lab (highest exposure to airborne soluble platinum, exposure to TPC and chloroplatinates): median time to diagnosis of sensitisation 37 months (range 7-52 months); 0.5 cases/100 person-months in the first 5 years of employment Autocat (intermediate exposure to airborne soluble platinum, exposure to TPC only): no cases of sensitisation in CPO sub-group or this group in the original cohort Sensitisation incidence calculations were restricted to first 60 months of employment to prevent long-term “survivor” bias.	platinum dichloride (TPC), Form: Airborne [possibly particulate matter] (full information in **Annex II**). **Reference** **Linnett PJ & Hughes EG 1999**

Subjects who transferred between operations were considered to have withdrawn at the date of transfer and were not included in the analysis for the operation to which they transferred.		
Study type: survey Type of population: occupational Subjects: - Number of subjects exposed: 1036 (the number of newly hired workers over the study duration was 1040, but for 4 of these workers, no information about their job history was available, or they had a job title for which no exposure estimate could be generated; hence the number of newly exposed workers was 1036) - Sex: 876 males and 164 females - Age: Average of 32.4 years - Race: No data - Demographic information: No data	In total, 1763 exposure measurements were available for analysis. Overall geometric mean levels of chloroplatinate are given per refinery in Table 1 (see below). Overall, information was available for more than 2000 workers, and the population size varied from around 100 to more than 1000 between refineries. Little more than 50% (1040) of all subjects started working since January 1, 2000. Incidence rates for platinum sensitization overall and by exposure category are shown in Table 2 (see below). On average, subjects were followed for 3.9 years. On average, cases became sensitized after 2.5 person years of follow-up, with a minimum of 0.36 (almost 4.5 months) and a maximum of 9.9 years. Overall, 2.4 cases were seen per 100 years of follow-up, with clear differences between refineries in sensitization rates but also between exposure categories between atopic and nonatopic subjects, smokers and nonsmokers, and men and women. Site 3 had the lowest sensitization rate, and this was also the site with the lowest prevalence of atopy and rigid pre-employment selection of nonsmokers at baseline for employment. At site 5, the atopy prevalence was similar to that of the general population, but the smoking prevalence at baseline was relatively low. Survival modeling of incidence data showed that exposure-response relations were observed for ‘‘current’’ exposure, as well as average and cumulative exposure, Table 3 (see below). The correlation between current and average exposure was very high (0.98), and thus associations between these exposure proxies and the incidence of sensitization can only be marginally different. The correlation between cumulative exposure and current and average exposure was considerably lower (0.72 and 0.74, respectively). Thus workers were reclassified considerably when using cumulative exposure instead of current or average exposure. For all 3 exposure measures, a gradually increasing risk was observed with increasing exposure, but for average exposure, the risk was reduced in the highest exposure category. The risk ratios (RRs) for both atopy and smoking were statistically significantly different from 1, with RRs of between 1.5	1 (reliable without restriction) supporting study experimental study **Test material** Chloroplatinum salts (as soluble platinum), Form: Airborne [possible total dust as opposed to inhalable fraction] (full information in **Annex II**). **Reference** **Heederik D, Jacobs J, Samadi S, van Rooy F, Portengen L and Houba R 2016**

	and 2. The relationship was strongest for current and average exposure, and weaker for cumulative exposure. For current exposure categories of ≤49, >49-≤100, >100-≤252 and >252 ng/m3, RRs were 1 (reference), 1.4, 2.2 and 3.2, respectively, the latter two values being statistically significant (p<0.005 or better). For average exposure, RRs were 1, 1.8, 4.2 and 3.0, respectively, for the ≤51.1, >51.1-≤105, >105-≤250 and >250 ng/m3 categories (all statistically significant, p<0.05 or better). Sex, refinery and age were not introduced as parameters in the final models. Interactions between atopy and exposure and smoking and exposure did not yield statistically significant interaction variables in addition to the main effects for exposure, atopy, and smoking, respectively. Thus the final model contained atopy, smoking, and exposure as main effects only. Analyses using penalized splines generally produced a more refined picture than analysis with categorical exposure data. A clear monotonic increasing exposure-response relation was seen for current platinum salt exposure up to a level of 200 ng/m3 and a leveling off at considerably higher exposure levels. Average exposure resulted in a similar exposure-response relation, but there was a tendency toward a slightly reduced risk at very high exposure levels. The use of cumulative exposure as an exposure proxy led to considerable recategorization of the population, and this resulted in a clear bell-shaped exposure-response relation. After a peak in sensitization risk between 1000 and 2000 ng/m3 per year, the risk was clearly reduced at higher cumulative exposures, indicating that susceptible subjects had become sensitized and were probably exhausted in the population, resulting in a survivor population.	

5.5.3. Summary and discussion of sensitisation

The following information is taken into account for any hazard / risk assessment:

Skin sensitisation

Occupational studies of exposed workers, together with many case reports, provide good evidence that certain soluble halogenated platinum salts are skin sensitisers. Urticaria (Type I immediate hypersensitivity) is most commonly reported, while allergic contact dermatitis appears to be rare. Results from laboratory animal studies support the human evidence. Skin sensitisation potential is essentially limited to complexes where halogen ligands are coordinated to the platinum atoms; hexachloroplatinic acid and the tetra- and hexachloroplatinate salts are mainly responsible for platinum-salt skin sensitisation.

Allergic respiratory tract sensitisation following occupational exposure to complex halogenated platinum compounds, in particular the chloroplatinates, is a well-established health hazard. Available epidemiology data have not yet permitted delineation of an induction threshold for complex halogenated platinum salt sensitivity (PSS) in workplace exposure scenarios.

Value used for CSA: adverse effect observed (sensitising)
Additional information:

No in vitro skin sensitisation studies were identified, or are required, as reliable in vivo studies are already available.

The development of skin sensitisation following occupational exposure to halogenated platinum compounds, in particular chloroplatinates, is a well-established health hazard, and has been addressed in comprehensive expert reviews (HCN, 2008; IPCS, 1991; SCOEL, 2011; US EPA, 2009; WHO, 2000, 2012). The following brief summary is based largely on information cited in these reviews and focuses on the key information to indicate an appropriate classification category according to the skin sensitisation criteria of Regulation (EC) No. 1272/2008, as amended.

WHO (2012) noted that urticaria (Type I immediate hypersensitivity) and allergic contact dermatitis are symptoms of platinum-specific allergic skin sensitisation in numerous case reports and occupational health studies on workers exposed to halogenated platinum salts (Baker et al., 1990; Bolm-Audorff et al., 1992; Calverley et al., 1995, 1999; Cristaudo et al., 2005; Hunter et al., 1945; IPCS, 1991; Marshall, 1952; Merget, 2000, Merget et al., 1988, 1999, 2000; Pepys, 1984; Pepys et al., 1972; WHO, 2000). Reactions are generally urticarial and eczematous in nature, while true allergic contact dermatitis from exposure to platinum compounds is rare (HCN, 2008). SCOEL and HCN noted that skin sensitisation potential is limited to complexes where halogen ligands are coordinated to the platinum atoms; hexachloroplatinic acid and the tetra- and hexachloroplatinate salts are mainly responsible for platinum-salt skin sensitisation. Uncharged complexes and complexes with ligands other than halogens appear to lack such potential (HCN, 2008; SCOEL, 2011).

Merget et al. (2000) reported the results of a 5-year prospective cohort study that found a dose-response relationship between airborne soluble platinum concentrations and newly occurring sensitisation cases. The study was performed during 1989-1995 (more than 20 years ago), and included 275 employees of a catalyst-production plant in Germany, of whom 115 worked in the production lines (‘high exposure’), 112 worked (regularly or irregularly) within the catalyst department but not in the production lines (‘low exposure’), and 48 never entered the catalyst building (‘no exposure’). 53% of the study population were already present when the study started. The subjects had undergone at least two examinations and had a negative response in a skin prick test against platinum at the initial survey. The results demonstrated that in a population of 160 workers, no new cases of sensitisation occurred during 5-year employment in the ‘no exposure’ and ‘low exposure’ areas but, in the ‘high exposure’ area, 14 new cases of sensitisation occurred in 115 exposed workers (11%). Smoking cigarettes was positively associated with the occurrence of new symptoms. It was concluded that exposures below the OEL value (generally 2000 ng Pt/m3) may still result in sensitisation (Merget et al., 2000) and WHO stated that “Qualitative evaluation of these data would suggest that halogenated platinum salts are potent or strong skin sensitizers” (WHO, 2012). However, the investigators themselves acknowledged that the study was not designed to establish a threshold for sensitisation induction and could not be used to establish an OEL (Merget et al., 2000). The major issues over characterisation of exposure were addressed in an industry report (EPMF, 2009) and SCOEL (2011) noted that the study was not conducted with the aim to find a no-observed-adverse-effect level (NOAEL), peak exposures were not quantified, high past exposures may have contributed to the sensitisation cases, exposure estimates were not based on the sampling, and exposures were highly

variable, all of which may lead to unreliable exposure estimates. SCOEL concluded that “the database does not allow the recommendation of an OEL for soluble platinum compounds” (SCOEL, 2011).

More recently, a new epidemiological study (Heederik et al., 2016) has provided better insights into respiratory sensitisation risk at low exposures (see the section on Respiratory Sensitisation, below), but did not focus on skin sensitisation aspects.

Although a guinea pig maximization test found no evidence of skin sensitisation potential for ammonium hexachloroplatinate (Middleton, 1977), three published laboratory animal studies (Dearman et al., 1998; Schuppe et al., 1997) provide support for the view that halogenated platinum salts are dermal sensitisers. Schuppe et al. (1997) reported a significant positive reaction in BALB/c mice exposed to 5% sodium hexachloroplatinate in a LLNA (adapted to avoid the use of radioactive label) and in a modified ear swelling test (MEST). At that 5% concentration, the ALN Index (which presumably reflects the Stimulation Index (SI)) in the LLNA test exceeded 3 [the level used to differentiate sensitisers from non-sensitisers]. If that concentration is used as the EC3 [the effective concentration required to induce a 3-fold increase in the proliferation of lymph node cells compared with vehicle-treated controls], then the potency category for this halogenated platinum salt would be in the moderate range [CLP Sub-category 1B]. Lower (unspecified) concentrations evidently did not increase the ALN Index (Schuppe et al., 1997). Dearman et al. (1998) reported increases in production of interferon-g expression [typical of a skin sensitiser; Th1 response] and interleukin (IL-10) [characteristic of respiratory sensitizers; Th2 response] for diammonium hexachloroplatinate when applied to the ears of BALB/c mice at exposure concentrations down to 0.25%. In isolation, these results might indicate a potency category of strong [Sub-category 1A]. However, Dearman et al. (1998) only evaluated cytokine release, and the experiment did not include a LLNA or development of EC3 values. In addition, it should be noted that both the LLNA and MEST in isolation are unable to differentiate between immediate (Th2 type) and delayed (Th1 type) hypersensitivity responses. Diammonium and disodium hexachloroplatinate are considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.

Most reports do not include (dermal or inhalation) exposure data, making thresholds for induction impossible to determine. In respect of elicitation, in one study a positive skin reaction was elicited by skin patch application of 15 µl of a 0.01M solution of hexachloroplatinic acid, in 2 of 153 workers at a catalyst manufacturing and recycling factory; 22 had a positive skin prick test (SPT) indicative of IgE antibody involvement to the same substance (Cristaudo et al., 2005). Although data on suitable patch test concentrations are limited, WHO (2012) noted that published occupational data are available on challenge doses associated with a positive SPT response to halogenated platinum salts. Two cited papers reported that the lowest exposure concentration of halogenated platinum salts required to elicit a positive SPT ranged from 10−9 to 10−3 g/ml (six orders of magnitude) among individuals previously sensitized to halogenated platinum salts (Biagini et al., 1985; Brooks et al., 1990).

WHO felt that the low elicitation dose for halogenated platinum salts, based on SPT and occupational exposure data suggests that these salts sit at the higher end of sensitiser potency. WHO also concluded that the published laboratory animal data suggest that the potency category for some halogenated platinum salts would be moderate or strong (WHO, 2012). Overall, the significant data gaps and inadequate dermal exposure data preclude determination of an elicitation dose threshold for halogenated platinum salts, and there is little information to inform a qualitative evaluation. Published data on low exposures are inadequate to evaluate whether some halogenated platinum salts might be classified as strong sensitizers.

As indicated above, assays such as LLNA and MEST cannot differentiate between Th2 and Th1 immune responses and therefore in the case of the chloroplatinates positive responses do not necessarily indicate that delayed contact hypersensitivity has been induced. There is significant published evidence (e.g. Dearman et al., 1998), and unpublished data within the industry sector, which strongly suggests that the Th2 arm is

preferentially induced on skin exposure to chloroplatinate salts and related Pt compounds. Extensive accumulated industrial experience from health surveillance systems in the platinum group metal sector indicates that exposure to complex halogenated salts of platinum, typified by soluble hexa- and tetra-chloroplatinates, results in the preferential induction of Th2 (IgE-mediated) responses in sensitisation reactions. These data encompass a sector historical record of more than 50 years, involving over 10 companies.

These chloroplatinate induced Th2-type responses involve activation of specific subsets of T lymphocytes and the cytokine products of these cells can be tracked with cytokine fingerprinting in both experimental toxicology studies and human clinical investigations. The end result of such activation is allergen-specific IgE antibody production, and the predominant reaction in symptomatic workers is respiratory sensitisation and/or allergic rhinoconjunctivitis, with contact urticaria being less commonly observed. In contrast, allergic contact dermatitis (ACD) as a result of non-IgE mediated mechanisms (i.e. Th1-based responses) has been rarely observed, particularly in terms of its occurrence in isolation from immediate hypersensitivity responses. It is estimated that ACD incidence accounts for <1% of symptomatic cases in sensitised worker populations.

Taking into account extensive human industrial experience of exposure to this substance where skin contact does not routinely result in allergic contract dermatitis (but can cause Th2 immediate hypersensitivity), the weight of evidence indicates that classification as Sub category 1B is appropriate for this substance (personal communication Johnson Matthey).

Several chloroplatinate compounds are being registered under REACH by the PMC: dipotassium tetrachloroplatinate (CAS RN 10025-99-7); dipotassium hexachloroplatinate (CAS RN 16921 30-5); diammonium hexachloroplatinate (CAS RN 16919-58-7); and hexachloroplatinic acid (CAS RN 16941-12-1). Occupational health studies, supported by case reports, provide sufficient evidence that halogenated platinum salts can induce skin sensitisation responses in exposed workers. Laboratory animal studies provide additional support for this potential. From the limited available data, dermal exposure thresholds for induction and elicitation cannot be robustly determined. The limited nature of the existing exposure data also precludes quantifying any relationship between dermal and inhalation exposure in inducing skin sensitisation. There is extensive evidence that these skin reactions can be mediated by Th2-type responses in humans, and this is supported by cytokine release profiles, SPT responses, and industry data indicative of IgE involvement. Therefore, it can be concluded that the available evidence is not supportive of the chloroplatinates having potent delayed contact hypersensitivity potential, and that the weight of evidence indicates the chloroplatinates should be classified as Sub-category 1B (low to moderate frequency of occurrence). In a recent non-guideline study, it was demonstrated that a single respiratory challenge to mice topically sensitised to ammonium hexachloroplatinate can induce dose dependent changes in pulmonary function indicative of an allergic lung response (Williams et al., 2015). This suggests that both dermal and inhalation exposure to chloroplatinates may play a role in occupational skin sensitisation and respiratory sensitisation/asthma, further supporting the decision to formulate a qualitative assessment approach (and consequent ‘high hazard’ banding) as most appropriate for the respiratory and dermal sensitisation endpoints.

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Discussion of human information:
See “Summary and discussion of human information” in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT

The following information is taken into account for any hazard / risk assessment:

Respiratory sensitisation

Value used for CSA: adverse effect observed (sensitising)
Additional information:

The development of allergic respiratory tract sensitisation following occupational exposure to halogenated platinum compounds, in particular chloroplatinates, is a well-established health hazard, and has been addressed in comprehensive expert reviews (HCN, 2008; IPCS, 1991; SCOEL, 2011; US EPA, 2009; WHO, 2000, 2012). The following brief summary is based largely on information cited in these reviews and focuses on the key information to indicate an appropriate classification category under the revised respiratory sensitisation criteria of Regulation (EC) No. 1272/2008, as amended.

Adverse occupational health effects following exposure to complex platinum salts have been reported as far back as a century ago (Karasek and Karasek, 1911). It was reported that 52 out of 91 (57%) precious metal workers in four British platinum refineries had symptoms of sneezing, wheezing and shortness of breath when exposed at airborne levels of between 0.9 and 1700 µg/m3 (Hunter et al., 1945).

A WHO (2012) evaluation cited a large number of case reports and occupational studies that identify the health effects in workers exposed to halogenated platinum salts – in particular certain chloroplatinates – as asthma, rhinitis and conjunctivitis (Baker et al., 1990; Bolm Audorff et al., 1992; Calverley et al., 1995; Cristaudo et al., 2005; Hunter et al., 1945; IPCS, 1991; Marshall, 1952; Merget, 2000; Merget et al., 1988, 1999, 2000; Pepys, 1984; Pepys et al., 1972; WHO, 2000). The WHO (2012) review noted that additional reports provide support for one or more of the above effects, consistent with respiratory sensitisers: viz asthma (Brooks et al., 1990; Merget et al., 1991, 1994, 1995, 1996), respiratory difficulties (Karasek and Karasek, 1911), inflammatory

changes in the respiratory tract (Merget et al., 1996; Roberts, 1951), bronchospasm (Calverley et al., 1999) and bronchial hyperactivity (Biagini et al., 1985; Brooks et al., 1990; Merget et al., 1991). A similar extensive list of relevant reports is provided in US EPA (2009). Asymptotic respiratory sensitisation (detected by skin prick testing; SPT) can proceed to occupational asthma and rhinitis if exposure is continued, and such symptoms may be severe (Friedman-Jimenez et al., 2000; Merget et al., 1999). Severe cases of allergic sensitisation to halogenated platinum salts have included workers with bluish skin due to insufficient oxygen in the blood, feeble pulse, and extreme breathing difficulty, requiring the subject to maintain an upright position to breath (Roberts, 1951). Review of published epidemiology indicates that for chloroplatinate salts, latency from first exposure to the evidence of respiratory sensitisation varies from a few months to about ten years, with the majority occurring within approximately 3 years (Cochrane et al., 2015; HCN, 2008; IPCS, 1991; SCOEL, 2011; US EPA, 2009; WHO, 2000, 2012).

The respiratory sensitisation effects detected in the workplace have been attributed to complex halogenated salts, where the platinum atom is directly coordinated to halide atoms, and not where the halide, such as chloride, is present in ionic form (Cochrane et al., 2015; HCN, 2008; SCOEL, 2011; US EPA, 2009). The work environment of a platinum refinery or platinum catalyst production plant where individuals become sensitised to platinum compounds evidently primarily involves exposure to halogenated platinum salts, mainly chloroplatinates, ammonium tetrachloroplatinate, ammonium hexachloroplatinate, sodium hexachloroplatinate, potassium tetrachloroplatinate, potassium hexachloroplatinate or hexachloroplatinic acid (Cochrane et al., 2015; Heederik et al., 2016; Hunter et al., 1945; Merget et al., 1999, 2000; Parrot et al., 1969).

The allergenic potential may be related to the degree of chlorination (Cleare et al., 1976; Cristaudo et al., 2005; Linnett and Hughes, 1999). Results from laboratory animal studies provide data supporting a relationship between allergenic potential and the degree of chlorination (Murdoch and Pepys, 1984a,b, 1985, 1986; Schuppe et al., 1992, 1997; WHO, 2012), and some data suggest that there is a correlation between activity and the degree of chlorination between the series of hexachloroplatinate and tetrachloroplatinate salts.

From the various studies carried out to date (early 2016), it has not been possible to define a robust induction threshold for respiratory sensitisation in occupationally-exposed humans. WHO (2000) noted that the incidence of PSS fell following the adoption of an occupational exposure limit (OEL) with a threshold limit value (TLV) for soluble platinum salts of 2 µg/m3 (as Pt) as an 8-hour time-weighted average (TWA). However, several epidemiological studies have reported respiratory tract sensitisation in chloroplatinate workers even where the estimated workplace air concentrations were below this 2 µg/m3 OEL (Baker et al., 1990; Bolm-Audorff et al., 1992; Heederik et al., 2016; Linnett and Hughes, 1999; Merget et al., 2000).

In recent Expert Group attempts to evaluate respiratory sensitisation risk at low exposures to complex halogenated platinum salts (SCOEL, 2011; US EPA, 2009), an epidemiological study by Merget et al. (2000) played a central role. However, the investigators themselves acknowledged that the study was not designed to establish a threshold for PSS induction and could not be used to establish an OEL (Merget et al., 2000). The major issues over characterisation of exposure were addressed in an industry report (EPMF, 2009) and SCOEL (2011) was unable to recommend an OEL based on this study. More recently, a new epidemiological study (Heederik et al., 2016) has provided better insights into respiratory sensitisation risk at low exposures.

The older Merget et al. (2000) publication reported the results of a 5-year prospective cohort study that found a dose-response relationship between airborne soluble platinum concentrations and newly occurring sensitisation cases. The study was performed during 1989-1995 (more than 20 years ago), and included 275 employees of a catalyst-production plant in Germany, of whom 115 worked in the production lines (‘high exposure’), 112 worked (regularly or irregularly) within the catalyst department but not in the production lines (‘low exposure’), and 48 never entered the catalyst building (‘no exposure’). 53% of the study population were already present when the study started. The subjects had undergone at least two examinations and had a negative response in a

skin prick test against platinum at the initial survey. The results demonstrated that in a population of 160 workers, no new cases of sensitisation occurred during 5-year employment in the 'no exposure' and 'low exposure' areas [The SCOEL (2011) summary of Merget et al. (2000) stated that the maximum concentrations of soluble platinum measured in the 'low-exposure' area were 8.6 and 1.5 ng/m3 in 1992 and 1993, respectively. In the 'high exposure' area, the maximum measured concentrations of soluble platinum were roughly 700 and 155 ng/m3 in 1992 and 1993, respectively. Personal sampling (of inhalable dust) in this area revealed a median value of 177 ng/m3 with a highest value of 3700 ng/m3; 3 samples out of 22 exceeded 2000 ng/m3 (8-hour sampling time). It was concluded that exposures below the occupational threshold limit value (generally 2000 ng Pt/m3) may still result in sensitisation; even exposure to soluble platinum salts at levels between 10 and 100 ng Pt/m3 may lead to sensitisation (Merget et al., 2000). However, important issues in regard to the exposure characterisation presented in this paper were subsequently noted (EPMF, 2009)] but, in the 'high exposure' area, 14 new cases of sensitisation occurred in 115 exposed workers (11%). Smoking cigarettes was positively associated with the occurrence of new symptoms. It was concluded that exposures below the OEL value (generally 2000 ng Pt/m3) may still result in sensitisation (Merget et al., 2000). Based on these results, SCOEL suggested that at exposure to levels below 10 ng/m3 sensitisation is not to be expected. Critically, SCOEL noted that the study was not conducted with the aim to find a no-observed-adverse-effect level (NOAEL), peak exposures had not been quantified, high exposures may have occurred in the past which could have contributed to the sensitisation cases, exposure estimates were not based on the sampling, and exposures were highly variable, all of which may lead to unreliable exposure estimates. SCOEL concluded that "the database does not allow the recommendation of an OEL for soluble platinum compounds" (SCOEL, 2011).

A recently-published retrospective cohort study designed to investigate PSS found a clear exposure-response relationship between chloroplatinate salts and respiratory sensitisation in workers. The study involved about 1040 refinery workers who newly joined one of five refineries during an 11-year period (1 January 2000 to 31 December 2010), and for whom a total of around 1760 personal time-weighted average exposure measurements (to soluble platinum; used as a surrogate for the various chloroplatinate intermediates in particulate and liquid aerosol forms) were available. Only personal time-weighted average measurements based on the inhalable or total dust fraction, and approximating to 8-hour workshift values were included in the exposure database. Sensitisation cases were detected by SPT, using a hexachloroplatinate salt, which is a method with high sensitivity and predictivity. The relationship was strongest for current (recent) and average exposure, and weaker for cumulative exposure. For current exposure categories of ≤49, >49 ≤100, >100-≤252 and >252 ng/m3, Risk Ratios (RRs) were 1 (reference), 1.4, 2.2 and 3.2, respectively, the latter two values being statistically significant ($p<0.005$ or better). For average exposure, RRs were 1, 1.8, 4.2 and 3.0, respectively, for the ≤51.1, >51.1-≤105, >105 ≤250 and >250 ng/m3 categories (all statistically significant at $p<0.05$ or better). The investigators concluded that "the exposure-relation for current exposure is characterized by an initial steep increase in risk starting at low exposure levels and levelling off at levels of greater than 200 ng/m3" (Heederik et al., 2016).

This recent, high-quality study (Heederik et al., 2016) is consistent with other epidemiology studies in demonstrating that PSS can be induced at estimated airborne soluble platinum concentrations (as a chloroplatinate surrogate measure) of less than 2 µg/m3 (2000 ng/m3) as an 8-hour TWA value. Although the study possessed higher statistical power than any previous epidemiology investigation of PSS, due to some limitations in the low-end exposure dataset it was not possible to define a robust induction threshold (airborne critical concentration) for respiratory sensitisation to chloroplatinates.

In summary, there is extensive epidemiological evidence (from cohort studies and case reports) that halogenated platinum salts, in particular chloroplatinates, can act as respiratory sensitisers, with a large proportion of the exposed workers developing symptoms if the occupational levels are sufficiently high. On continued exposure, asymptomatic respiratory sensitisation (detected by SPT) can proceed to occupational asthma and rhinitis, and such symptoms may be severe. There is a lack of information with regards the particular compounds involved, but the human data, together with supporting laboratory animal studies, indicate the more highly chlorinated forms such as hexachloroplatinate and tetrachloroplatinate are more active as respiratory sensitisers than the less chlorinated forms.

Several chloroplatinate compounds are being registered under REACH by the PMC: dipotassium tetrachloroplatinate (CAS RN 10025-99-7); dipotassium hexachloroplatinate (CAS RN 16921 30-5); diammonium hexachloroplatinate (CAS RN 16919-58-7); and hexachloroplatinic acid (CAS RN 16941-12-1). Given the frequency of occurrence of respiratory sensitisation in workers exposed to sufficiently high occupational levels, and the severity of the symptoms that may develop, particularly if exposure is continued, the available data indicate that it is appropriate to classify these substances as respiratory sensitisers, in sub-category 1A, according to EU CLP criteria. The available epidemiology data have not yet permitted delineation of an induction threshold for PSS in workplace exposure scenarios. In a recent non-guideline study, it was demonstrated that a single respiratory challenge to mice topically sensitised to ammonium hexachloroplatinate can induce dose dependent changes in pulmonary function indicative of an allergic lung response (Williams et al., 2015). This suggests that both dermal and inhalation exposure to chloroplatinates may play a role in occupational respiratory sensitisation/asthma, further supporting the decision to formulate a qualitative assessment approach (and consequent 'high hazard' banding) as most appropriate for the respiratory and dermal sensitisation endpoints.

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Justification for classification or non classification:

The well-known and extensive data set for halogenated platinum compounds indicates that classification for both skin and respiratory sensitisation are required for dipotassium hexachloroplatinate.

As discussed above, available evidence is not supportive of dipotassium hexachloroplatinate having potent delayed contact hypersensitivity potential. The weight of evidence indicates that this compound should be classified for skin sensitisation in sub-category 1B (low to moderate frequency of occurrence), according to EU CLP criteria (EC 1272/2008).

Given the high frequency of occurrence of respiratory sensitisation in workers exposed to sufficiently high occupational levels of chloroplatinates, and the severity of the symptoms that may develop, particularly if exposure is continued, the available data would indicate that it is appropriate to classify dipotassium hexachloroplatinate as a respiratory sensitiser, in sub-category 1A, according to EU CLP criteria (EC 1272/2008).

Discussion of human information:
See “Summary and discussion of human information” in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

The results of studies are summarised in the following table:

Table 5.7. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks
rat [common rodent species] (Crj: CD(SD) [rat]) male/female short-term repeated dose toxicity: oral (oral: gavage) Vehicle: corn oil Exposure: 28 days. (Once daily.) according to OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents) ; according to EU Method B.7 (Repeated Dose (28 Days) Toxicity (Oral))	NOAEL: 10 mg/kg bw/day (actual dose received) (male/female) based on: (test mat.) No general systemic effects seen at 10 mg/kg bw/day LOAEL: 30 mg/kg bw/day (actual dose received) (male) based on: (test mat.) Reduction in body weight gain compared to control group.	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Hansen B 2015**
rat [common rodent species] (Crj: CD(SD) [rat]) male/female short-term repeated dose toxicity: oral (oral: gavage) Vehicle: corn oil Exposure: 28 days. (Once daily.) according to OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents) ; according to EU Method B.7 (Repeated Dose (28 Days) Toxicity (Oral))	NOAEL: 10 mg/kg bw/day (actual dose received) (male/female) based on: (test mat.) No general systemic effects seen at 10 mg/kg bw/day LOAEL: 30 mg/kg bw/day (actual dose received) (male) based on: (test mat.) Reduction in body weight gain compared to control group.	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloroplatinate, (full information in **Annex II**). **Reference** **Hansen B 2015**
Justification for type of information: substance is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		

5.6.1.2. Repeated dose toxicity: inhalation

No relevant information available.

5.6.1.3. Repeated dose toxicity: dermal

No relevant information available.

5.6.1.4. Repeated dose toxicity: other routes

No relevant information available.

5.6.2. Human information

No relevant information available.

5.6.3. Summary and discussion of repeated dose toxicity

The following information is taken into account for any hazard / risk assessment:

Key Information:

In an OECD Test Guideline 407 study, to GLP, rats were administered diammonium hexachloroplatinate by gavage for 28 days. The systemic toxicity NOAEL was 10 mg/kg bw/day on the basis of clinical signs of toxicity (including reduced body weight and growth) in the mid and high dose groups (30 and 100 mg/kg bw/day), resulting in morphological changes to the kidneys and stomach (Hansen, 2015a).

In support, in an OECD Test Guideline 421 reproductive/developmental toxicity screening study, rats (12/sex/group) were administered diammonium hexachloroplatinate by oral gavage at doses of 0, 10, 30 or 100 mg/kg bw/day for at least 35 days. The study NOAEL was established to be 30 mg/kg bw/day for systemic toxicity (Hansen, 2015b).

No repeated dose toxicity studies by the inhalation or dermal route were identified, or are required.

Value used for CSA (via oral route - systemic effects):
adverse effect observed
(NOAEL: 10mg/kg bw/day; subacute, rat [common rodent species])

Value used for CSA (inhalation - systemic effects):
no study available

Value used for CSA (inhalation - local effects):
no study available

Value used for CSA (dermal - systemic effects):
no study available

Value used for CSA (dermal - local effects):
no study available

Additional information:

No relevant human data were identified, or repeated dose toxicity laboratory animal data with dipotassium hexachloroplatinate.

However, a reliable 28-day oral gavage repeated dose toxicity and a reproduction/developmental screening

toxicity study have been conducted with diammonium hexachloroplatinate. Diammonium hexachloroplatinate is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.

In a 28-day repeated dose oral toxicity study, conducted according to OECD Test Guideline 407 and to GLP, rats (5/sex/group) were gavaged with diammonium hexachloroplatinate via stomach tube at doses of 0 (vehicle control, given corn oil), 10, 30 or 100 mg/kg bw/day. Rats were observed for signs of toxicity and mortality, and changes in body weight. Neurobehaviour was assessed (using a functional observation battery). On day 29, blood samples were collected for the analysis of haematological parameters and clinical chemistry. This was immediately followed by sacrifice and scheduled necropsy, in which a comprehensive range of organs and tissues were examined macroscopically and microscopically. Males in the mid-dose group had reduced body weight and body weight gain, compared to controls, and mid-dose females were found to have histopathological lesions in the kidneys (tubular basophilia and hyaline casts) and stomach. In the high-dose group, body weights and body weight gain were affected in both sexes, and lesions of the kidneys and stomach had increased in incidence and severity. Additional findings were noted in the kidney (lymphocytic infiltration, fibrosis, tubular dilation and tubular necrosis) and stomach (lympho-histio-granulocytic infiltration, lymphocytic or eosinophilic infiltration, and/or a chronic/subacute and ulcerative inflammation) at the high dose. Furthermore, high-dose animals were observed to be salivating after treatment. Other clinical signs of toxicity in high-dose females were piloerection, reduced motility, reduced amount of faeces, hunched posture, haemorrhagic nose and/or snout and a decreased body temperature. Under the conditions of this study, the no-observed-adverse-effect level (NOAEL) for systemic toxicity was 10 mg/kg bw/day (Hansen, 2015a).

In support, in a GLP OECD Test Guideline 421 reproductive/developmental toxicity screening study, rats (12/sex/group) were administered diammonium hexachloroplatinate by oral gavage at doses of 0, 10, 30 or 100 mg/kg bw/day for at least 35 days. Parental (F0) animals were observed for clinical signs of toxicity throughout the study, with body weights and food consumption monitored. At necropsy, animals were subjected to external and internal macroscopic examinations for any abnormalities or pathological changes. Special attention was paid to the reproductive organs. Two females in the high-dose group died prematurely. Surviving high-dose animals displayed slight to extreme salivation, piloerection, and/or pale faeces were reported. Increased water consumption was observed in high-dose males. Salivation and piloerection were also observed in low- and mid-dose animals. In the high-dose group, body weights were significantly reduced compared to controls, and cellular changes to the stomach and kidneys were also reported. No test item-related microscopic changes were noted in the reproductive organs at any dose level. The study NOAEL was established to be 30 mg/kg bw/day for systemic toxicity (Hansen, 2015b).

According to REACH Annex VIII (EC 1907/2006), repeated dose toxicity studies only need to be conducted on one species taking into consideration the most appropriate route of administration regarding human exposure.

Justification for classification or non classification:

Based on the histopathological effects on the kidney observed at 30 mg/kg bw/day and above in the 28-day rat study with diammonium hexachloroplatinate, dipotassium hexachloroplatinate should also be classified as STOT RE1 according to EU CLP criteria (EC 1272/2008). The observed effects on the stomach are likely the result of local irritancy.

Detailed information on the Mode of Action is available in **Annex III.**

Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

The results of in vitro genotoxicity studies are summarised in the following table:

Table 5.8. In vitro genotoxicity studies:

Method	Results	Remarks
bacterial reverse mutation assay [in vitro gene mutation study in bacteria] (in vitro gene mutation study in bacteria - Type of genotoxicity: gene mutation) S. typhimurium, other: TA97a, TA98, TA100 and TA102 [bacteria] (with and without met. act.) Test concentrations: The test substance was dissolved in distilled water and diluted to 5-500 ug/plate [or possibly 10, 50, 100 or 500 ug/plate] in all four tester strains, in the absence or presence of (4% and 10%) S9. The number of revertant colonies on the plates were recorded after 48 hours of incubation in the dark at 37degC. Positive control substance(s): methylmethanesulfonate Positive control substance(s): 2-aminofluorene according to guideline Revised test protocol of Maron and Ames (1983) ; equivalent or similar to guideline OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria]	Test results: positive for S. typhimurium, other: TA97a, TA98, TA100 and TA102 [bacteria]; met. act.: with genotoxicity: positive cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: positive controls valid: Test results: positive for S. typhimurium, other: TA98, TA100 and TA102 [bacteria]; met. act.: without genotoxicity: positive cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: positive controls valid: Test results: negative for S. typhimurium, other: TA97a [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: positive controls valid:	2 (reliable with restrictions) key study experimental study **Test material** Potassium hexachloroplatinate (IV); dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Bunger J. et al. 1996**
mammalian cell gene mutation assay [gene mutation] (in vitro gene mutation study in mammalian cells - Type of genotoxicity: gene mutation) Chinese hamster Ovary (CHO) [mammalian cell line] (without met. act.) Test concentrations: Including 10 and 60 uM [possibly 1-100 µM] Positive control substance(s): ethylmethanesulphonate equivalent or similar to guideline OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test) [in vitro gene mutation study in mammalian cells]	Test results: positive - weak for Chinese hamster Ovary (CHO) [mammalian cell line]; met. act.: without genotoxicity: positive - weak cytotoxicity: cytotoxicity - not significant at 10 uM; growth/cloning efficiency reduced by 50% at 34/50 uM, respectively vehicle controls valid: negative controls valid: valid positive controls valid: valid	2 (reliable with restrictions) key study experimental study **Test material** dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, Form: In [presumably aqueous] solution (full information in **Annex II**). **Reference** **Taylor R. T. et al. 1979**
in vitro mammalian cell micronucleus test [in vitro cytogenicity / micronucleus study] (in vitro cytogenicity / micronucleus study - Type of genotoxicity: other: chromosome damage	Test results: negative for mammalian cell line, other: Human peripheral mononuclear blood cells (lymphocytes) [mammalian cell	2 (reliable with restrictions) key study experimental study

(micronuclei)) mammalian cell line, other: Human peripheral mononuclear blood cells (lymphocytes) [mammalian cell line] (without met. act.) Test concentrations: Concentrations of 0, 5, 10, 20 or 40 µM Positive control substance(s): mitomycin C according to guideline non standard method as described by Fenech M (1993) Mut Res 285, 35-44 ; equivalent or similar to guideline OECD Guideline 487 (In vitro Mammalian Cell Micronucleus Test) [in vitro cytogenicity / micronucleus study]	line]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity - Toxicity reported at 40 µM vehicle controls valid: negative controls valid: positive controls valid:	**Test material** K2PtCl6; Potassium hexachloroplatinate; dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Gebel T et al. 1997**
bacterial reverse mutation assay [in vitro gene mutation study in bacteria] (in vitro gene mutation study in bacteria - Type of genotoxicity: gene mutation) S. typhimurium TA 98 [bacteria] (without met. act.) S. typhimurium TA 100 [bacteria] (without met. act.) Test concentrations: In the initial study, the test substance was dissolved in distilled water and introduced onto a dish with the test culture in doses of 0.1, 1, 10, 100 or 1000 µg/plate, in the absence of a mammalian metabolic activation system. A second experiment (doses not explicit in paper, but a dose with “maximum level of effect” - 25 ug/plate - was said to be taken as the “midpoint”, and smaller and larger doses were also tested) to refine the dose dependence of the effect was undertaken, in strainTA 98. It is possible that a range of doses was also tested in strain TA100, although no “midpoint” dose was identifiable due to a lack of mutagenic effect. Positive control substance(s): no guideline followed Ability to induce mutations in Salmonella typhimurium strains. Limited Ames test.	Test results: positive - weak for S. typhimurium TA 98 [bacteria]; met. act.: without genotoxicity: positive - weak cytotoxicity: not specified vehicle controls valid: not specified negative controls valid: not specified positive controls valid: not specified Test results: negative for S. typhimurium TA 100 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: not specified vehicle controls valid: not specified negative controls valid: not specified positive controls valid: not specified	2 (reliable with restrictions) supporting study experimental study **Test material** dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Suraikina T.I. et al. 1979**
SOS/umu assay [in vitro DNA damage and/or repair study] (in vitro DNA damage and/or repair study - Type of genotoxicity: DNA damage and/or repair) E. coli, other: PQ37 [bacteria] (without met. act.) Test concentrations: Dose range was 11-367 µM Positive control substance(s): 4-nitroquinoline-N-oxide	Test results: negative for E. coli, other: PQ37 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity - Cytotoxicity threshold was 92 µM (the highest non-toxic substance concentration that was tested (ap activity >50%)). vehicle controls valid:	2 (reliable with restrictions) supporting study experimental study **Test material** Potassium hexachloroplatinate; dipotassium hexachloroplatinate(

non-standard method as described by Quillardet P and Hofnung M (1985) Mut Res 147, 65-78 Bacterial SOS chromotest for DNA damage	negative controls valid: positive controls valid:	2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Gebel T et al. 1997**
SOS/umu assay [in vitro DNA damage and/or repair study] (in vitro DNA damage and/or repair study - Type of genotoxicity: DNA damage and/or repair) E. coli, other: PQ37 [bacteria] (without met. act.) Test concentrations: 11-367 µM Positive control substance(s): 4-nitroquinoline-N-oxide according to guideline non standard method as described by Quillardet P and Hofnung M (1985) Mut Res 147, 65-78 Bacterial SOS chromotest for DNA damage in the strain Escherichia coli PQ37	Test results: negative for E. coli, other: PQ37 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity - Cytotoxicity reported at 92 µM vehicle controls valid: not specified negative controls valid: positive controls valid:	2 (reliable with restrictions) supporting study experimental study **Test material** dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Lantzsch H & Gebel T 1997**

5.7.1.2. In vivo data

The results of in vivo genotoxicity studies are summarised in the following table:

Table 5.9. In vivo genotoxicity studies

Method	Results	Remarks
mammalian comet assay [in vivo mammalian cell study: DNA damage and/or repair] (in vivo mammalian cell study: DNA damage and/or repair) rat (Wistar [rat]) male oral: gavage 37.5mg/kg bw/day (actual dose received) 75mg/kg bw/day (actual dose received) 150mg/kg bw/day (actual dose received) Ethyl methanesulphonate. - Route of administration: Gavage. - Doses / concentrations: 200 mg/kg bw, dissolved in physiological saline, administered twice. according to guideline OECD Guideline 489 (In vivo Mammalian Alkaline Comet Assay) [in vivo mammalian cell study: DNA damage and/or repair]	Genotoxicity: negative - Kidney: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Liver: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Glandular stomach: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Eurlings IMJ 2020**

	results incl. tables' (male) toxicity: yes vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Duodenum: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:	
mammalian erythrocyte micronucleus test [in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus] (in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus) rat (Wistar [rat]) male oral: gavage 37.5mg/kg bw/day (actual dose received) 75mg/kg bw/day (actual dose received) 150mg/kg bw/day (actual dose received) Cyclophosphamide. - Route of administration: Gavage. - Doses / concentrations: A single dose of 19 mg/kg bw, dissolved in physiological saline. according to guideline OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) [in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus]	Genotoxicity: negative - cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes - One high-dose animal died after the first dose, and was replaced by an additional animal. Clinical signs of toxicity were observed in the high-dose group: hunched posture (4/5 animals), lethargy (5/5 animals) and diarrhoea (1/5 animals). vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Eurlings IMJ 2020**
mammalian comet assay [in vivo mammalian cell study: DNA damage and/or repair] (in vivo mammalian cell study: DNA damage and/or repair) rat (Wistar [rat]) male oral: gavage 37.5mg/kg bw/day (actual dose received) 75mg/kg bw/day (actual dose received) 150mg/kg bw/day (actual dose received) Ethyl methanesulphonate. - Route of administration: Gavage. - Doses / concentrations: 200 mg/kg bw, dissolved	Genotoxicity: negative - Kidney: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Liver: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes	1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate) **Test material** dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, Form: not specified (full information in **Annex II**).

in physiological saline, administered twice. according to guideline OECD Guideline 489 (In vivo Mammalian Alkaline Comet Assay) [in vivo mammalian cell study: DNA damage and/or repair]	vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Glandular stomach: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Duodenum: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:	**Reference** **Eurlings IMJ 2020**
Justification for type of information: For this category of four hexachloroplatinate(IV) substances, it is proposed that, in aqueous solution and in biological media (e.g. gastric fluid), the cations (ammonium, hydrogen, potassium or sodium) would dissociate, leaving the core hexachloroplatinate(IV) complex as the common product and toxicologically-active species. It should be noted that this represents a chemical transformation and not a "biotransformation"; no metabolism of the hexachloroplatinate(IV) complex is anticipated to occur in vivo. More details on this read-across approach are provided in IUCLID Section 13.		
mammalian erythrocyte micronucleus test [in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus] (in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus) rat (Wistar [rat]) male oral: gavage 37.5mg/kg bw/day (actual dose received) 75mg/kg bw/day (actual dose received) 150mg/kg bw/day (actual dose received) Cyclophosphamide. - Route of administration: Gavage. - Doses / concentrations: A single dose of 19 mg/kg bw, dissolved in physiological saline. according to guideline OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) [in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus]	Genotoxicity: negative (male) toxicity: yes - One high-dose animal died after the first dose, and was replaced by an additional animal. Clinical signs of toxicity were observed in the high-dose group: hunched posture (4/5 animals), lethargy (5/5 animals) and diarrhoea (1/5 animals). vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:	1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate) **Test material** dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, Form: not specified (full information in **Annex II**). **Reference** **Eurlings IMJ 2020**
Justification for type of information: For this category of four hexachloroplatinate(IV) substances, it is proposed that, in aqueous solution and in biological media (e.g. gastric fluid), the cations (ammonium,		

hydrogen, potassium or sodium) would dissociate, leaving the core hexachloroplatinate(IV) complex as the common product and toxicologically-active species. It should be noted that this represents a chemical transformation and not a “biotransformation”; no metabolism of the hexachloroplatinate(IV) complex is anticipated to occur in vivo. More details on this read-across approach are provided in IUCLID Section 13.

5.7.2. Human information

No relevant information available.

5.7.3. Summary and discussion of mutagenicity

The following information is taken into account for any hazard / risk assessment (genetic toxicity in vitro):

Dipotassium hexachloroplatinate was mutagenic in a bacterial reverse mutation (Ames) assay using four Salmonella typhimurium strains (TA97a, TA98, TA100 and TA102) when tested in the presence and absence of a rat liver metabolic activation (S9) system (Bunger et al., 1996).

In a well-conducted in vitro mammalian gene mutation test using CHO cells, dipotassium hexachloroplatinate was weakly mutagenic when tested up to cytotoxic concentrations, in the absence of metabolic activation (Taylor et al., 1979).

Dipotassium hexachloroplatinate did not induce micronuclei in the cytokinesis-block micronucleus test with human lymphocytes, when tested at up to cytotoxic concentrations (Gebel et al., 1997).

Value used for CSA (genetic toxicity in vitro): Genetic toxicity: adverse effect observed (positive)

The following information is taken into account for any hazard / risk assessment (genetic toxicity in vivo):

The in vivo genotoxicity of diammonium hexachloroplatinate, as evaluated by its ability to induce micronuclei in polychromatic erythrocytes and to cause DNA damage, was assessed in a combined study following OECD 474 and 489 and according to GLP. Male Wistar rats (5/group) were given gavage doses of 37.5, 75 or 150 mg/kg bw/day of the test item on three consecutive days, or a vehicle control. The highest-tested dose was limited by clinical signs of toxicity, including mortalities, observed in a dose range finding study. Comet analyses were conducted on preparations of liver, glandular stomach, duodenum and kidney tissues and micronuclei were analysed in bone marrow cells.

There was no increase in the number of micronucleated polychromatic erythrocytes in any treatment group. There was no increase in % tail intensity in the liver, kidney, glandular stomach or duodenum, indicating that the test item was not genotoxic to these tissues. As such, and as platinum was detected in the plasma of the test animals, diammonium hexachloroplatinate -and via read across also dipotassium hexachloroplatinate- was concluded to be non-genotoxic in vivo.

Value used for CSA (genetic toxicity in vivo): Genetic toxicity: no adverse effect observed (negative)

Justification for classification or non classification

Based on the existing data set, dipotassium hexachloroplatinate does not currently meet the criteria for classification as a germ cell mutagen (category 1A/1B or 2) under EU CLP criteria (EC 1272/2008).

Relevant studies: Genetic toxicity in vitro, Ames (KEY) - Bunger et al. (1996)
Relevant studies: Genetic toxicity in vitro, micronucleus (KEY) - Gebel et al. (1997)
Relevant studies: Genetic toxicity in vitro, mouse lymphoma (KEY) - Taylor et al. (1979)

Relevant studies: Genetic toxicity in vivo, micronucleus (KEY) - Eurlings (2020).source
Relevant studies: Genetic toxicity in vivo, comet (KEY) - Eurlings (2020).target
Relevant studies: Genetic toxicity in vivo, micronucleus (KEY) - Eurlings (2020).target
Relevant studies: Genetic toxicity in vivo, comet (KEY) - Eurlings (2020).source
Additional information:

Dipotassium hexachloroplatinate was assessed for mutagenic activity in a bacterial reverse mutation

(Ames) assay, similar to OECD Test Guideline 471, using Salmonella typhimurium strains TA97a, TA98, TA100 and TA102 and tested at up to 500 µg/plate in the presence and absence of a metabolic activation system (S9) derived from phenobarbital- and beta-naphthoflavone-induced rat livers. (It is not clear whether the di- or mono-ammonium form was used; the recommended strain TA1535 was omitted.) Mutagenic effects were seen in all four strains in the presence of metabolic activation and in all but strain TA97a in its absence. Although no cytotoxicity data were provided for the test material, the minimum toxic dose for the platinum salts was apparently 100 µg/plate (Bunger et al., 1996). This study conforms to OECD guidelines, aside from the lack of inclusion of a fifth tester strain.

In a limited Ames assay involving two strains (TA98 and TA100) of S. typhimurium bacteria, dipotassium hexachloroplatinate was tested at up to 1 mg/plate in the absence of S9. A weak mutagenic effect was reported for strain TA98; there was no evidence of mutagenicity in strain TA100 (Suraikina et al., 1979).

Dipotassium hexachloroplatinate was tested for genotoxicity in an in vitro mammalian gene mutation test using Chinese Hamster Ovary (CHO) cells deficient in HPRT (hypoxanthine-guanine phosphoribosyl transferase). Cells were tested only in the absence of a metabolic activation system. A 2-3-fold increase in the 8-AGR mutant frequency versus the spontaneous control was seen upon repeated subculture [prolonged exposure] with a non-cytotoxic concentration of 10 µM. This increase was apparent after 10 population doublings; the trend towards it was observed at 5 population doublings. Dipotassium hexachloroplatinate was determined to be weakly mutagenic to mammalian cells in the absence of metabolic activation under the conditions of the test (Taylor et al., 1979).

In a well-conducted study, similar to that described by OECD Test Guideline 487, the ability of dipotassium hexachloroplatinate to induce micronuclei in human peripheral mononuclear blood cells (lymphocytes) was assessed, in the absence of a metabolic activation system. The mean numbers of micronuclei in binucleate cells were 4, 5.5, 7.5 and 4 at test concentrations of 0, 5, 10 and 20 µM, respectively; there was no statistically significant change compared to the negative control. Severe cytotoxicity was observed at 40 µM. In conclusion, the test substance did not cause chromosome damage (micronuclei) in the cytokinesis-block micronucleus test with human lymphocytes (Gebel et al., 1997).

Dipotassium hexachloroplatinate did not cause DNA damage in a bacterial SOS chromotest, when tested at up to cytotoxic concentrations in the absence of metabolic activation (Gebel et al., 1997; Lantzsch and Gebel, 1997).

In a combined rat micronucleus test and comet assay following OECD 474 and 489, there was no increase in

the number of micronucleated polychromatic erythrocytes and no increase in % tail intensity in liver, kidney, glandular stomach or duodenum in rats given gavage doses of 37.5, 75 or 150 mg/kg bw/day of the test item on three consecutive days (Eurlings, 2020).

Several Expert Groups have assessed the toxicity profile of platinum, and various platinum compounds, including the assessment of CMR properties. All reviews have indicated that platinum compounds have been reported to be mutagenic in a range of in vitro studies (HCN, 2008; EMA, 2008; SCOEL, 2011; WHO, 1991). Cisplatin and related compounds are known DNA-reactive carcinogens and, as these compounds are better investigated due to their pharmaceutical properties, this has been confirmed in vivo. As cisplatin-type substances differ in chemical reactivity (liability of ligands, number of active sites etc.) it is reasonable to expect that not all forms of platinum are carcinogenic (HCN, 2008). Limited experimental data on carcinogenicity for other platinum compounds give no evidence of activity that would meet classification criteria (HCN, 2008; SCOEL, 2011).

Despite the generally positive in vitro results identified for the platinum compounds in various bacterial/mammalian cell mutagenicity assays (supported by some mammalian cell cytogenicity tests), the in vivo relevance of these in vitro findings remains unclear. Indeed, the new, high-quality in vivo data showed diammonium hexachloroplatinate itself -and via read-across also dipotassium hexachloroplatinate- to be conclusively non -genotoxic.

References

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Detailed information on the Mode of Action is available in **Annex III.**

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

No relevant information available.

5.8.1.2. Carcinogenicity: inhalation

No relevant information available.

5.8.1.3. Carcinogenicity: dermal

No relevant information available.

5.8.1.4. Carcinogenicity: other routes

No relevant information available.

5.8.2. Human information

No relevant information available.

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

The results of studies on fertility are summarised in the following table:

Table 5.9. Studies on fertility

Method	Results	Remarks
rat (Crj: CD(SD) [rat]) male/female screening for reproductive / developmental toxicity - based on test type (migrated information) oral: gavage Doses / Concentrations: 10 mg/kg bw/day Basis: actual ingested low dose Doses / Concentrations: 30 mg/kg bw/day Basis: actual ingested intermediate dose Doses / Concentrations: 100 mg/kg bw/day Basis: actual ingested high dose Vehicle: corn oil Exposure: Males were dosed from test days 1-35 (inclusive), including 2 weeks prior to mating, the mating period and approximately 2 weeks post-mating. Females were dosed from test day 1 (2 weeks prior to mating), throughout mating and gestation, until day 3 post-partum or the day before sacrifice (from test day 41 for the first sacrificed females to test day 57 for the last sacrificed female). (Once daily.) according to OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	**First parental generation (P0)** NOAEL - General toxicity (PO) 30 mg/kg bw/day (actual dose received)) (male/female) based on: see 'Remark' - Two high-dose animals died prematurely (test days 8 and 23). No or reduced body weight gain and reduced food consumption was reported in high-dose males and females. Test item-related stomach and kidney lesions were reported in high-dose males and females. NOAEL - Reproductive toxicity (PO) 30 mg/kg bw/day (actual dose received)) (female) based on: Slightly increased post-implantation loss and decreased birth index were noted in the high-dose group. This was attributed to a single female with all dead implantations and 2 other females with post-implantations of 23.1% and 18.2%. **F1 generation** NOAEL : 100 mg/kg bw/day (actual dose received) (male/female) based on: No general systemic effects seen in the F1 generation at the highest tested dose **Overall reproductive toxicity** not specified Lowest effective dose / concentration Relation to other toxic effects:	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Hansen B 2015**
rat (Crj: CD(SD) [rat]) male/female screening for reproductive /	**First parental generation (P0)** NOAEL - General toxicity (PO) 30	2 (reliable with restrictions) key study

developmental toxicity oral: gavage Doses / Concentrations: 10 mg/kg bw/day Basis: actual ingested low dose Doses / Concentrations: 30 mg/kg bw/day Basis: actual ingested intermediate dose Doses / Concentrations: 100 mg/kg bw/day Basis: actual ingested high dose Vehicle: corn oil Exposure: Males were dosed from test days 1-35 (inclusive), including 2 weeks prior to mating, the mating period and approximately 2 weeks post-mating. Females were dosed from test day 1 (2 weeks prior to mating), throughout mating and gestation, until day 3 post-partum or the day before sacrifice (from test day 41 for the first sacrificed females to test day 57 for the last sacrificed female). (Once daily.) according to OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	mg/kg bw/day (actual dose received)) (male/female) based on: see 'Remark' - Two high-dose animals died prematurely (test days 8 and 23). No or reduced body weight gain and reduced food consumption was reported in high-dose males and females. Test item-related stomach and kidney lesions were reported in high-dose males and females. NOAEL - Reproductive toxicity (PO) 30 mg/kg bw/day (actual dose received)) (female) based on: Slightly increased post-implantation loss and decreased birth index were noted in the high-dose group. This was attributed to a single female with all dead implantations and 2 other females with post-implantations of 23.1% and 18.2%. **F1 generation** NOAEL : 100 mg/kg bw/day (actual dose received) (male/female) based on: No general systemic effects seen in the F1 generation at the highest tested dose **Overall reproductive toxicity** not specified Lowest effective dose / concentration Relation to other toxic effects:	read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloroplatinate, (full information in **Annex II**). **Reference** **Hansen B 2015**
Justification for type of information: substance is considered to fall within the scope of the read-across category "hexachloroplatinate(IV) compounds". See section 13 in IUCLID for full read-across justification report.		

Toxicity to reproduction: other studies

No relevant information available.

5.9.1.2. Human information

No relevant information available.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

The results of studies on developmental toxicity are summarised in the following table:

Table 5.10. Studies on developmental toxicity

Method	Results	Remarks
rat (Crj: CD(SD) [rat]) oral: gavage Vehicle: corn oil Exposure: Males were dosed from test days 1-35 (inclusive), including 2 weeks prior to mating, the mating period and	**Maternal animals:** NOAEL: 100 mg/kg bw/day (actual dose received) based on: (test mat.) **Fetuses:** Fetal abnormalities not specified	1 (reliable without restriction) key study experimental study **Test material**

approximately 2 weeks post-mating. Females were dosed from test day 1 (2 weeks prior to mating), throughout mating and gestation, until day 3 post-partum or the day before sacrifice (from test day 41 for the first sacrificed females to test day 57 for the last sacrificed female). (Once daily.) according to OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	NOAEL: 100 mg/kg bw/day (actual dose received) based on: (test mat.) **Overall developmental toxicity:** not specified Lowest effective dose / concentration: Relation to maternal toxicity:	diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Hansen B 2015**
rat (Crj: CD(SD) [rat]) oral: gavage Vehicle: corn oil Exposure: Males were dosed from test days 1-35 (inclusive), including 2 weeks prior to mating, the mating period and approximately 2 weeks post-mating. Females were dosed from test day 1 (2 weeks prior to mating), throughout mating and gestation, until day 3 post-partum or the day before sacrifice (from test day 41 for the first sacrificed females to test day 57 for the last sacrificed female). (Once daily.) according to OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	**Maternal animals:** NOAEL: 100 mg/kg bw/day (actual dose received) based on: (test mat.) **Fetuses:** Fetal abnormalities not specified NOAEL: 100 mg/kg bw/day (actual dose received) based on: (test mat.) **Overall developmental toxicity:** not specified Lowest effective dose / concentration: Relation to maternal toxicity:	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloroplatinate, (full information in **Annex II**). **Reference** **Hansen B 2015**
Justification for type of information: substance is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		

5.9.2.2. Human information

No relevant information available.

5.9.3. Summary and discussion of reproductive toxicity

Effects on fertility

The following information is taken into account for any hazard / risk assessment:

In an OECD Test Guideline 421 reproduction and developmental toxicity screening study, to GLP, parental (F0) rats (12/sex/group) were administered diammonium hexachloroplatinate by oral gavage at up to 100 mg/kg bw/day for 14 days pre-mating, through mating, and (for females) throughout gestation and up to lactation day 3. Clinical signs of toxicity (including premature death, reduced body weight and growth) were observed in the high-dose groups, resulting in morphological changes to the kidneys and stomach. There was a significant increase in post-implantation loss and an accompanying decrease in birth index (although live birth index was unaffected). The study NOAEL was established to be 30 mg/kg bw/day for both systemic and reproductive toxicity (Hansen, 2015b).

Value used for CSA (route: oral):
adverse effect observed (NOAEL): 30mg/kg bw/day (subacute, rat [common rodent species])

Value used for CSA (route: dermal):
no study available

Value used for CSA (route: inhalation):
no study available

Additional information:

No relevant data in humans were identified or reproductive toxicity laboratory animal data with dipotassium hexachloroplatinate.

However, a reliable reproduction/developmental screening toxicity study has been conducted with diammonium hexachloroplatinate. Diammonium hexachloroplatinate is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.

The potential of diammonium hexachloroplatinate to adversely affect the fertility and reproductive parameters of CD rats was investigated in a reproductive and developmental screening study conducted according to OECD Test Guideline 421 and to GLP. The test material (in corn oil) was administered by oral gavage. Males were dosed for 35 days (14 days pre-mating, during the mating period and for approximately 14 days post-mating. Females were dosed for 14 days pre-mating, through mating, gestation and up to post-partum day 3 (test day 41-57). Three dose groups (10, 30 and 100 mg/kg bw/day) and a control group were used, each containing 12 animals of each sex. Parental (F0) animals were observed for clinical signs of toxicity throughout the study, with body weights and food consumption monitored. At necropsy, animals were subjected to external and internal macroscopic examinations for any abnormalities or pathological changes. Special attention was paid to the reproductive organs. The numbers of implantation sites and corpora lutea were recorded. Histopathological examination was performed on the ovaries, testes and epididymides of all animals in the control and high-dose groups, with special emphasis on the qualitative stages of spermatogenesis and histopathology of interstitial testicular structure. A number of reproductive indices were calculated from the collected data. Two females in the high-dose group died prematurely. Surviving high-dose animals displayed slight to extreme salivation, piloerection, and/or pale faeces were reported. Increased water consumption was observed in high-dose males. Salivation and piloerection were also observed in low- and mid-dose animals. In the high-dose group, body weights were significantly reduced compared to controls, and cellular changes to the stomach and kidneys were also reported. A significantly increased percentage post-implantation loss was reported in high-dose females, leading to a significant reduction in birth index (although live birth index was unaffected). No test item-related microscopic changes were noted in the reproductive organs at any dose level. The study NOAEL was established to be 30 mg/kg bw/day for both systemic and reproductive toxicity (Hansen, 2015b).

No reproductive toxicity studies by the inhalation or dermal route were identified, or are required.

Developmental toxicity

The following information is taken into account for any hazard / risk assessment:

In an OECD Test Guideline 421 reproduction and developmental toxicity screening study, to GLP, parental

(F0) rats (12/sex/group) were administered diammonium hexachloroplatinate by gavage at 0 (corn oil), 10, 30 or 100 mg/kg bw/day. A single female with all dead implantations and two others with high post-implantation losses caused a slight increase in overall post-implantation loss and concurrent decrease in birth index, in dams at the highest tested dose. No adverse effects on reproductive parameters of parent males (F0 animals), or on developmental of offspring (FI generation), were observed at any dose, resulting in a NOAEL of 100 mg/kg bw/day. (Hansen, 2015b).

Value used for CSA (route: oral):
no adverse effect observed (NOAEL): 100mg/kg bw/day (subacute; rat [common rodent species])

Value used for CSA (route: dermal):
no study available

Value used for CSA (route: inhalation):
no study available

Additional information:

No relevant data in humans were identified or reproductive/developmental toxicity laboratory animal data with dipotassium hexachloroplatinate.

However, a reliable reproduction/developmental screening toxicity study has been conducted with diammonium hexachloroplatinate. Diammonium hexachloroplatinate is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.

The potential of diammonium hexachloroplatinate to adversely affect the development of rats was investigated in a guideline reproductive and developmental screening study conducted according to OECD Test Guideline 421 and to GLP. The test material (in corn oil) was administered to rats by oral gavage. Males were dosed for 35 days (14 days pre-mating, during the mating period and for approximately 14 days post mating. Females were dosed for 14 days pre-mating, through gestation and up to post-partum day 3 (test day 41-57). Three dose groups (10, 30 and 100 mg/kg bw/day) and a control group were used, each containing 12 animals of each sex. Parental (F0) animals were observed for clinical signs of toxicity throughout the study, with body weights and food consumption monitored. At necropsy, animals were subjected to external and internal macroscopic examinations for any abnormalities or pathological changes. Special attention was paid to the reproductive organs. Pups were carefully examined for gross abnormalities at necropsy (on post-partum day 4). Two females in the high-dose group died prematurely. Surviving high-dose animals displayed slight to extreme salivation, piloerection, and/or pale faeces were reported. Salivation and piloerection were also observed in low- and mid-dose animals. A significantly increased percentage post-implantation loss was reported in high-dose females, leading to a significant reduction in birth index (although live birth index was unaffected). No test item-related microscopic changes were noted in the reproductive organs at any dose level. There was no developmental toxicity effect (survival index, body weight, gross abnormalities) at any dose level. Consequently, the NOAEL for developmental toxicity was 100 mg/kg bw/day, the highest dose tested (Hansen, 2015b).

No developmental toxicity studies by the inhalation or dermal route were identified, or are required.

Justification for classification or non classification:

In a reliable guideline reproductive and developmental screening study with diammonium hexachloroplatinate, no adverse effects on reproductive parameters (sexual function or fertility) were seen at doses that did not also cause maternal toxicity and no microscopic effects on the reproductive organs were observed at any dose level; no adverse effects on development of offspring were apparent. As such, classification of dipotassium hexachloroplatinate for reproductive/developmental toxicity is not required, according to EU CLP criteria (EC 1272/2008).

Detailed information on the Mode of Action is available in **Annex III.**

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

No relevant information available.

5.10.1.2. Immunotoxicity

No relevant information available.

5.10.1.3. Specific investigations: other studies

No relevant information available.

5.10.1.4. Additional toxicological effects

No relevant information available.

5.10.2. Human information

No relevant information available.

5.11. Derivation of DNEL(s) and other hazard conclusions

5.11.1. Overview of typical dose descriptors for all endpoints

Table 5.11. Available dose-descriptor(s) per endpoint as a result of its hazard assessment

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type
Acute toxicity	oral	adverse effect observed (LD50): 195mg/kg bw
Acute toxicity	dermal	no study available
Acute toxicity	inhalation	no study available
Irritation / Corrosivity	skin	adverse effect observed (irritating)

Irritation / Corrosivity	eye	adverse effect observed (irreversible damage)
Irritation / Corrosivity	resp. tract	no study available
Sensitisation	skin	adverse effect observed (sensitising)
Sensitisation	resp. tract	adverse effect observed (sensitising)
Repeated dose toxicity	oral	adverse effect observed (NOAEL): 10mg/kg bw/day (subacute; rat [common rodent species]) Target system/organs:urinary
Repeated dose toxicity	dermal (systemic effects)	no study available
Repeated dose toxicity	dermal (local effects)	no study available
Repeated dose toxicity	inhalation (systemic effects)	no study available
Repeated dose toxicity	inhalation (local effects)	no study available
Mutagenicity	in vitro / in vivo	In vitro: adverse effect observed (positive) In vivo: no study available
Reproductive toxicity: effects on fertility	oral	adverse effect observed (NOAEL): 30mg/kg bw/day (subacute; rat [common rodent species])
Reproductive toxicity: effects on fertility	dermal	no study available
Reproductive toxicity: effects on fertility	inhalation	no study available
Reproductive toxicity: developmental toxicity	oral	no adverse effect observed (NOAEL): 100mg/kg bw/day (subacute; rat [common rodent species])
Reproductive toxicity: developmental toxicity	dermal	no study available
Reproductive toxicity: developmental toxicity	inhalation	no study available

5.11.2. Selection of the DNEL(s) or other hazard conclusions for critical health effects

Table 5.12. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	high hazard (no threshold derived)	sensitisation (respiratory tract)
Inhalation	Systemic effects -	medium hazard (no threshold	acute toxicity

	Acute	derived)	(Oral)
Inhalation	Local effects - Long-term	high hazard (no threshold derived)	sensitisation (respiratory tract)
Inhalation	Local effects - Acute	high hazard (no threshold derived)	sensitisation (respiratory tract)
Dermal	Systemic effects - Long-term	high hazard (no threshold derived)	sensitisation (respiratory tract)
Dermal	Systemic effects - Acute	medium hazard (no threshold derived)	acute toxicity (Oral)
Dermal	Local effects - Long-term	medium hazard (no threshold derived)	sensitisation (skin)
Dermal	Local effects - Acute	medium hazard (no threshold derived)	sensitisation (skin)
Eyes	Local effects	medium hazard (no threshold derived)	

Inhalation Systemic effects - Long-term

Further explanation on hazard conclusions:

[See discussion section (Hazard via inhalation route: systemic effects following long-term exposure).]

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions:

[See discussion section (Hazard via inhalation or dermal route: systemic effects following acute exposure).]

Inhalation Local effects - Long-term

Further explanation on hazard conclusions:

[See discussion section (Hazard via inhalation route: local effects following long-term or acute exposure).]

Inhalation Local effects - Acute

Further explanation on hazard conclusions:

[See discussion section (Hazard via inhalation route: local effects following long-term or acute exposure).]

Dermal Systemic effects - Long-term

Further explanation on hazard conclusions:

[See discussion section (Hazard via dermal route: systemic effects following long-term exposure).]

Dermal Systemic effects - Acute

Further explanation on hazard conclusions:

[See discussion section (Hazard via inhalation or dermal route: systemic effects following acute exposure).]

Dermal Local effects - Long-term

Further explanation on hazard conclusions:

[See discussion section (Hazard via dermal route: local effects following long-term or acute exposure).]

Dermal Local effects - Acute

Further explanation on hazard conclusions:

[See discussion section (Hazard via dermal route: local effects following long-term or acute exposure).]

Discussion:

Hazard via inhalation route: systemic effects following long-term exposure

As no relevant data on effects of repeated inhalation exposure to dipotassium hexachloroplatinate in laboratory animals are available, route-to-route extrapolation to calculate an inhalation DNEL from reliable studies (repeated-dose oral toxicity and reproductive/developmental toxicity screening) on a member of the "hexachloroplatinate(IV) compounds" category, diammonium hexachloroplatinate, was considered a suitable alternative (particularly as first pass effects are not expected to be significant for an inorganic compound).

In a guideline (OECD TG 407) 28-day gavage toxicity study, conducted according to GLP, rats (5/sex/dose) were administered diammonium hexachloroplatinate doses of 0, 10, 30 or 100 mg/kg bw/day. Males in the mid-dose group had reduced body weight and body weight gain (likely a consequence of reduced food consumption, possibly due to the local effects on the stomach), compared to controls, and mid-dose males and females were found to have lesions in the kidneys and stomach. In the high-dose group, body weights and body weight gain were affected in males and females, and lesions of the kidneys and stomach - additional to those also present in mid-dose animals - were reported. Accordingly, the NOAEL was established as 10 mg/kg bw/day (Hansen, 2015a).

In a guideline reproductive/developmental screening study (OECD TG 421), using the same gavage dose groups, high-dose parental animals displayed similar stomach and kidney lesions as those seen in the 28-day toxicity study. In this study, the NOAEL for general toxicity was set as 30 mg/kg bw/day. Females in the high-dose group also displayed slightly increased post-implantation loss and decreased birth index, although this was attributed to a single female with all dead implantations and 2 other females with high post-implantation losses. The NOAEL for fertility effects was, nevertheless, set at 30 mg/kg bw/day. There were no developmental effects seen at any dose (developmental NOAEL 100 mg/kg bw/day)(Hansen, 2015b).

Overall, the systemic NOAEL of 10 mg/kg bw/day (equivalent to 4.39 and 10.95 mg/kg bw/day for elemental platinum and dipotassium hexachloroplatinate, respectively, based on MWt ratios[1]) from the repeated-dose

oral toxicity study was taken as the critical point of departure for calculating the long-term systemic DNEL.

Laboratory studies provide only very limited insights into the extent of absorption of platinum compounds following inhalation. When two volunteers inhaled mainly diammonium hexachloroplatinate at calculated mean air concentrations of 1.7 and 0.15 Pt µg/m3, respectively, urinary Pt concentrations peaked (15-100-fold increases were seen) about 10 hr later. The results indicated rapid absorption and urinary excretion, but gave no quantitative insights into the extent of absorption (Schierl et al., 1998). Urinary Pt measurements in rats following an acute inhalation of radiolabelled Pt, PtO2, PtCl4 or Pt(SO4)2 (particle diameter around 1 µm) indicated only small fractions of the administered dose were absorbed, even for the two soluble salts. Most of the radiolabel appeared in the faeces, presumably reflecting mucociliary clearance and a lack of significant absorption from the gastrointestinal tract (Moore et al., 1975a).

Available data indicate that absorption of soluble Pt compounds is also very low following oral exposure. In rats, less than 0.5% of an oral dose of radiolabelled PtCl4 was absorbed (Moore et al., 1975b,c). Similar results were obtained when Pt(SO4)2 was administered orally to mice (Lown et al., 1980). Following REACH guidance, the worst-case (and, therefore, most health-precautionary) scenario for DNEL calculation is obtained by considering the minimum absorption by the ‘starting’ route. Therefore, for this oral-to-inhalation extrapolation, a figure of 0.5% oral absorption has been used, taken from the laboratory study in rats. In line with the guidance, the worst-case of 100% absorption after inhalation has still been assumed for the ‘end’ route (which is clearly significantly higher than the available, albeit limited, data indicates, and thus almost certainly over-precautionary).

Expressed as the source substance, diammonium hexachloroplatinate, the corrected inhalatory NOAEC (worker, 8 h exposure/day) = oral NOAEL*(1/sRv[rat])*(ABS[oral-rat]/ABS[inh-human]) *(sRV[human]/wRV) = 10 mg/kg bw/day*(1/0.38 m3/kg bw/day)*(0.5/100)*(6.7 m3 [8h]/10 m3 [8h]) = 0.088 mg/m3. This equates to a dipotassium hexachloroplatinate exposure of 0.097 mg/m3.

It is noted that the standard respiratory rate conversion figure (0.38 m3/kg bw/day) already incorporates a factor of 4 for allometric scaling from rat to human. An assessment factor (AF) for allometric scaling is not considered to be justified in this scenario, given that the metabolism of inorganic metal cations is conventionally assumed not to occur to any relevant extent. Moreover, ECHA guidance notes that “allometric scaling is an empirical approach for interspecies extrapolation of various kinetic processes generally applicable to substances which are renally excreted, but not to substances which are highly extracted by the liver and excreted in the bile. It appears that species differences in biliary excretion and glucuronidation are independent of caloric demand (Walton et al. 2001)” (ECHA, 2012a). Oral toxicokinetic studies have demonstrated that, while gastrointestinal absorption of platinum is very low, the absorbed fraction is excreted predominantly via the faecal route (Moore et al., 1975b). It is therefore considered appropriate to increase the corrected inhalatory NOAEC by a factor of 4.

Dose descriptor starting point (after route to route extrapolation) = Corrected inhalatory NOAEC (worker, 8 h exposure/day)*4 = 0.088*4 = 0.35 mg/m3, which equates to a corrected NOAEC of 0.39 mg/m3in terms of dipotassium hexachloroplatinate.

Application of the assessment factors (overall AF 75) described above to this corrected inhaled NOAEC gives a systemic long-term inhalation DNEL for dipotassium hexachloroplatinate of 0.0052 mg/m3 [5.2 µg/m3], which equates to an elemental platinum exposure of 0.0021 mg/m3 [2.07 µg/m3].

Recent epidemiological studies (including Heederick et al., 2016, a retrospective cohort study of about 1040 platinum refinery workers) have provided some evidence that platinum salt sensitisation can be induced at airborne soluble platinum concentrations below 2 µg/m3. In addition, a non-guideline study demonstrated that a single respiratory challenge to mice topically sensitised to ammonium hexachloroplatinate can induce dose-dependent changes in pulmonary function indicative of an allergic lung response (Williams et al., 2015). This suggests that both dermal and inhalation exposure to chloroplatinates may play a role in occupational respiratory sensitisation/asthma. Consequently, the most appropriate and health precautionary approach was deemed to be to formulate a qualitative assessment (with 'high hazard' banding and recommended RMMs/OCs in Table E.3-1 of ECHA, 2012b) for systemic exposure to workers by inhalation. [For further discussion of the potential respiratory sensitisation and irritation, including that reported in recent epidemiological studies, please see the 'Hazard via inhalation route: local effects following long-term or acute exposure' section, below]. (It is anticipated that this qualitative approach with its associated stringent RMMs/OC requirements will also be protective for general systemic toxic effects (with due consideration of the DNEL that would be applied to the latter).

Hazard via inhalation or dermal route: systemic effects following acute exposure

DNELs for acute toxicity should be calculated if an acute toxicity hazard, leading to classification and labelling (i.e. under EU CLP regulations) has been identified and there is a potential for high peak exposures (this is only usually relevant for inhalation exposures).

There are no data in relation to acute inhalation or dermal exposure to dipotassium hexachloroplatinate (or closely-related surrogates). In an acute oral toxicity study in rats, an LD50 value of around 195 mg/kg bw was reported for dipotassium hexachloroplatinate. When groups (5/sex) of animals were administered single gavage doses of 100, 215 or 464 mg/kg bw, all animals died at the top dose while 4 males and 3 females died at the mid dose. The acute oral LD50 was determined (using probit analysis) to be 184 mg/kg bw in males, 212 mg/kg bw in females and 195 mg/kg bw for both sexes combined (Berthold, 1995a). On this basis, dipotassium hexachloroplatinate was classified for its acute oral toxicity in category 3, according to EU CLP criteria (EC 1272/2008).

"A qualitative risk characterisation for this endpoint could be performed for substances of very high or high acute toxicity classified in Category 1, 2 and 3 according to CLP… when the data are not sufficiently robust to allow the derivation of a DNEL" (ECHA, 2012b). It is, therefore, considered suitably health precautionary to adopt the "moderate" hazard banding, and to consider the recommended RMMs/OCs in Table E.3-1 of ECHA (2012b).

Hazard via inhalation route: local effects following long-term or acute exposure

The development of allergic sensitisation following exposure to halogenated platinum compounds via the inhalation route is a well-established human health hazard associated with occupational exposure, and has been the subject of a number of comprehensive expert reviews (HCN, 2008; IPCS, 1991; Ravindraet al., 2004; SCOEL, 2011; US EPA, 2009; WHO, 2000; 2012). There is extensive epidemiological evidence (from cohort studies and case reports) that halogenated platinum salts, in particular chloroplatinates, can act as respiratory sensitisers, with exposed workers developing symptoms if the occupational levels are sufficiently high. Asymptomatic respiratory sensitisation (detected by skin prick testing; SPT) can proceed to occupational asthma and rhinitis if exposure is continued, and such symptoms may be severe.

In most occupational studies, the individual platinum compounds involved cannot be identified because workers are unlikely to be exposed to a single platinum compound. Work by Cristaudo et al. (2005), and Linnett and Hughes (1999) indicated that the allergenic potential may be related to the degree of chlorination. Results from laboratory animal studies provide data supporting a relationship between allergenic potential and the degree of chlorination (Murdoch and Pepys, 1986, 1985, 1984a,b; Schuppe et al., 1992, 1997; WHO, 2012), and some data suggest that there is a correlation between activity and the degree of chlorination between the series of hexachloroplatinate and tetrachloroplatinate salts.

A recently-published retrospective cohort study designed to investigate platinum salt sensitisation (PSS) found a clear exposure-response relationship between chloroplatinate salts and respiratory sensitisation in workers. The study involved about 1040 refinery workers who newly joined one of five refineries during an 11-year period (1 January 2000 to 31 December 2010), and for whom a total of around 1760 personal time weighted average exposure measurements (to soluble platinum; used as a surrogate for the various chloroplatinate intermediates in particulate and liquid aerosol forms) were available. Only personal time-weighted average measurements based on the inhalable or total dust fraction, and approximating to 8-hour workshift values were included in the exposure database. Sensitisation cases were detected by SPT using a hexachloroplatinate salt, which is a method with high sensitivity and predictivity. The relationship was strongest for current (recent) and average exposure, and weaker for cumulative exposure. For current exposure categories of ≤49, >49-≤100, >100-≤252 and >252 ng/m3, Risk Ratios (RRs) were 1 (reference), 1.4, 2.2 and 3.2, respectively, the latter two values being statistically significant ($p<0.005$ or better). For average exposure, RRs were 1, 1.8, 4.2 and 3.0, respectively, for the ≤51.1, >51.1-≤105, >105-≤250 and >250 ng/m3 categories (all statistically significant at $p<0.05$ or better). The investigators concluded that “the exposure-relation for current exposure is characterized by an initial steep increase in risk starting at low exposure levels and levelling off at levels of greater than 200 ng/m3” (Heederick et al., 2016).

This recent, high-quality study is consistent with other epidemiology studies in demonstrating that PSS can be induced at estimated airborne soluble platinum concentrations (as a chloroplatinate surrogate measure) of less than 2 µg/m3 (2000 ng/m3) as an 8-hour time-weighted average value. Although the study possessed higher statistical power than any previous epidemiology investigation of PSS, due to some limitations in the low-end exposure dataset it was not possible to define a robust induction threshold (airborne critical concentration) for respiratory sensitisation to chloroplatinates.

Given the frequency of occurrence of respiratory sensitisation in workers exposed to sufficiently high occupational levels of chloroplatinates, and the severity of the symptoms that may develop, particularly if exposure is continued, the available data indicate that it is appropriate to classify dipotassium hexachloroplatinate as a respiratory sensitiser, in sub-category 1A, according to EU CLP criteria. The available epidemiology data has not yet permitted delineation of an induction threshold for PSS in workplace exposure scenarios. In a recent non-guideline study, it was demonstrated that a single respiratory challenge to mice topically sensitised to ammonium hexachloroplatinate can induce dose-dependent changes in pulmonary function indicative of an allergic lung response (Williams et al., 2015). This suggests that both dermal and inhalation exposure to chloroplatinates may play a role in occupational respiratory sensitisation/asthma, further supporting the decision to formulate a qualitative assessment approach as most appropriate and health precautionary for the local effects to the respiratory tract.

It is, therefore, considered suitably health precautionary to adopt the “high” hazard banding, and to consider the recommended RMMs/OCs in Table E.3-1 of ECHA (2012b).

Hazard via dermal route: systemic effects following long-term exposure

As no relevant data on effects of repeated dermal exposure to dipotassium hexachloroplatinate in humans or laboratory animals are available, route-to-route extrapolation to calculate a dermal DNEL from reliable studies (repeated-dose oral toxicity and reproductive/developmental toxicity screening) on a member of the "hexachloroplatinate(IV) compounds" category, diammonium hexachloroplatinate, was considered a suitable alternative (particularly as first pass effects are not expected to be significant for an inorganic compound). These two studies have been described in detail above ["Hazard via inhalation route: systemic effects following long-term exposure"] (Hansen, 2015a,b).

The oral NOAEL of 10 mg/kg bw/day for repeated dose effects seen in the Hansen (2015a) study on diammonium hexachloroplatinate was taken as the health-precautionary critical point of departure for calculating the long-term systemic dermal DNEL for dipotassium hexachloroplatinate. This equates to a NOAEL of 4.39 mg/kg bw/day for elemental platinum and 10.95 mg/kg bw/day for dipotassium hexachloroplatinate (based on MWt ratios). This point of departure is also expected to be sufficiently protective against fertility or developmental effects.

This derivation has utilised REACH guidance. In order to make the most health-precautionary derivation, the worst-case scenario is obtained by the minimum absorption by the 'starting' route. Therefore, for this oral-to-dermal extrapolation, a figure of 0.5% oral absorption has been used based on experimental data in rats (Moore, 1975b,c). The default assumption in the REACH guidance is that dermal absorption will not be higher than by the oral route (ECHA, 2012a).

However, two in vitro permeation studies on a related chloroplatinate substance, dipotassium tetrachloroplatinate, indicated a greater degree of dermal absorption [about 5-8%] than this default process would assume. Using a K2PtCl4 solution (0.3 mg Pt/ml in synthetic sweat) and full thickness skin from six donors (three African and three Caucasian), 4.8 and 2.3%, respectively (as mean values), diffused into the skin in 24 hr; the receptor solutions contained a further 3.4 and 0.5%, respectively (Franken et al., 2015). A slightly earlier paper reported mean skin diffusion and receptor solution percentages of 2.2% and 2.3%, respectively, in similar studies on full thickness skin from four Caucasian females (Franken et al., 2014). Apart from these studies, very little information appears to be available regarding dermal absorption of platinum compounds.

Furthermore, evidence of skin irritation was seen in a non-guideline patch test (Middleton, 1978), and in a skin sensitisation study (Middleton, 1977), both carried out on diammonium hexachloroplatinate. Irritation, manifesting as swelling of the ear, was also seen in a skin sensitisation test (using the mouse ear swelling test method) conducted on disodium hexachloroplatinate, a member of the "hexachloroplatinate(IV) compounds" category (Schuppe et al., 1997b). In addition, dipotassium hexachloroplatinate was found to be immediately corrosive when instilled into the eyes of rabbits (Berthold, 1995b), and is corrosive to metals (Harlan, 2011). As such, the possibility that dipotassium hexachloroplatinate has the potential to disrupt the skin barrier (potentially facilitating dermal uptake) cannot be ruled out (despite it not being classified for skin irritation).

A high dermal bioavailability is unlikely, notably based on its high water solubility as well as experimental dermal penetration data (human in vitro studies) for a closely-related surrogate [indicating about 5-8% dermal absorption]. However, the potential of dipotassium hexachloroplatinate to disrupt skin barrier function, facilitating increased dermal penetration, cannot be excluded, especially considering its known corrosivity to metals and to the eyes of rabbits. A value of 20% absorption is, therefore, proposed.

Dose descriptor starting point, in terms of the source substance diammonium hexachloroplatinate (after route to

route extrapolation) = NOAEL*(ABS[oral-rat]/ABS[der-human]) = 10 mg/kg bw/day*(0.5%/20%) = 0.25 mg/kg bw/day. This equates to a dipotassium hexachloroplatinate exposure of 0.274 mg/kg bw/day.

Application of the assessment factors (overall AF 75, described above) to this corrected dermal NOAEL gives a systemic long-term dermal DNEL for dipotassium hexachloroplatinate of 3.65 µg/kg bw/day, which equates to an elemental platinum exposure of 1.46 µg/kg bw/day.

However, in a recent non-guideline study, it was demonstrated that a single respiratory challenge to mice topically sensitised to ammonium hexachloroplatinate can induce dose-dependent changes in pulmonary function indicative of an allergic lung response (Williams et al., 2015). This suggests that both dermal and inhalation exposure to chloroplatinates may play a role in occupational respiratory sensitisation/asthma. As such, the most appropriate and health precautionary approach was deemed to be to formulate a qualitative assessment (with 'high hazard' banding and recommended RMMs/OCs in Table E.3-1 of ECHA, 2012b) for systemic exposure to workers by the dermal route. [For further discussion of the potential respiratory sensitisation and irritation, including that reported in recent epidemiological studies, please see the 'Hazard via inhalation route: local effects following long-term or acute exposure' section, above].

Hazard via dermal route: local effects following long-term or acute exposure

No convincing evidence of skin sensitisation was found in the only study accepted as specifically investigating this endpoint, a Guinea Pig Maximisation Test (GPMT) following a protocol considered equivalent to OECD Test Guideline 406. In the induction phase, ten females were given an intradermal injection of a saturated solution of the related platinum salt, diammonium hexachloroplatinate, followed a week later by a topical application of 50% w/w test material in petroleum jelly. Two weeks after this, a challenge topical application of 10% w/w in petroleum jelly was administered. Eight out of ten animals showed reactions 24 hours after challenge administration, but only 2/10 reactions were still observable a further 24 hours later. No reactions were seen when the animals were re-challenged a week later with lower concentrations (1 and 5%) of the test material. The study authors considered that the reactions were the result of irritation, and concluded that diammonium hexachloroplatinate was not a skin sensitiser (Middleton, 1977).

Three other available studies are relevant but might not clearly differentiate between respiratory and skin sensitisers. The first used an adaptation of the murine Local Lymph Node Assay (LLNA) method and found that cytokine levels in the lymph nodes after application of diammonium hexachloroplatinate (0.25, 0.5 or 1% in DMSO) to the ears of female mice (5/group) were comparable to those seen following testing with known respiratory (trimellitic anhydride) and skin (2,4-dinitrochlorobenzene) sensitisers (Dearman et al., 1998).

The other two studies were carried out on the structurally-related disodium hexachloroplatinate. The first used a similar protocol to the LLNA and found a 23-fold increase in the number of proliferating auricular lymph node (ALN) cells, 48 hours after application of a 5% solution in acetone to the ears of five female mice on 4 consecutive days. The response was said to be similar to that induced by the known skin sensitiser, oxazolone (Schuppe et al., 1997a). The same investigators also carried out a 'mouse ear swelling test' (MEST), a scientifically-acceptable study despite not following a harmonised guideline. In this study, a 5% solution of disodium hexachloroplatinate in acetone was applied to the right ear of 4-5 female mice. Challenges were applied to the left ear of the treated animals using 0.5 or 2% solutions, 6 days and 4, 8, and 20 weeks after induction. Significant increases in left ear thickness were seen in animals challenged with 2% disodium hexachloroplatinate, and the study authors concluded that the test substance was a skin sensitiser (Schuppe et al., 1997b).

The proliferative responses reported in the studies described above can be indicative of a skin or respiratory sensitisation effect. Given that reports of skin sensitisation in humans after exposure to chloroplatinate compounds are uncommon, and considering the well-documented potential for this class of compounds to cause respiratory sensitisation, it is considered that the critical hazard following exposure by the dermal route is respiratory sensitisation. Pending further investigations, it is considered suitably health-precautionary to retain the classification of dipotassium hexachloroplatinate as a skin sensitiser, in sub-category 1B, according to EU CLP criteria.

According to ECHA (2012b) guidance “moderate skin sensitisers (classified in Sub-category 1B in CLP) are allocated to the moderate hazard category band on the basis that exposure to these moderate skin sensitising substances should be well-controlled”. Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2012b). It should be noted that control of potential respiratory sensitisation risk via skin exposure is the predominating concern, but that the RMMs/OCs associated with the “high hazard” banding for respiratory sensitisation (as discussed in more detail, above) are considered to be sufficiently protective.

Hazard for the eyes

In a GLP study conducted according to OECD Test Guideline 405, the eye irritancy potential of dipotassium hexachloroplatinate was assessed. About 100 mg of the solid test material was instilled into the conjunctival sac of the left eye of one White Russian rabbit, and the ocular response assessed. Within 24 hours, the cornea was opaque and the iris was not discernible through the opacity. Due to the severity of the corrosive effects observed, the other two test animals were not used and dipotassium hexachloroplatinate was classified as corrosive to the eye (category 1) (Berthold, 1995b).

On this basis, dipotassium hexachloroplatinate has been allocated to the “moderate” hazard band. Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2012b).

[1]MWts: Pt metal, 195.08 g mol-1; Diammonium hexachloroplatinate, 443.87 g mol-1; Dipotassium hexachloroplatinate, 485.98 g mol-1

Table 5.13. Hazard conclusions for the general population

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Inhalation	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Inhalation	Local effects - Long-term	hazard unknown but no further hazard information necessary as no	

		exposure expected	
Inhalation	Local effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Systemic effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Local effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Local effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Oral	Systemic effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Oral	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Eyes	Local effects	medium hazard (no threshold derived)	

Inhalation Systemic effects - Long-term

Further explanation on hazard conclusions:

See Discussion section

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions:

See Discussion section

Inhalation Local effects - Long-term

Further explanation on hazard conclusions:

See Discussion section

Inhalation Local effects - Acute

Further explanation on hazard conclusions:

See Discussion section

Dermal Systemic effects - Long-term

Further explanation on hazard conclusions:

See Discussion section

Dermal Systemic effects - Acute

Further explanation on hazard conclusions:

See Discussion section

Dermal Local effects - Long-term

Further explanation on hazard conclusions:

See Discussion section

Dermal Local effects - Acute

Further explanation on hazard conclusions:

See Discussion section

Oral Systemic effects - Long-term

Further explanation on hazard conclusions:

See Discussion section

Oral Systemic effects - Acute

Further explanation on hazard conclusions:

See Discussion section

Discussion:

DNELs have been derived only for workers, not for consumers/general population. No uses have been identified in which consumers are exposed to dipotassium hexachloroplatinate. In all uses with potential consumer exposure due to service life of articles, dipotassium hexachloroplatinate is chemically transformed into another substance before reaching the consumers, and the subsequent lifecycle steps after this transformation are included in the assessment of the newly-formed substance. Regarding the general population, and following the criteria outlined in ECHA guidance R16 (2016), an assessment of indirect exposure of

humans via the environment for dipotassium hexachloroplatinate has not been performed as the registered substance is manufactured/imported/marketed at <100 tpa and is not classified as CMR.

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1. Explosivity

No relevant information available.
Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: Dipotassium hexachloroplatinate - harmonised

Related composition: Dipotassium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification: data conclusive but not sufficient for classification

Name: Dipotassium hexachloroplatinate - self classification

Related composition: Dipotassium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification: data conclusive but not sufficient for classification

6.2. Flammability

Flammability

The available information on flammability is summarised in the following table:

Table 6.1. Information on flammability

Method	Results	Remarks
flammable solids according to UN Manual of Tests and Criteria: Test N.1 (Test method for readily combustible solids)	Evaluation of results: not classified based on GHS criteria Study results: Flammable gasses (lower and upper explosion limits): Aerosols: Flammable solids: burning rate test: preliminary screening test (Pile failed to ignite during the two minutes that the Bunsen flame was applied.) Pyrophoric solids: Pyrophoric liquid: Self-heating substances/mixtures: Substances/ mixture which in contact with water emit flammable gases: Remarks: Pile failed to ignite during the two minutes that the Bunsen flame was applied..	1 (reliable without restriction) key study experimental study **Test material** dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Tremain SP, Atwal SS 2011**

Discussion

The following information is taken into account for any hazard / risk assessment:
Flammability
Key value for chemical safety assessment: Flammability: not classified

Dipotassium hexachloroplatinate is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.

Additional information:

Tremain and Atwal (2011) is a GLP compliant study following UN N1 method and is considered suitable for use as the key study for this endpoint. Dipotassium hexachloroplatinate is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.

Flash Point

No relevant information available.
Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: Dipotassium hexachloroplatinate - harmonised

Related composition: Dipotassium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification (gas): data conclusive but not sufficient for classification
Classification (liquid): data conclusive but not sufficient for classification
Classification (solid): data conclusive but not sufficient for classification

Name: Dipotassium hexachloroplatinate - self classification

Related composition: Dipotassium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification (gas): data conclusive but not sufficient for classification
Classification (liquid): data conclusive but not sufficient for classification
Classification (solid): data conclusive but not sufficient for classification

Justification for classification or non-classification:

Based on a GLP-compliant study following UN N1 method dipotassium hexachloroplatinate is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.

6.3. Oxidising potential

The available information on the oxidising potential is summarised in the following table:

Table 6.2. Information on oxidising potential

<table>
<tr><th>Method</th><th>Results</th><th>Remarks</th></tr>
<tr><td>oxidising solids
Contact with: powdered cellulose (3 min) equivalent or similar to UN Manual of Tests and Criteria: Test O.1 (Test for oxidizing solids)</td><td>Evaluation of results: GHS criteria not met
Test results:
Oxidising solids:
1:1 sample-to-cellulose ratio: burning rate: (mixture does not ignite and burn)
4:1 sample-to-cellulose ratio: burning rate: (mixture does not ignite and burn)
Remarks:
<table><tr><td>Results</td><td></td><td></td></tr><tr><td>3:7 (by mass) cellulose</td><td></td><td></td></tr></table></td><td>1 (reliable without restriction)
weight of evidence migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase]

Test material
hexachloroplatinic acid / 16941-12-1 /</td></tr>
</table>

and potassium bromate reference mixture		
Test Number	Burning Time (seconds)	Observations
1	91	Mixture burned with an orange and greenish blue flame with some spluttering
2	138	Mixture burned with an orange and blue flame with spluttering
3	123	Mixture burned with an orange and blue flame with spluttering
4	112	Mixture burned with an orange and blue flame with spluttering
5	114	Mixture burned with an orange and blue flame with spluttering

241-010-7,
Form: not specified (full information in **Annex II**).

Reference
Walker JA, White DF 2011

1:1 (by mass) test item and cellulose mixture			
1	-	Grey fumes emitted: no ignition. Some charring of the mixture	
2	-	Grey fumes emitted: no ignition. Some charring of the mixture	
3	-	Grey fumes emitted: no ignition. Some charring of the mixture	
4	-	Grey fumes emitted: no ignition. Some charring of the mixture	
5	-	Grey fumes emitted: no ignition. Some charring of the mixture	
4:1 (by mass) test item and cellulose mixture			

	1	-	Mixture appears to be boiling and blackening. Liquefying observed. No ignition
	2	-	Mixture appears to be boiling, black liquid. Grey fumes. No ignition
	3	-	Mixture appears to be boiling, black liquid. Grey fumes. No ignition
	4	-	Mixture appears to be charred and melted. Grey fumes. No ignition
	5	-	Mixture appears to be boiling, black liquid. Grey fumes. No ignition
	Test item was fine powder but did contain some larger granules. Whole of test item was ground to a fine powder		
oxidising solids Contact with: powdered cellulose (3 min) equivalent or similar to UN Manual of Tests and Criteria: Test O.1 (Test for oxidizing solids)	Evaluation of results: GHS criteria not met Test results: Oxidising solids: 1:1 sample-to-cellulose ratio: burning rate: (mixture does not ignite and burn)		1 (reliable without restriction) weight of evidence migrated information: read-across from

	4:1 sample-to-cellulose ratio: burning rate: (mixture does not ignite and burn) Remarks: **Results of 3:7 (by mass) reference mixture of potassium bromate and cellulose** **Test Number** / **Burning Time (s)** / **Observations** 1 / 147 / An orange/blue spluttering fla	supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** 85392-65-0 / 286-924-7; Tetraammonium decachloro-mu-oxodiruthenate (4-), (full information in **Annex II**). **Reference** **Tremain SP, Atwal SS 2011**

			me wh ich lef t da rk gr ey as h				
	2	13 9	An or an ge/ bl ue spl utt eri ng fla me wh ich lef t da rk gr ey as h				
	3	11 6	An or an ge/ bl ue spl utt eri ng fla me wh ich lef t da rk gr ey as h				
	4	13 3	An or an				

			ge/blue spluttering flame which left dark grey ash			
	5	145	An orange/blue spluttering flame which left dark grey ash			
	Results of 4: 1 (by mass) test item and					

cellulose mixture

Test Number	Burning Time (s)	Observations
1	-	Pale grey smoke, no sign of ignition during the 3 minutes the power was applied
2	-	Dark grey smoke, no sign of ig

			nition during the 3 minutes the power was applied
	3	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied
	4	-	Dark grey smoke,

			no sign of ignition during the 3 minutes the power was applied				
	5	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied				

Results of 1:1 (by mass) test item and cellulose mixture							
1	-	Pale grey smoke, the pile was slightly charred					
2	-	Pale grey smoke, the pile was slightly charr					

		ed				
3	-	Pale grey smoke, the pile was slightly charred				
4	-	Pale grey smoke, the pile was slightly charred				
5	-	Pale grey smoke, the pile was slightly charred				

The 4:1 and 1:1 test item:cellulose mixtures

	did not ignite and burn during the 3 minutes that the power was applied. This indicates that the test item is not an oxidising solid. Authors state that the material, length and diameter of wire met method specifications and the appropriate combination of current and voltage was used. therefore as the physical parameters of the wire and the power dissipation met the method specifications, the deviation from the electrical resistance of the wire had no effect on the test.	

Discussion

The following information is taken into account for any hazard / risk assessment:

On the basis of read-across from other substances with co-ordinated chloride, in the 4 + oxidation state (tetraammonium decachloro-mu-oxodiruthenate and hexachloroplatinic acid), dipotassium hexachloroplatinate is not considered to be oxidising.

Value used for CSA:
Oxidising properties: non oxidising

Additional information:

The oxidising properties of dipotassium hexachloroplatinate are read across from other substances with co-ordinated chloride, in the 4+ oxidation state (tetraammonium decachloro-mu-oxodiruthenate and hexachloroplatinic acid). Neither of these substances are oxidising based on GLP-compliant studies following UN method O.1 (Tremain and Atwal 2011, Walker and White 2011), there is also supplementary evidence that other metal chlorides are also not oxidizing. For example, other Group VIII transition metals such as cobalt (II) chloride, iron (II), iron(III) and nickel(II) chloride. Copper(I) chloride from the adjacent Group IB is also not classified for oxidizing properties. There is therefore no evidence that any transition metal chloride is an oxidant. Supplementary evidence also comes from the non-transition metal chlorides and there is no evidence from two centuries of industrial and academic experience that these substances are oxidants.

On the basis of read-across dipotassium hexachloroplatinate is not classified as an oxidising solid.

Classification according to GHS

Name: Dipotassium hexachloroplatinate - harmonised

Related composition: Dipotassium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification (gas): data conclusive but not sufficient for classification
Classification (liquid): data conclusive but not sufficient for classification
Classification (solid): data conclusive but not sufficient for classification

Name: Dipotassium hexachloroplatinate - self classification

Related composition: Dipotassium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification (gas): data conclusive but not sufficient for classification

Classification (liquid): data conclusive but not sufficient for classification
Classification (solid): data conclusive but not sufficient for classification

Justification for classification or non-classification:

On the basis of read-across from other substances with co-ordinated chloride in the 4+ oxidation state, dipotassium hexachloroplatinate is not classified as an oxidising solid.

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

7.1.1. Fish

7.1.1.1. Short-term toxicity to fish

The results are summarised in the following table:

Table 7.1. Short-term effects on fish

Method	Results	Remarks
Oncorhynchus mykiss (previous name: Salmo gairdneri) freshwater short-term toxicity to fish according to OECD Guideline 203 (Fish, Acute Toxicity Test) ; according to EU Method C.1 (Acute Toxicity for Fish)	LC50 (96h): 25.78 mg/L element - Pt (nominal) based on: mortality (95 % Confidence Interval: 18.15 - 36.63 mg Pt/L) LC50 (96h): 76.55 mg/L test mat. (nominal) based on: mortality (95 % Confidence Intervals: 53.89 - 108.75 mg test item/L) NOEC (96h): 21 mg/L test mat. (nominal) based on: mortality NOEC (96h): 7.07 mg/L element - Pt (nominal) based on: mortality LOEC (96h): 46 mg/L test mat. (nominal) based on: mortality LOEC (96h): 15.49 mg/L element - Pt (nominal) based on: mortality	1 (reliable without restriction) key study experimental study **Test material** 16941-12-1 / 241-010-7, Form: liquid (full information in **Annex II**). **Reference** **Pawlowski S and Wydra V 2005**
Danio rerio (previous name: Brachydanio rerio) freshwater short-term toxicity to fish according to OECD Guideline 203 (Fish, Acute Toxicity Test) ; according to EU Method C.1 (Acute Toxicity for Fish)	LC50 (96h): >11.1 mg Pt/L element (meas. (arithm. mean)) based on: mortality LC50 (96h): >55.1 mg 2AE/L 2AE (meas. (arithm. mean)) based on: mortality	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate, compound with 2-amino-ethanol, Form: liquid (full information in **Annex II**). **Reference** **Muth-Kohne E 2016**
Danio rerio (previous name: Brachydanio rerio) freshwater - source water (Cristaline bottled water from Fismes, Marne, France) short-term toxicity to fish according to Afnor: Essai des eaux determination de la toxicite aigue d'une substance vis-a-vis de Brachydanio rerio No 85.202 NFT, pp 90-303	LC50 (96h): 26 mg/L element (dissolved fraction) (meas. (not specified)) based on: mortality	2 (reliable with restrictions) key study experimental study **Test material** Hexachloroplatinic acid; 16941-12-1 / 241-010-7, (full information in

		Annex II). **Reference** **Par R Jouhaud, S Biagianti-Risbourg, F Arsac and G Vernet 1999**

7.1.1.2. Long-term toxicity to fish

No relevant information available.

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 7.2. Short-term effects on aquatic invertebrates

Method	Results	Remarks
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 0.052 mg/L element - Pt (nominal) based on: mobility (95 % Confidence Interval: 0.044 - 0.064 mg Pt/L) EC50 (48h): 0.13 mg/L test mat. (nominal) based on: mobility (95 % Confidence Interval: 0.11 - 0.16 mg test item/L) NOEC (48h): 0.056 mg/L test mat. (nominal) based on: mobility NOEC (48h): 0.022 mg/L element - Pt (nominal) based on: mobility	1 (reliable without restriction) key study experimental study **Test material** 16941-12-1 / 241-010-7, Form: solid (full information in **Annex II**). **Reference** **Shacklady LG, Mullee DM 2001**
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 20.48 µg/L element - pt (nominal) based on: mobility (95 % Confidence Intervals: 19.06 - 21.99 µg Pt/L) EC50 (48h): 60.8 µg/L test mat. (nominal) based on: mobility (95 % Confidence Intervals: 56.6 - 65.3 µg test item/L) NOEC (48h): 42 µg/L test mat. (nominal) based on: mobility NOEC (48h): 14.15 µg/L element - Pt (nominal) based on: mobility LOEC (48h): 62 µg/L test mat. (nominal) based on: mobility LOEC (48h): 20.88 µg/L element - Pt (nominal) based on: mobility	1 (reliable without restriction) key study experimental study **Test material** 16941-12-1 / 241-010-7, Form: liquid (full information in **Annex II**). **Reference** **Moll M and Wydra V 2005**
Daphnia magna freshwater semi-static according to OECD Guideline 202	EC50 (48h): 481 µg/L element (meas. (TWA)) based on: mortality (EC50 calculated by extrapolation - 95% Confidence Interval: 374 - 968 µg Pt/L)	1 (reliable without restriction) key study experimental study

(Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 742 µg/L test mat. (meas. (TWA)) based on: mortality (EC50 calculated by extrapolation - 95% Confidence Interval: 577 - 1493 µg test item/L) NOEC (48h): >=572 µg/L test mat. (meas. (TWA)) based on: mortality NOEC (48h): >=371 µg/L element (meas. (TWA)) based on: mortality EC10 (48h): 426 µg/L test mat. (meas. (TWA)) based on: mortality (95% Confidence Interval: 338 - 535 µg test item/L) EC10 (48h): 276 µg/L element - Pt (meas. (TWA)) based on: mortality (95% Confidence Interval: 219 - 347 µg Pt/L)	**Test material** Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid (full information in **Annex II**). **Reference** **Simon M 2014**
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 108 µg/L element (nominal) based on: mortality EC50 (48h): 284 µg/L test mat. (nominal) based on: mortality NOEC (48h): 200 µg/L test mat. (nominal) based on: mortality NOEC (48h): 76 µg/L element (nominal) based on: mortality	1 (reliable without restriction) key study experimental study **Test material** Platinate(2-), hexachloro-, diammonium; diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid (full information in **Annex II**). **Reference** **Simon M 2014**
Daphnia magna freshwater semi-static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia)	NOEC (48h): >=10.9 mg/L element - Pt (meas. (arithm. mean)) based on: mobility EC50 (48h): >902 mg/L test mat. (nominal) based on: mobility EC50 (48h): >54.8 mg/L 2-amino-ethanol (2AE) (meas. (arithm. mean)) based on: mobility EC50 (48h): >10.9 mg/L element - Pt (meas. (arithm. mean)) based on: mobility NOEC (48h): >=902 mg/L test mat. (nominal) based on: mobility NOEC (48h): >=54.8 mg/L 2-amino-ethanol (2AE) (meas. (arithm. mean)) based on: mobility	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate, compound with 2-amino-ethanol, Form: liquid (full information in **Annex II**). **Reference** **Simon M 2016**
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	EC50 (48h): 140 µg/L element (meas. (not specified)) based on: mobility	2 (reliable with restrictions) key study experimental study

		Test material Hexachloroplatinic acid (hydrate) / 26023-84-7, (full information in **Annex II**). **Reference** **Okamoto A et al 2015**
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	EC50 (48h): 110 µg/L element (meas. (not specified)) based on: immobility LC50 (48h): 157 µg/L element (meas. (not specified)) based on: lethality	2 (reliable with restrictions) key study experimental study **Test material** Hexachloroplatinic acid, Form: Resin (full information in **Annex II**). **Reference** **Zimmermann S et al 2017**

7.1.2.2. Long-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 7.3. Long-term effects on aquatic invertebrates

Method	Results	Remarks
Daphnia magna freshwater long-term toxicity to aquatic invertebrates no guideline followed A standard guideline was not followed, but the study is well documented and the method used is considered to be acceptable.	NOEC (21d): 7 µg/L element - Pt (estimated) based on: reproduction (Determined as EC16/2) EC16 (21d): 14 µg/L element - Pt (not specified) based on: reproduction LC50 (21d): 520 µg/L element - Pt (not specified) based on: mortality (95% Confidence Limits: 437 - 619 µg/L) EC50 (21d): 82 µg/L element - Pt (not specified) based on: reproduction	2 (reliable with restrictions) key study experimental study **Test material** Hexachloroplatinic acid, (full information in **Annex II**). **Reference** **Biesinger KE, Christensen GM 1972**

7.1.3. Algae and aquatic plants

The results are summarised in the following table:

Table 7.4. Effects on algae and aquatic plants

Method	Results	Remarks
Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006]	EC50 (72h): 6.63 mg/L element - Pt (meas. (geom. mean)) based on: growth rate (95% Confidence Interval: 6.25 - 7.08 mg Pt/L) EC10 (72h): 1.98 mg/L element - Pt (meas. (geom. mean)) based on: growth rate (95% Confidence Interval: 1.70 - 2.23 mg Pt/L) EC50 (72h): 3.45 mg/L test mat. (meas. (geom. mean)) based on: yield (95% Confidence Interval: 2.96 - 4.03 mg test item/L) EC50 (72h): 2.24 mg/L element - Pt (meas. (geom. mean)) based on: yield (95% Confidence Interval: 1.92 - 2.61 mg Pt/L) EC50 (72h): 10.2 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95% Confidence Interval: 9.66 - 11.0 mg test item/L) NOEC (72h): 0.946 mg/L test mat. (meas. (geom. mean)) based on: yield NOEC (72h): 0.613 mg/L element - Pt (meas. (geom. mean)) based on: yield NOEC (72h): 1.76 mg/L test mat. (meas. (geom. mean)) based on: growth rate NOEC (72h): 1.14 mg/L element - Pt (meas. (geom. mean)) based on: growth rate EC10 (72h): 1.2 mg/L test mat. (meas. (geom. mean)) based on: yield (95% Confidence Interval: 0.84 - 1.52 mg test item/L) EC10 (72h): 0.778 mg/L element - Pt (meas. (geom. mean)) based on: yield (95% Confidence Interval: 0.546 - 0.989 mg Pt/L) EC10 (72h): 3.06 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95% Confidence Interval: 2.63 - 3.45 mg test item/L)	1 (reliable without restriction) key study experimental study **Test material** Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid: crystalline (full information in **Annex II**). **Reference** **Wenzel A 2014**
Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006] ; according to EU Method C.3 (Algal Inhibition test)	EC50 (72h): 3.3 mg/L element - Pt (nominal) based on: growth rate (95 % Confidence Intervals: 2.41 - 4.63 mg Pt/L) EC10 (72h): 490 µg/L element (dissolved fraction) (nominal) based on: growth rate (EC10 calculated based on reported data and using TRAP 1.30a) EC50 (72h): 3.925 mg/L test mat. (nominal) based on: biomass (95 % Confidence Intervals: 1.930 - 7.393 mg test item/L) EC50 (72h): 1.32 mg/L element - Pt (nominal) based on: biomass (95 % Confidence Intervals: 0.65 - 2.49 mg Pt/L) EC50 (72h): 9.808 mg/L test mat. (nominal) based on: growth rate (95 % Confidence Intervals: 7.145 - 13.750 mg test item/L) NOEC (72h): 0.62 mg/L test mat. (nominal) based on: biomass NOEC (72h): 0.209 mg/L element - Pt (nominal) based on: biomass NOEC (72h): 1.85 mg/L test mat. (nominal)	1 (reliable without restriction) key study experimental study **Test material** 16941-12-1 / 241-010-7, Form: liquid (full information in **Annex II**). **Reference** **Pawlowski S and Wydra V 2005**

	based on: growth rate NOEC (72h): 0.623 mg/L element - Pt (nominal) based on: growth rate LOEC (72h): 1.85 mg/L test mat. (nominal) based on: biomass LOEC (72h): 0.62 mg/L element - Pt (nominal) based on: biomass LOEC (72h): 5.56 mg/L test mat. (nominal) based on: growth rate LOEC (72h): 1.87 mg/L element - Pt (nominal) based on: growth rate	
Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006] ; according to EU Method C.3 (Algal Inhibition test)	EC50 (72h): 0.96 mg/L element - platinum (meas. (TWA)) based on: growth rate (95% Confidence Interval: 0.8 - 1.16 mg Pt/L) EC10 (72h): 310 µg/L element (dissolved fraction) (meas. (TWA)) based on: growth rate (EC10 value self-calculated based on reported data using TRAP v1.30a) EC50 (72h): 1.3 mg/L test mat. (meas. (TWA)) based on: biomass (95% Confidence Interval: 1.1 - 1.4 mg test item/L) EC50 (72h): 0.52 mg/L element - platinum (meas. (TWA)) based on: biomass (95% Confidence Interval: 0.44 - 0.56 mg Pt/L) EC50 (72h): 2.4 mg/L test mat. (meas. (TWA)) based on: growth rate (95% Confidence Interval: 2.0 - 2.9 mg test item/L) NOEC (72h): 0.97 mg/L test mat. (meas. (TWA)) based on: not specified NOEC (72h): 0.386 mg/L element - platinum (meas. (TWA)) based on: not specified	1 (reliable without restriction) key study experimental study **Test material** 16941-12-1 / 241-010-7, Form: solid (full information in **Annex II**). **Reference** **Mead C, Mullee DM 2001**
Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006]	EC50 (72h): 0.117 mg Pt/L element (meas. (not specified)) based on: growth rate (95%-CL lower = 0.080 mg Pt/L. 95%-CL upper = 0.185 mg Pt/L) EC10 (72h): 0.007 mg Pt/L element (meas. (not specified)) based on: growth rate (95%-CL lower = 0.022 mg Pt/L. 95%-CL upper = 0.013 mg Pt/L) EC50 (72h): 0.021 mg Pt/L element (meas. (not specified)) based on: Yield (95%-CL lower = 0.017 mg Pt/L. 95%-CL upper = 0.026 mg Pt/L.) EC50 (72h): 0.433 mg 2AE/L 2AE (meas. (not specified)) based on: growth rate (95%-CL lower = 0.294 mg 2AE/L. 95%-CL upper = 0.681 mg 2AE/L) EC50 (72h): 0.073 mg 2AE/L 2AE (meas. (not specified)) based on: Yield (95%-CL lower = .0.45 mg 2AE/L. 95% CL-upper = 0.117 mg 2AE/L) EC50 (72h): 0.682 mg/L test mat. (meas. (not specified)) based on: growth rate (95%-CL lower = 0.466 mg/L 95%-CL upper =	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, (full information in **Annex II**). **Reference** **Wenzel A 2016**

	1.08 mg/L. Test item concentration calculated based on measured Pt concentrations.) EC50 (72h): 0.125 mg/L test mat. (meas. (not specified)) based on: Yield (95%-CL lower = 0.101 mg/L. 95%-CL upper = 0.149 mg/L. Test item concentration calculated based on measured Pt concentrations.) EC10 (72h): 0.09 mg Pt/L element (meas. (not specified)) based on: yield (95%-CL lower = 0.05 mg Pt/L. 95%-CL upper = 0.013 mg Pt/L) EC10 (72h): 0.021 mg 2AE/L 2AE (meas. (not specified)) based on: growth rate (95%-CL lower = 0.006 mg 2AE/L. 95%CL-upper = 0.042 mg 2AE/L) EC10 (72h): 0.032 mg 2AE/L 2AE (meas. (not specified)) based on: Yield (95%-CL lower = 0.022 mg 2AE/L. 95%-CL upper = 0.048 mg 2AE/L) EC10 (72h): 0.039 mg/L test mat. (meas. (not specified)) based on: growth rate (95%-CL lower = 0.012 mg/L. 95%-CL upper = 0.077 mg/L. Test item concentration calculated based on measured Pt concentrations.) EC10 (72h): 0.055 mg/L test mat. (meas. (not specified)) based on: Yield (95%-CL lower = 0.032 mg/L. 95%-CL upper= 0.073 mg/L. Test item concentration calculated based on measured Pt concentrations.)	
Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with Scenedesmus subspicatus and Selenastrum capricornutum)	EC50 (48h): 1300 µg/L element (meas. (not specified)) based on: growth (95%CI 1100-1500 µg Pt/L) EC10 (48h): 380 µg/L element (meas. (not specified)) based on: growth (95%CI 270-540 µg Pt/L)	2 (reliable with restrictions) key study experimental study **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference** **Sorensen S et al 2016**
Chlamydomonas reinhardtii (algae) freshwater toxicity to aquatic algae and cyanobacteria according to ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with Scenedesmus subspicatus and Selenastrum capricornutum)	EC50 (48h): 7100 µg/L element (meas. (not specified)) based on: growth (95%CI 6300-8100 µg Pt/L) EC10 (48h): 1500 µg/L element (meas. (not specified)) based on: growth (95%CI 1100-2000 µg Pt/L) EC50 (48h): 360000 µg/L element (meas. (not specified)) based on: 14C assimilation (95% CI 240000-540000 µg Pt/L) EC10 (48h): 35000 µg/L element (meas. (not specified)) based on: 14C assimilation (95%CI 16000-78000 µg Pt/L)	2 (reliable with restrictions) key study experimental study **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference**

		Sorensen S et al 2016

7.1.4. Sediment organisms

No relevant information available.

7.1.5. Other aquatic organisms

No relevant information available.

7.2. Terrestrial compartment

7.2.1. Toxicity to soil macro-organisms

The results are summarised in the following table:

Table 7.5. Effects on soil macro-organisms

Method	Results	Remarks
Enchytraeus crypticus [Annelida] (annelids) toxicity to soil macroorganisms except arthropods: long-term (laboratory study) Substrate: artificial soil according to OECD Guideline 220 (Enchytraeid Reproduction Test)	EC10 (28d): 300 mg/kg soil dw element (nominal) based on: reproduction (EC10 value calculated based on reported results using TRAP v1.30a) EC50 (28d): 695 mg/kg soil dw element (nominal) based on: reproduction (EC50 value calculated based on reported results using TRAP v1.30a) EC50 (28d): 161.9 µmol/L test mat. (nominal) based on: reproduction EC50 (28d): 93.75 µmol/L element - Pt (nominal) based on: reproduction EC50 (28d): 54.54 mg/L test mat. (nominal) based on: reproduction EC50 (28d): 31.58 mg/L element - Pt (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference** **Havelkova. B et al. 2014**
Folsomia candida [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: soil toxicity to terrestrial arthropods: long-term (laboratory study) according to OECD Guideline 232 (Collembolan Reproduction Test in Soil)	NOEC (28d): 5 µmol/L test mat. (nominal) based on: reproduction (- corresponds to 0.19 mg Pt/kg (dry soil)) EC10 - self-calculated from data using log-logistic model by minimising unweighted squared residuals sum (28d): 0.36 mg/kg soil dw element (nominal) based on: reproduction EC10 (28d): 33.6 mg/kg soil dw element (nominal) based on: reproduction (EC10 recalculated based on reported data using TRAP v1.30a) EC50 (28d): 200.4 µmol/L test mat. (nominal) based on: reproduction (corresponding to 7.43 mg Pt/kg(dw)) EC50 (28d): 421 mg/kg soil dw element (nominal) based on: reproduction (EC50 value recalculated based on reported data	2 (reliable with restrictions) supporting study experimental study **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference** **Nemcova B et al 2012**

	using TRAP v1.30a)	

7.2.2. Toxicity to terrestrial plants

No relevant information available.

7.2.3. Toxicity to soil micro-organisms

No relevant information available.

7.2.4. Toxicity to other terrestrial organisms

The results are summarised in the following table:

Table 7.6. Effects on terrestrial arthropods

Method	Results	Remarks

7.3. Atmospheric compartment

No relevant information available.

7.4. Microbiological activity in sewage treatment systems

The results are summarised in the following table:

Table 7.7. Effects on micro-organisms

Method	Results	Remarks
activated sludge of a predominantly domestic sewage freshwater static according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] ; according to EU Method C.11 (Biodegradation: Activated Sludge Respiration Inhibition Test)	EC10 (3h): 648 mg/L element - Pt (nominal) based on: inhibition of total respiration NOEC (3h): 320 mg/L test mat. (nominal) based on: inhibition of total respiration NOEC (3h): 207 mg/L element - Pt (nominal) based on: inhibition of total respiration NOEC (3h): 1000 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration NOEC (3h): 648 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration EC10 (3h): 1000 mg/L test mat. (nominal) based on: inhibition of total respiration EC10 (3h): >1000 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration EC10 (3h): >648 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration EC50 (3h): >1000 mg/L test mat. (nominal) based on: inhibition of total respiration EC50 (3h): >648 mg/L element - Pt (nominal) based on: inhibition of total respiration	1 (reliable without restriction) key study experimental study **Test material** Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid: crystalline (full information in **Annex II**). **Reference** **Muckle M 2014**

	EC50 (3h): >1000 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration EC50 (3h): >648 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration	
activated sludge of a predominantly domestic sewage freshwater static according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] ; according to EU Method C.11 (Biodegradation: Activated Sludge Respiration Inhibition Test)	EC10 (3h): 2.35 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 2.15 - 2.55 mg/L) NOEC (3h): 3.2 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate NOEC (3h): 1.26 mg/L element - Pt (nominal) based on: inhibition of total respiration NOEC (3h): 10 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration NOEC (3h): 3.92 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration EC10 (3h): 6 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 5.5 - 6.5 mg/L) EC10 (3h): 8.2 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 6.0 - 11 mg/L) EC10 (3h): 3.21 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 2.35 - 4.31 mg/L) EC50 (3h): 103 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 96 - 110 mg/L) EC50 (3h): 40.33 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 37.58 - 43.065 mg/L) EC50 (3h): 83 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 76 - 91 mg/L) EC50 (3h): 32.49 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 29.75 - 35.63 mg/L)	1 (reliable without restriction) key study experimental study **Test material** Hexachloroplatinic acid, Form: Resin (full information in **Annex II**). **Reference** **Muckle M 2015**
activated sludge of a predominantly domestic sewage freshwater static according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] ; according to EU Method C.11 (Biodegradation: Activated Sludge Respiration Inhibition	EC10 (3h): 20.58 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 14.41 - 25.73 mg/L. Without ATU.) NOEC (3h): 60 mg/L test mat. (nominal) based on: inhibition of total respiration (Without ATU.) NOEC (3h): 10.29 mg/L element - Pt (nominal) based on: inhibition of total	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate, compound with 2-

Test)	respiration (Without ATU.) NOEC (3h): 130 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (With ATU.) NOEC (3h): 22.3 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (With ATU.) EC10 (3h): 120 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 84- 150 mg/L. Without ATU.) EC10 (3h): 170 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 140 - 210 mg/L. With ATU.) EC10 (3h): 29.16 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 24.01 - 36.02 mg/L. With ATU.) EC50 (3h): 1100 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 850 - 1400 mg/L. Without ATU.) EC50 (3h): 188.65 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 146 - 240.1 mg/L. Without ATU.) EC50 (3h): 1400 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: not determined. With ATU.) EC50 (3h): 240.1 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: not determined. With ATU.)	amino-ethanol, Form: liquid (full information in **Annex II**). **Reference** **Muckle M 2016**

7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1. Toxicity to birds

No relevant information available.

7.5.2. Toxicity to mammals

No relevant information available.

7.6. PNEC derivation and other hazard conclusions

7.6.1. PNEC derivation and other hazard conclusions

Table 7.8. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	PNEC aqua (freshwater): 0.14µg/L	Assessment factor: 50 Extrapolation method: assessment factor

	Intermittent releases:	PNEC aqua (freshwater) cfr. PNEC derivation report (IUCLID Section 13)
Marine water	PNEC aqua (marine water): 0.014µg/L Intermittent releases:	Assessment factor: 500 Extrapolation method: assessment factor PNEC aqua (marine water) cfr. PNEC derivation report (IUCLID Section 13)
Sediments (freshwater)	PNEC sediment (freshwater): 0.261mg/kg sediment dw	Extrapolation method: equilibrium partitioning method PNEC sediment (freshwater) cfr. PNEC derivation report (IUCLID Section 13)
Sediments (marine water)	PNEC sediment (marine water): 0.026mg/kg sediment dw	Extrapolation method: equilibrium partitioning method PNEC sediment (marine water) cfr. PNEC derivation report (IUCLID Section 13)
Sewage treatment plant	PNEC STP: 235µg/L	Assessment factor: 10 Extrapolation method: assessment factor PNEC STP cfr. PNEC derivation report (IUCLID Section 13)
Soil	PNEC soil: 0.005mg/kg soil dw	Extrapolation method: equilibrium partitioning method PNEC soil cfr. PNEC derivation report (IUCLID Section 13)
Air	no hazard identified:	This substance is not expected to contribute to ozone depletion, ozone formation, global warming or acidification. Therefore, the evaluation of atmospheric risk is not required.
Secondary poisoning	no potential for bioaccumulation:	A secondary poisoning assessment is not required for dihydrogen hexahydroxyplatinate and dihydrogen hexahydroxyplatinate,compound with 2-aminoethanol (1:2) as they do not have the potential to cause toxic effects if accumulated in higher organisms, as it is not classified as H360 “May damage fertility or the unborn child”, H361 “Suspected of damaging fertility or the unborn child”, H362 “May cause harm to breastfed children”, H372 “Causes damage to organs through prolonged or repeated exposure” or H373 “May cause damage to organs through prolonged or repeated exposure”.

		For exachloroplatinic acid, diammonium hexachloroplatinate and dipotassium hexachloroplatinate, no or insufficient data are available at present, but exposure to chloroplatinates in the environment is expected to be very limited.

Conclusion on environmental classification

Environmental classification for the platinum(IV) substances under consideration is based on the lowest acute and chronic threshold values from the Pt(IV) ecotoxicity test data:

-acute ERV: lowest acute threshold value is 99 µg Pt/L (geometric mean EC50 value with D. magna, based on the experimental results for hexachloroplatinic acid (n=3), dihydrogen hexahydroxoplatinate and diammonium hexachloroplatinate)

-chronic ERV: lowest chronic threshold value is 7 µg Pt/L (NOEC value (calculated as EC16/2) with D. magna, based on the experimental results for hexachloroplatinic acid.

The derivation of both ERV values is detailed in the read-across justification report (cfr. IUCLID Section 13) and PNEC derivation report (cfr. IUCLID Section 13).

For classification purposes, these ERVs have been recalculated to the values expressed as the concentration of the substance (conversion based on molecular weight conversion from soluble ion to the substance considered – cfr. details in below table). This results in a classification as Acute Category 1 and Chronic Category 1 for all substances contained in the below table. Acute and chronic M-factors are based on the value of the substance-specific acute and chronic ERV, as outlined in ECHA Guidance on the application of the CLP criteria (version 5.0; ECHA, 2017) - cfr. below table.

However, and as explained in the read-across justification document attached in IUCLID section 13, for platinum (IV) substances, there is some uncertainty related to potential observed (and currently unexplained) differences in effects thresholds observed between chloride and hydroxide coordinated Pt(IV) substances. As will be shown, under ecologically relevant conditions, they will all respeciate to a similar [Pt(OH)2]0species. However, the kinetics of this process are currently unknown.

Therefore, the approach for hazard assessment and classification considers these potential/temporal differences in toxicity due to the co-ordinating ligands: the classification is derived based on the substance specific test data and based on the test data for the category as described below. **The most conservative classification will be applied.**

				Classification using category data	Classification using substance specific data						
	Molecular formula	MW	Pt (wt%)	Acute ERV (µg TI/L)	Chronic ERV (µg TI/L)	Aq Acute classif	Aq Chron classif	Acute ERV (µg TI/L)	Chronic ERV (µg TI/L)	Aq Acute classif	Aq Chron classif
Diammonium hexachloroplatinate	(NH4)2[PtCl6]	443.87	43.9	221.7	15.9	Aq Acute 1, M=1	Aq Chron 1, M=1	284 (Simon,2014)$	17 (Biesinger&Christensen,1972)$	Aq Acute 1, M=1	Aq Chron 1, M=1

Dipotassium hexachloroplatinate	K2[PtCl6]	485.98	40.1	242.7	17.4	Aq Acute 1, M=1	Aq Chron 1, M=1	51 (Moll& Wydra, 2005)£	17 (Biesinger&Christensen, 1972)£	Aq Acute 1, M=10	Aq Chron 1, M=10
Hexachloroplatinic acid	H2[PtCl6]	409.8	47.6	204.7	14.7	Aq Acute 1, M=1	Aq Chron 1, M=1	60.8 (Moll& Wydra, 2005)*	14 (Biesinger&Christensen, 1972)*	Aq Acute 1, M=10	Aq Chron 1, M=10
Dihydrogen hexahydroxyplatinate	H2[PtOH6]	299.14	65.2	149.4	10.7	Aq Acute 1, M=1	Aq Chron 1, M=1	742 (Simon, 2014)+	946 (Wenzel, 2014)+	Aq Acute 1, M=1	Aq Chron 1, M=1
Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2)	(HO-C2H4-NH3)2Pt(OH)6	421.3	46.3	210.4	15.1	Aq Acute 1, M=1	Aq Chron 1, M=1	682 (Wenzel, 2016)%	39 (Wenzel, 2016)%	Aq Acute 1, M=1	Aq Chron 1, M=1

* Environmental classification is assessed based on the lowest acute and chronic values from ecotoxicity tests performed with the substance itself. For this substance, the lowest acute value is a 48-hour EC50 of 0.0608 mg test item L-1 (0.0205 mg Pt L-1) for aquatic invertebrates(mobility) and the lowest chronic value is a 21-day NOEC value of 0.007 mg Pt L-1 (0.014 mg test item L-1) for Daphnia, based on reproduction. A full chronic dataset (fish, Daphnia and algae) is not available for this substance, therefore classification has been assessed based on both the acute and chronic data, with the worst case classification assigned. An environmental classification of Acute Category 1, Chronic Category 1 is assigned to this substance, based on the acute data. As the lowest EC50 value is >0.01 ≤ 0.1 an acute M factor of 10 is assigned. A chronic M factor of 10 is also assigned, to match the acute M factor, as the classification has been determined based on acute data.

$ Environmental classification is assessed based on the lowest acute and chronic values from ecotoxicity tests. Algae and fish toxicity values are read across from hexachloroplatinic acid. The lowest acute value is a 48-hour EC50 of 0.284 mg diammonium hexachloroplatinate L-1 (0.108 mg Pt L-1) based on the short-term toxicity study on aquatic invertebrates performed with the substance itself. The lowest chronic value is a 21-day NOEC value of 0.007 mg Pt L-1 for Daphnia, based on reproduction, read across from hexachloroplatinic acid. Converting the NOEC value to a concentration of diammonium hexachloroplatinate based on molecular weight gives a NOEC of 0.016 mg diammonium hexachloroplatinate L-1. As a complete chronic dataset (fish, Daphnia and algae) is not available, classification is assessed based on both the acute and chronic data and the worst case classification assigned to the substance. Based on the acute data, an environmental classification of Acute Category 1, Chronic Category 1 is assigned to this substance. As the lowest EC50 value is >0.1 ≤ 1 an acute M factor of 1 is assigned. A chronic M factor of 1 is also assigned, to match the acute M factor, as the classification has been determined based on acute data.

£ Environmental classification is assessed based on the lowest acute and chronic values from ecotoxicity tests. For this substance, all values are read across from hexachloroplatinic acid. For classification purposes, these values have been expressed as concentrations of dipotassium hexachloroplatinate, converted based on molecular weight. The lowest acute value is a 48-hour EC50 of 0.0205 mg Pt L-1for aquatic invertebrates(mobility) and the lowest chronic value is a 21-day NOEC value of 0.007 mg Pt L-1 for Daphnia, based on reproduction. This results in an EC50 of 0.051 mg dipotassium hexachloroplatinate L-1 and a NOEC of 0.017 mg dipotassium hexachloroplatinate L- 1. A full chronic dataset (fish, Daphnia and algae) is not available for this substance,

therefore classification has been assessed based on both the acute and chronic data, with the worst case classification assigned. An environmental classification of Acute Category 1, Chronic Category 1 is assigned to this substance, based on acute data. As the lowest EC50 value is >0.01 ? 0.1 an acute M factor of 10 is assigned. A chronic M factor of 10 is also assigned, to match the acute M factor, as the classification has been determined based on acute data

+ Environmental classification is assessed based on the lowest acute and chronic values from ecotoxicity tests performed with the substance itself. The lowest acute value is a 48 -hour EC50 of 0.742 mg test item L-1 (0.481 mg Pt L-1) for aquatic invertebrates(mobility) and the lowest chronic value is a 72-hour NOEC of 0.946 mg test item L-1 (0.613 mg Pt L-1) for algae (yield and growth rate). For this substance, the only chronic data available is an algal NOEC, therefore classification is assessed based on both the acute and chronic data and the worst case classification assigned to the substance. Based on these results, an environmental classification of Acute Category 1, Chronic Category 1 is assigned. As the lowest EC50 value is >0.1 ≤ 1 an acute M factor of 1 is assigned. A chronic M factor of 1 is also assigned, to match the acute M factor, as the classification has been determined based on acute data.

% Environmental classification is assessed based on the lowest acute and chronic values from ecotoxicity tests. A full base set of ecotoxicity data are available for this substance, and both platinum and 2-aminoethanol concentrations were analysed in the studies. For fish and Daphnia, no effects were observed up to the highest test concentration. Classification of this substance is therefore based on the algal results and test item concentrations in the study were determined based on measured platinum concentrations. The lowest acute value is a 48-hour EC50 of 0.682 mg test item L-1 (growth rate) and the lowest chronic value is a 72-hour EC10 of 0.039 mg test item L-1 (growth rate). For this substance, the only chronic data available is an algal EC10, therefore classification is assessed based on both the acute and chronic data and the worst case classification assigned to the substance. Based on these results, an environmental classification of Acute Category 1, Chronic Category 1 is assigned to this substance. As the lowest EC50 value is >0.1 ≤ 1 an acute M factor of 1 is assigned. A chronic M factor of 1 is also assigned, to match the acute M factor, as the classification has been determined based on acute data.

General discussion

This substance is a member of the category of “Platinum(IV) substances“. As such,

the data requirements for this substance are covered by relevant and reliable experimental test data generated for all members of this category via a read-across approach.

A read-across justification report and PNEC derivation report are attached in IUCLID Annex 13.

8. PBT AND vPvB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

8.1.1. PBT/vPvB criteria and justification

No relevant information available.

8.1.2. Summary and overall conclusions on PBT or vPvB properties

Assessment entity linked:
dipotassium hexachloroplatinate. View the assessment entity table in chapter 1.3 **here**;
Pt(IV) dissolved. View the assessment entity table in chapter 1.3 **here**

Overall conclusion: PBT assessment does not apply.

Justification:

A PBT assessment is not required for this substance as it is inorganic.

8.2. Emission characterisation

9. EXPOSURE ASSESSMENT (and related risk characterisation)

The sections 9 and 10 of this CSR have been generated with Chesar 3.5.

9.0. Introduction

9.0.1. Overview on uses

See the description of the various uses in section 2 of the CSR.

9.0.2. Assessment entity groups

As described in section 1 of the CSR several sets of substance properties are needed for the human health and environmental assessment. Therefore assessment entities (AEs) have been defined (see section 1.3), for which relevant properties have been reported in section 1 to 7.
Each contributing scenario has been assessed using the properties of one or more assessment entities, grouped into "assessment entity groups". The defined assessment entity groups are reported in the following table.

Table 9.1. Assessment entity groups

Assessment entity group (AEG) name	Composition of AEG	Remarks
Pt dissolved for ENV RA	• 100% Pt(IV) dissolved	**Relevant for the assessment of contributing scenarios for:** - Environment and Man via environment **Method for calculating the RCR across the AEs:** Summed RCR
Dipotassium hexachloroplatinate for OCC RA	• 100% dipotassium hexachloroplatinate	**Relevant for the assessment of contributing scenarios for:** - Workers/Consumers **Method for calculating the RCR across the AEs:** Summed RCR

9.0.3. Introduction to the assessment for the environment

9.0.3.1. Tonnage

Assessed tonnage: 30 tonnes/year based on:

- 30 tonnes/year manufactured

The following table provides the tonnage per use and the local tonnages used in the assessment for each environmental contributing activity. The local tonnage corresponds to a tonnage at the site for uses taking place at industrial sites and to a tonnage assumed for a town of 10 000 inhabitants for widespread uses.

Table 9.2. Tonnage for assessment

ES#	Exposure scenario (ES) name and related environmental contributing scenarios	Tonnage per use (t/year)	Daily local tonnage (t/day)	Annual local tonnage (t/year)
ES1 (M)	Manufacture of the substance (as such)	30		
	- Manufacture of the substance (as such) ES 1.1 (ERC 1)		0.091	30
	- Manufacture of the substance (as such) ES 1.2 (ERC 1)		0.091	30
ES2 (IS)	Use as an intermediate	30		
	- Use as an intermediate ES 1.1 (ERC 6a)		0.091	30
	- Use as an intermediate ES 1.2 (ERC 6a)		0.091	30

9.0.3.2. Scope and type of assessment for the environment

The scope of exposure assessment and type of risk characterisation required for the environment are described in the following table based on the hazard conclusions presented in section 7.

Table 9.3. Type of risk characterisation required for the environment

Protection target	Assessment entity	Risk characterisation type	Hazard conclusion (see section 7)
Fresh water	Pt(IV) dissolved	Quantitative	PNEC aqua (freshwater) = 0.14 µg/L
Sediment (freshwater)	Pt(IV) dissolved	Quantitative	PNEC sediment (freshwater) = 0.261 mg/kg sediment dw
Marine water	Pt(IV) dissolved	Quantitative	PNEC aqua (marine water) = 0.014 µg/L
Sediment (marine water)	Pt(IV) dissolved	Quantitative	PNEC sediment (marine water) = 0.026 mg/kg sediment dw
Sewage Treatment Plant	Pt(IV) dissolved	Quantitative	PNEC STP = 235 µg/L
Air	Pt(IV) dissolved	Not needed	No hazard identified
Agricultural soil	Pt(IV) dissolved	Quantitative	PNEC soil = 5.23E-3 mg/kg soil dw
Predator’s prey (freshwater)	Pt(IV) dissolved	Not needed	No potential for bioaccumulation
Predator’s prey (marine water)	Pt(IV) dissolved	Not needed	No potential for bioaccumulation
Top predator’s prey (marine water)	Pt(IV) dissolved	Not needed	No potential for bioaccumulation
Predator’s prey (terrestrial)	Pt(IV) dissolved	Not needed	No potential for bioaccumulation

9.0.3.3. Fate and distribution parameters

Physicochemical properties used for exposure estimation

The following substance properties are used in the fate estimation done by EUSES. They correspond to the “value used for CSA” reported in sections 1 and 4.

Table 9.4. Substance key phys-chem and fate properties

Substance property	Pt(IV) dissolved
Molecular weight	≥ 195.0
Molecular weight used for the assessment	195.0
Vapour pressure	1E-12 Pa at 20 °C
Water solubility	11 g/L at 20 °C
Log Kp (solids-water in soil)	1.57
Log Kp (solids water in sediment)	3.27
Log Kp (solids-water in suspended matter)	3.27
Log Kp (solids-water in raw sewage sludge)	3.27

Substance property	Pt(IV) dissolved
Log Kp (solids-water in settled sewage sludge)	3.27
Log Kp (solids-water in activated sewage sludge)	3.27
Log Kp (solids-water in effluent sewage sludge)	3.27

Fate (release percentage) in the modelled biological sewage treatment plant

In a standard (modelled) biological STP, the emissions are distributed in the following way:

Assessment entities	Pt(IV) dissolved
Release to water	42.9%
Release to air	0%
Release to sludge	57.1%
Release degraded	0%

The above fractions are calculated by the SIMPLETREAT model integrated in EUSES for the following assessment entities: dipotassium hexachloroplatinate.
The fractions reported in the above table have been set by the assessor for some assessment entities.
Explanation for Pt(IV) dissolved:
Based on European STP monitoring programme. Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Platinum Group Metals in Industrial Effluent during Sewage Treatment. In: Abstracts Book of the SETAC Europe 26th Annual Meeting – 22-26 May 2016, Nantes, France, Society of Environmental Toxicology and Chemistry

9.0.3.4. Comments on assessment approach for the environment

The regional concentrations are reported in section 10.2.1.1. The local Predicted Exposure Concentrations (PECs) reported for each contributing scenario correspond to the sum of the local concentrations (Clocal) and the regional concentrations (PEC regional).
Fourteen sites involved in the production and processing of Pt substances submitted local emission and exposure information for locations in Germany, Switzerland, Belgium, Austria, the Netherlands, Italy and UK. These sites produce and process a number of different Pt compounds and it is important to note that the environment emissions cannot be allocated to a specific substance, activity or process because they are generally collected to a central treatment plant and discharged as a single discharge (e.g. emissions from wastewater treatment plant, WWTP). As a consequence, the environmental exposure estimates relate to Pt originating from the production/use of Pt metal as well as multiple Pt compounds. A sector approach rather than a substance approach is therefore taken to environmental exposure assessment for Pt.
Monitoring data from the Pt processing sector were applied where available (i.e. for manufacturers) or refinements were made to the release factors detailed by SpERCs on the basis of the monetary value of Pt compounds. The use of site-specific monitoring data to generate representative sector emission values resulted in RCR values of <1 for all environmental compartments for the manufacturers who also use Pt compounds as intermediates at the same sites. In the absence of site-specific or representative emission data for downstream users the release factors (RFs) detailed in the SpERCs were adjusted based on the monetary value of Pt compounds. The RFs in SpERCs are generally based on measured emissions from sites producing or using base metals such as nickel, tin and zinc. Due to the considerably higher monetary value of Pt it is considered that emissions from the manufacture and use of platinum substances are likely to be at least an order of magnitude lower and release factors for water and air from the SpERCs have been adjusted accordingly. This is supported by the available measured data for manufacture and use as intermediates at industrial sites, i.e. the selected release factor to water for manufacture and intermediate use of platinum compounds based on sector data (median RF of 11.9 g/T based on data from 10 sites) is 168 times lower than the relevant SpERC-defined release factors (2,000 g/T based on 90P of reported site-specific release factors). Similarly, limited data on emissions to air from four sites processing platinum compounds indicate a mean RF of 15.7 g/T, which is 19 times lower than the relevant SpERC value (300 g/T based on 90P from site data). An order of magnitude reduction in release estimate is therefore considered to be a reasonably conservative adjustment and emissions to water and air based on RFs taken from the SpERC documents have been adjusted to 10% of the recommended value.

Summary information gathered from the Pt industry:

Value	Site Tonnage (tpa Pt, 2012-15)	Emission days per site (d/yr)	
		Water	Air
Median (50P)	9.2	330	345
90th % Percentile (90P)	29.8	365	365
Min	-	190	240
Max	-	365	365
n	14	11	8
Selected for Exposure Scenario	30 (90P)	330 (lowest 50P)	

Value	Release factor (RF) (g/T)	On-site effluent flow (m^3/d)	STP flow (m^3/d)	River flow rate (m^3/d)	Dilution factor to STP	Dilution factor STP to river
Median (50P)	11.9	58.9	25000	6972480	2253.2	32
90P	275	450	177587	16000000	11282	641
10P	0.3	2.5	2995	51083.4	24	17
Min	0.4	3	2950	2950	19	2
Max	500	2592	1344000	16000000	22818	641
N	10	11	10	8	7	7
Selected for ES 1.1 & 2.1 Freshwater – via STP	11.9 (50P)	60 (50P)	3000 (10P STP flow rate)		50 (based on median effluent flow rate & 10P STP flow)	32 (median dilution factor)
Selected for ES 1.2 & 2.2 Freshwater – direct discharge to water		3000		1000 max (dilution factor for only site with direct discharge is 4800)		

9.0.3.5. Scope and type of assessment for man via environment

The exposure assessment for man via environment is not needed.
An assessment of indirect exposure of humans via the environment is generally only conducted if:
• the tonnage >1 000 t/y or
• the tonnage >100 t/Y and the substance is classified as STOT RE 1; or as a carcinogen or mutagen (any category); or as toxic to reproduction (categories 1A or 1B). (ECHA (2016) Guidance on information requirements and chemical safety assessment. Chapter R16: Environmental exposure estimation (Version 3.0, February 2016))

9.0.4. Introduction to the assessment for workers

9.0.4.1. Scope and type of assessment for workers

The scope of exposure assessment and type of risk characterisation required for workers are described in the following table based on the hazard conclusions presented in section 5.11.

Table 9.5. Type of risk characterisation required for workers

Route	Type of effect	Assessment entity	Risk characterisation type	Hazard conclusion (see section 5.11)
Inhalation	Systemic effects - long term	dipotassium hexachloroplatinate	Qualitative	High hazard (no threshold derived)
	Systemic effects - acute	dipotassium hexachloroplatinate	Qualitative	Medium hazard (no threshold derived)
	Local effects - long term	dipotassium hexachloroplatinate	Qualitative	High hazard (no threshold derived)
	Local effects - acute	dipotassium hexachloroplatinate	Qualitative	High hazard (no threshold derived)
Dermal	Systemic effects - long term	dipotassium hexachloroplatinate	Qualitative	High hazard (no threshold derived)
	Systemic effects - acute	dipotassium hexachloroplatinate	Qualitative	Medium hazard (no threshold derived)
	Local effects - long term	dipotassium hexachloroplatinate	Qualitative	Medium hazard (no threshold derived)
	Local effects - acute	dipotassium hexachloroplatinate	Qualitative	Medium hazard (no threshold derived)
Eye	Local effects	dipotassium hexachloroplatinate	Qualitative	Medium hazard (no threshold derived)

9.0.4.2. Comments on assessment approach for workers

Assessment approach related to toxicological hazard:

For the chloroplatinate (ClPt) substances, where a qualitative assessment methodology has been applied according to ECHA Guidance on Information Requirements and Chemical Safety Assessment, Part E: Risk Characterisation (ECHA, 2016), numerical exposure estimates have also been derived. However, the inhalation exposure estimate has not been directly compared to the OEL value of 2 µg/m3 (as soluble Pt) for complex halogenated platinum salts—including chloroplatinates—which is currently in force at national level in most EU territories. This is due to reservations about the OEL's scientific robustness and whether it is fully health-protective in respect of chloroplatinate respiratory sensitisation; as addressed by an EU SCOEL assessment (SCOEL, 2011). Instead, corresponding to approaches set out in ECHA Practical Guide 15 (ECHA, 2012), expert judgement has been applied to set a benchmark value of 0.1 µg/m3 (based on airborne soluble Pt as a surrogate measure).This benchmark value has been derived from a recently published retrospective study (Heederik et al., 2015) involving 1040 refinery workers in five different refineries over eleven year period from January 2000 to December 2010.This high quality study found a clear exposure-response relationship between chloroplatinate salts and respiratory sensitisation in workers and using a risk modelling approach based upon the 'Dutch Health Council' (1% excess risk in workplace of initiating Pt salt sensitisation) estimated that to be protective for workers the exposure level should be below 0.1 µg/m3. Although work is continuing to refine this value it is considered to align with a categorisation of "low exposure". As set out elsewhere in this document, calculated final personal exposure levels in the occupational ES in Section 9 of the CSR of the individual platinum substances integrate exposure reduction adjustments due to use of RPE, as relevant for each ES. Requirements for use of RPE, and the associated RPE Assigned Protection Factors (APF), have been based on control of exposure so as not to exceed the selected benchmark value. Risk characterisation statements made for the various ES are also aligned with the application of this benchmark value.

GENERAL GOOD OCCUPATIONAL HYGIENE PRACTICES
In the platinum industry, good occupational hygiene practices are followed to ensure safe handling of platinum substances. Generally, inhalation (e.g. dust should not be blown off with compressed air) and ingestion (e.g. no eating and smoking in the workplace, regular cleaning with suitable cleaning devices) must be avoided. More specific measures include:
(i) work clothing is not taken home,
(ii) good general ventilation in the workplace is always ensured,
(iii) regular training in workplace hygiene practice and proper use of personal protective equipment (where relevant).

SPECIFIC MEASURES TO MINIMISE THE RISK FOR RESPIRATORY SENSITISATION
Each contributing exposure scenarios (CES) below describes the conditions of use to ensure safe use of the substance. In addition to the described operational conditions and risk management measures in the CES at the process level and general good occupational hygiene practices as outlined above, common measures are required whenever chloroplatinates are present in a workplace. These measures include technical and organisational measures that are implemented in the platinum industry.

TECHNICAL MEASURES
- High level of containment wherever possible.
- Closed systems allow for easy maintenance.
- Wherever possible, all process systems are kept under negative pressure.
- Chloroplatinates are handled in dedicated areas.

ORGANISATIONAL MEASURES
- All machinery/systems and risk management measure are regularly tested for proper functioning.
- Training of workers in use of PPE, equipment and specifically for handling chloroplatinates.
- Training of personnel for emergency situations.
- Permits required for not-authorized personnel for entering the work area.

QUALITATIVE RISK CHARACTERISATION FOR RESPIRATORY SENSITISATION
The quantitative exposure assessment for the individual CES as reported below generally indicates very low exposure levels for the dermal and the inhalation route for chloroplatinates indicating efficient risk management measures at the process level. In addition, organisational measures ensure that any residual exposures are controlled. Contamination of adjacent workplaces is excluded by stringent housekeeping measures such as immediate and careful removal of any contamination of surfaces. It is therefore concluded that the risk for respiratory sensitisation is minimised to an extent as technical feasible by the application of all relevant state-of-the-art risk mitigation measures.

QUALITATIVE RISK CHARACTERISATION FOR OTHER EFFECTS
Due to the stringent conditions in place to protect for respiratory sensitisation any other adverse health effects that can be caused by chloroplatinates are inherently prevented.Please refer to the document “Methodology applied in the occupational exposure scenarios for platinum substances” as annexed to the CSR for further information on the applied methodology for the occupational exposure assessment.

General information on risk management related to toxicological hazard:

GENERAL INFORMATION RELATED TO PERSONAL PROTECTIVE EQUIPMENT FOR WORKERS
Use of personal protective equipment for each of the exposure routes listed below is required as described here, unless exposure to the substance can be excluded for the respective route(s) of exposure. Such exclusion of exposure may be determined by: (i) the physical appearance of the substance in the specific type of application (e.g. wetting the substance can effectively prevent from the emission of dust), (ii) the emission potential resulting from the nature of the process (e.g. splashes, emission of dust can be excluded in a closed process), (iii) applied exposure prevention measures (segregation of the emission source or separation of the worker from the emission source), and (iv) the amount of the handled/emitted material during use in relation to the room size (i.e. dilution factor) under consideration of the prevailing air exchange rates during use.

DERMAL ROUTE (SKIN PROTECTION)
When dermal protective equipment is required, specific information is provided in the occupational exposure scenarios below. Further, dermal protective equipment is to be selected in consideration of mechanical, cold or heat stress or any other physico-chemical hazards as relevant for the conducted tasks and working environment in addition to the effectiveness of the equipment to control exposure. Certified safety clothing including coveralls and safety shoes are generally worn. Protective gloves comply with EN 374 and are changed according to manufacturer’s information or when damaged, whatever is the earlier.

INHALATION ROUTE (RESPIRATORY PROTECTION)
When respiratory protective equipment (RPE) is required, specific information on the required assigned protection factor (APF) is provided in the occupational exposure scenarios below. RPE should be selected based on the given APF according to EN 529 and should comply with national legislation. If RPE has to be worn, an APF of 10 represents the required minimum level of protection. RPE shall only be worn if the following principles are implemented in parallel: The duration of work should take into account the additional

physiological stress for the worker due to the breathing resistance and mass of the RPE itself and due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore: (i) be healthy (especially in view of medical problems that may affect the use of RPE), and (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The devices recommended in the ES which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and supply of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of workers.

EYE/FACE PROTECTION
Eye/face protective equipment is to be selected in consideration of mechanical, cold or heat stress or any other physico-chemical hazards as relevant for the conducted tasks and working environment in addition to the effectiveness of the equipment to control exposure.

General information on risk management related to physicochemical hazard:

Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.
The substance is classified as Metal corrosivity category 1, therefore do not handle until all safety precautions have been read and understood. Taking into consideration the precautionary statements all uses of the substance for all users can be considered safe regarding corrosion to metals.

9.0.5. Introduction to the assessment for consumers

Exposure assessment is not applicable as there are no consumer-related uses for the substance.

9.1. Exposure scenario 1: Manufacture - Manufacture of the substance (as such)

Environment contributing scenario(s):		
CS 1	Manufacture of the substance (as such) ES 1.1	ERC 1
CS 2	Manufacture of the substance (as such) ES 1.2	ERC 1
Worker contributing scenario(s):		
CS 3	Raw material handling of dry/dusty materials	PROC 26
CS 4	Raw material handling of non to low dusty platinum substances	PROC 21
CS 5	Raw material handling of liquid platinum substances	PROC 8b, PROC 9
CS 6	Raw material handling of platinum substances in fully contained systems	PROC 1
CS 7	Sampling/Evaluation of solid platinum substances	PROC 15
CS 8	Sampling/Evaluation of liquid platinum substances	PROC 15
CS 9	Wet processing in fully contained systems	PROC 1
CS 10	Wet processing in not fully contained systems	PROC 2, PROC 3; PROC 4; PROC 5
CS 11	Separation/Filtration in fully contained systems	PROC 1
CS 12	Separation/Filtration of non to low dusty platinum substances	PROC 2, PROC 3; PROC 4
CS 13	Separation/Filtration of liquid platinum substances	PROC 2, PROC 3; PROC 4
CS 14	Washing/Drying in fully contained systems	PROC 1
CS 15	Washing/Drying of non to low dusty platinum substances	PROC 2, PROC 3; PROC 4
CS 16	Washing/Drying of liquid platinum substances	PROC 2, PROC 3
CS 17	Washing/Drying at elevated temperature	PROC 2, PROC 3
CS 18	Calcination in fully contained systems	PROC 1
CS 19	Milling/Grinding/Sieving	PROC 1
CS 20	Packaging/Filling of dry/dusty platinum substances	PROC 26
CS 21	Packaging/Filling of non to low dusty platinum substances	PROC 21
CS 22	Packaging/Filling of liquid platinum substances	PROC 8b, PROC 9
CS 23	Packaging/Filling in fully contained systems	PROC 1
CS 24	Cleaning and maintenance: vacuum cleaning	PROC 26
CS 25	Cleaning and maintenance: wet cleaning	PROC 8a

Further description of the use:

Dipotassium hexachloroplatinate is built by reaction of concentrated aqueous Dihydrogen hexachloroplatinic acid with aqueous Potassium hydroxide. Due to low solubility, K2PtCl6precipitates immediately. It’s separated washed and dried.

9.1.1. Env CS 1: Manufacture of the substance (as such) ES 1.1 (ERC 1)

Assessment entity group used for the assessment of this contributing scenario: Pt dissolved for ENV RA

9.1.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 30 tonnes/year *74.7 tonnes dipotassium hexachloroplatinate (30 tonnes Pt metal equivalent); 90P from sector data*

• Daily use amount at site: <= 0.091 tonnes/day *Based on 330 days per year (50P from sector data)*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 57.1%]
• Discharge rate of STP: >= 3E3 m3/day
• Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the platinum content of the waste is elevated enough, internal or external recovery/recycling should be considered.* *Fraction of daily/annual use expected in waste: 0%* *Appropriate waste codes: 06 04 05*, 06 05 02*, 10 07 01, 10 07 02, 10 07 03, 10 07 05, 10 08 16, 15 02 02*, 16 01 18, 16 08 01, 16 08 06*, 16 08 07*, 19 08 06*, 20 01 40* *Suitable disposal: Hazardous waste produced during the manufacture and downstream use is sent to a recycler only marginal amounts are sent to a landfill or an incinerator. Waste containing platinum is recycled for almost a 100%* *A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2016)*
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 9.3E4 m3/day
• Discharge to: Freshwater only

Fate (release percentage) in the biological sewage treatment plant

The biological STP is site specific and the releases to the various compartments have been set by the assessor for some assessment entities. They are distributed in the following way:

Assessment entities	**Pt(IV) dissolved**
Release to water	42.9%
Release to air	0%
Release to sludge	57.1%
Release degraded	0%

Explanation for Pt(IV) dissolved:
Based on European STP monitoring programme. Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Platinum Group Metals in Industrial Effluent during Sewage Treatment. In: Abstracts Book of the SETAC Europe 26th Annual Meeting – 22-26 May 2016, Nantes, France, Society of Environmental Toxicology and Chemistry

9.1.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.6. Local releases to the environment

Release	**Assessment entity**	**Release estimation method**	**Explanations**
Water	Pt(IV) dissolved	Estimated release factor	**Release factor before on site RMM:** 1.19E-3% **Release factor after on site RMM:** 1.19E-3% **Local release rate:** 1.08E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99 % (sector data)

Release	Assessment entity	Release estimation method	Explanations
			Release factor after on-site treatment: 11.9 g/T (50P from sector data)
Air	Pt(IV) dissolved	Estimated release factor (SpERC RF for 'Manufacture of metal compounds)	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 2.73E-3 kg/day **Explanation:** Treatment of air emissions by wet scrubbers and filters (e.g. fabric, bag, HEPA). Release factor after on-site treatment: 30 g/T (10% of SpERC RF for 'Manufacture of metal compounds')
Non agricultural soil	Pt(IV) dissolved	Estimated release factor	**Release factor after on site RMM:** 0%

9.1.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.7. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Fresh water	Pt(IV) dissolved	**Local PEC:** 4.74E-6 mg/L RCR = 0.034	Final RCR = 0.034
Sediment (freshwater)	Pt(IV) dissolved	**Local PEC:** 8.84E-3 mg/kg dw RCR = 0.034	Final RCR = 0.034
Sewage Treatment Plant	Pt(IV) dissolved	**Local PEC:** 1.55E-4 mg/L RCR = 6.59E-4	Final RCR < 0.01
Agricultural soil	Pt(IV) dissolved	**Local PEC:** 1.22E-3 mg/kg dw RCR = 0.234	Final RCR = 0.234

9.1.2. Env CS 2: Manufacture of the substance (as such) ES 1.2 (ERC 1)

Assessment entity group used for the assessment of this contributing scenario: Pt dissolved for ENV RA

9.1.2.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 30 tonnes/year *74.7 tonnes dipotassium hexachloroplatinate (30 tonnes Pt metal equivalent); 90P from sector data*
• Daily use amount at site: <= 0.091 tonnes/day *Based on 330 days per year (50P from sector data)*
Conditions and measures related to biological sewage treatment plant
• Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the platinum content of the waste is elevated enough, internal or external recovery/recycling should be considered.* *Fraction of daily/annual use expected in waste: 0%* *Appropriate waste codes: 06 04 05*, 06 05 02*, 10 07 01, 10 07 02, 10 07 03, 10 07 05, 10 08 16, 15 02 02*, 16 01 18, 16 08 01, 16 08 06*, 16 08 07*, 19 08 06*, 20 01 40* *Suitable disposal: Hazardous waste produced during the manufacture and downstream use is sent to a recycler only marginal amounts are sent to a landfill or an incinerator. Waste containing platinum is recycled*

for almost a 100% *A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2016)*
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 3E6 m3/day
• Discharge to: Freshwater only
• Discharge rate of effluent: >= 3E3 m3/day

9.1.2.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.8. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pt(IV) dissolved	Estimated release factor	**Release factor before on site RMM:** 1.19E-3% **Release factor after on site RMM:** 1.19E-3% **Local release rate:** 1.08E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99 % (sector data) Release factor after on-site treatment: 11.9 g/T (50P from sector data)
Air	Pt(IV) dissolved	Estimated release factor (SpERC RF for 'Manufacture of metal compounds)	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 2.73E-3 kg/day **Explanation:** Treatment of air emissions by wet scrubbers and filters (e.g. fabric, bag, HEPA). Release factor after on-site treatment: 30 g/T (10% of SpERC RF for 'Manufacture of metal compounds')
Non agricultural soil	Pt(IV) dissolved	Estimated release factor	**Release factor after on site RMM:** 0%

9.1.2.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.9. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Fresh water	Pt(IV) dissolved	**Local PEC:** 3.83E-7 mg/L RCR = 2.74E-3	Final RCR < 0.01
Sediment (freshwater)	Pt(IV) dissolved	**Local PEC:** 7.14E-4 mg/kg dw RCR = 2.74E-3	Final RCR < 0.01
Agricultural soil	Pt(IV) dissolved	**Local PEC:** 1.22E-3 mg/kg dw RCR = 0.234	Final RCR = 0.234

9.1.3. Worker CS 3: Raw material handling of dry/dusty materials (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.3.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Exterior exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances are always handled in at least partly-contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (see the dermal exposure pattern below).	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.10. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.09 µg/m³ (Measured data: Pt monitoring database including RPE with APF = 40) **Supportive exposure (not used for RC):** 3.63 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 3.7
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #1 (GSD=3.7) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Pt monitoring database including RPE with APF = 40 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 3.7
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #1 (GSD=3.7) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 40.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of the use of appropriate gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2. Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.4. Worker CS 4: Raw material handling of non to low dusty platinum substances (PROC 21)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: Low *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Exterior exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Containment due to physical form *The physical form of the platinum substance may be considered as some containment considerably reducing emissions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (see the dermal exposure pattern below).	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.11. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.04 µg/m³ (Measured data: Pt monitoring database including RPE with APF = 10) **Supportive exposure (not used for RC):**	Risk adequately controlled

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
		0.38 µg/m³ (Measured data: Pt monitoring database)	
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Pt monitoring database including RPE with APF = 10 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 10.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.5. Worker CS 5: Raw material handling of liquid platinum substances (PROC 8b, PROC 9)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low *It is noted that spraying operations are not covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum	

	Method
substances: - *Generic local exhaust ventilation* - *Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances are always handled in at least partly-contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (see the dermal exposure pattern below).	
• Removal of residuals: Splashes *Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.12. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.04 µg/m³ (Measured data: Analogous data including RPE with APF = 10) **Supportive exposure (not used for RC):** 0.38 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt

Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 10 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 10.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level (< 1µg/kg bw/day) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.6. Worker CS 6: Raw material handling of platinum substances in fully contained systems (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.6.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant (fully contained systems)*	
• Maximum emission potential of the substance: Unknown *Not relevant (fully contained systems)*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• Potential for contamination *Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.*	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin	

	Method
(medium hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.6.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.13. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.01 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: All
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 12
Explanation: The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2. Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.7. Worker CS 7: Sampling/Evaluation of solid platinum substances (PROC 15)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances in solid form are always handled in at least partly-contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. Although automation may not be possible during this task, an incidental or intermittent contact level is achieved by limiting the number of exposure events (see the dermal exposure pattern below).	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.7.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.14. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.08 µg/m³ (Measured data: Pt monitoring database including RPE with APF = 40) **Supportive exposure (not used for RC):** 3.25 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 14 ; GSD: 4.3
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #05 (GSD=4.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Pt monitoring database including RPE with APF = 40 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 14 ; GSD: 4.3
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #05 (GSD=4.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 40.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2. Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.8. Worker CS 8: Sampling/Evaluation of liquid platinum substances (PROC 15)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.8.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low *It is noted that spraying operations are not covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	

	Method
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Containment due to physical form *The physical form of the platinum substance may be considered as some containment considerably reducing emissions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. Although automation may not be possible during this task, an incidental or intermittent contact level is achieved by limiting the number of exposure events (see the dermal exposure pattern below).	
• Removal of residuals: Splashes *Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.8.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.15. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.02 µg/m³ (Measured data: Analogous data including RPE with APF = 10) **Supportive exposure (not used for RC):** 0.15 µg/m³ (Measured data: Analogous data)	Risk adequately controlled

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: tracesClPt instead of ClPt data as exposure estimate was higher
Inhalation exposure, long term concentration: Number of measured data points: 5 ; GSD: 5.8
Explanation: The estimated exposure level represents the maximum value multiplied with 1.5 of the exposure distribution for estimate #07 (GSD=5.8) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.
Monitoring data (ClPt) Inhalation, systemic, long-term:
Number of measured data points: 2
The estimated exposure level represents the maximum value of the exposure distribution multiplied with 1.5 for estimate #06 (GSD=5.1).

Analogous data including RPE with APF = 10 for dipotassium hexachloroplatinate:
Identity of the substance used: tracesClPt instead of ClPt data as exposure estimate was higher
Inhalation exposure, long term concentration: Number of measured data points: 5 ; GSD: 5.8
Explanation: The estimated exposure level represents the maximum value multiplied with 1.5 of the exposure distribution for estimate #07 (GSD=5.8) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 10.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.9. Worker CS 9: Wet processing in fully contained systems (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.9.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant (fully contained systems)*	
• Maximum emission potential of the substance: Unknown *Not relevant (fully contained systems)*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum	

	Method
substances: - *Generic local exhaust ventilation* - *Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• Potential for contamination *Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.*	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.9.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.16. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.01 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: All
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the “Methodology applied in the Occupational Exposure Scenarios for Platinum Substances” document.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 12

Explanation: The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.10. Worker CS 10: Wet processing in not fully contained systems (PROC 2, PROC 3; PROC 4; PROC 5)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.10.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low *It is noted that spraying operations are not covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances are always handled in at least partly-contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (see the dermal exposure pattern below).	
• Removal of residuals: Splashes *Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

	Method
Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.10.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.17. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.07 µg/m³ (Measured data: Pt monitoring database including RPE with APF = 10) **Supportive exposure (not used for RC):** 0.68 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 21 ; GSD: 2.5
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #09 (GSD=2.5) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Pt monitoring database including RPE with APF = 10 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #09 (GSD=2.5) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 10.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level (< 1µg/kg bw/day) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.11. Worker CS 11: Separation/Filtration in fully contained systems (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.11.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant (fully contained systems)*	
• Maximum emission potential of the substance: Unknown *Not relevant (fully contained systems)*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• Potential for contamination *Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.*	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.11.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.18. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.01 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: All
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 12
Explanation: The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.12. Worker CS 12: Separation/Filtration of non to low dusty platinum substances (PROC 2, PROC 3; PROC 4)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.12.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: Low *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Exterior exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	

	Method
• Level of containment: Containment due to physical form *The physical form of the platinum substance may be considered as some containment considerably reducing emissions. Chloroplatinates are additionally handled in at least partly enclosed systems. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.12.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.19. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.1 µg/m³ (Measured data: Pt monitoring database including RPE with APF = 40) **Supportive exposure (not used for RC):** 4.08 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.29 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 13 ; GSD: 5.6
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #013 (GSD=5.6) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Pt monitoring database including RPE with APF = 40 for dipotassium hexachloroplatinate:

Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 13 ; GSD: 5.6
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #013 (GSD=5.6) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 40.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 17
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDE in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.13. Worker CS 13: Separation/Filtration of liquid platinum substances (PROC 2, PROC 3; PROC 4)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.13.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low *It is noted that spraying operations are not covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Exterior exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Containment due to physical form *The physical form of the platinum substance may be considered as some containment considerably reducing emissions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Removal of residuals: Splashes *Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	

	Method
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.13.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.20. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.07 µg/m³ (Measured data: Pt monitoring database including RPE with APF = 10) **Supportive exposure (not used for RC):** 0.69 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 5 ; GSD: 8.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution multiplied with 1.5 for estimate #011 (GSD=8.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Pt monitoring database including RPE with APF = 10 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 5 ; GSD: 8.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution multiplied with 1.5 for estimate #011 (GSD=8.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 10.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level (<1µg/kg bw/day) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.14. Worker CS 14: Washing/Drying in fully contained systems (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.14.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant (fully contained systems)*	
• Maximum emission potential of the substance: Unknown *Not relevant (fully contained systems)*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• Potential for contamination *Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.*	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note*	

	Method
that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.14.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.21. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.01 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: All
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 12
Explanation: The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.15. Worker CS 15: Washing/Drying of non to low dusty platinum substances (PROC 2, PROC 3; PROC 4)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.15.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: Low *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation:	

	Method
0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances are always handled in at least partly contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.15.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.22. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.1 µg/m³ (Measured data: Analogous data including RPE with APF = 40) **Supportive exposure (not used for RC):** 4.08 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:

Identity of the substance used: ClPt separation/filtration
Inhalation exposure, long term concentration: Number of measured data points: 13 ; GSD: 5.6
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #013 (GSD=5.6) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 40 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt separation/filtration
Inhalation exposure, long term concentration: Number of measured data points: 13 ; GSD: 5.6
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #013 (GSD=5.6) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 40.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.16. Worker CS 16: Washing/Drying of liquid platinum substances (PROC 2, PROC 3)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.16.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low *It is noted that spraying operations are not covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances are always handled in at least partly contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Removal of residuals: Splashes *Splashes are to be removed immediately, before drying. Please refer to the*	

	Method
introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Incidental	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.16.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.23. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.07 µg/m³ (Measured data: Analogous data including RPE with APF = 10) **Supportive exposure (not used for RC):** 0.69 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt separation/filtration
Inhalation exposure, long term concentration: Number of measured data points: 5 ; GSD: 8.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution multiplied with 1.5 for estimate #011 (GSD=8.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 10 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt separation/filtration
Inhalation exposure, long term concentration: Number of measured data points: 5 ; GSD: 8.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution multiplied with 1.5 for estimate #011 (GSD=8.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 10.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni

Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level (<1µg/kg bw/day) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.17. Worker CS 17: Washing/Drying at elevated temperature (PROC 2, PROC 3)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.17.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid *Dry/dusty solid*	
• Maximum emission potential of the substance: Medium *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Maximum process temperature: 150 °C	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: - *Integrated exhaust ventilation* *A minimum efficiency of 90 % has to be assured.*	
• Level of containment: Partly contained systems	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching*	

	Method
contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.17.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.24. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.07 µg/m³ (Measured data: Analogous data including RPE with APF = 20) **Supportive exposure (not used for RC):** 1.35 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt calcination
Inhalation exposure, long term concentration: Number of measured data points: 4 ; GSD: 2.6
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #17 (GSD=2.6) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 20 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt calcination
Inhalation exposure, long term concentration: Number of measured data points: 4 ; GSD: 2.6
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #17 (GSD=2.6) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 10.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level (<1µg/kg bw/day) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.18. Worker CS 18: Calcination in fully contained systems (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate

for OCC RA

9.1.18.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant (fully contained systems)*	
• Maximum emission potential of the substance: Unknown *Not relevant (fully contained systems)*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• Potential for contamination *Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.*	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.18.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.25. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.01 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: All
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 12
Explanation: The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.19. Worker CS 19: Milling/Grinding/Sieving (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.19.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant (fully contained systems)*	
• Maximum emission potential of the substance: Unknown *Not relevant (fully contained systems)*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• Potential for contamination *Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.*	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin	

	Method
(medium hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.19.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.26. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.01 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: All
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 12
Explanation: The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2. Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.20. Worker CS 20: Packaging/Filling of dry/dusty platinum substances (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.20.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Exterior exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (see the dermal exposure pattern below).	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.20.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.27. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.23 µg/m³ (Measured data: Pt monitoring database including RPE with APF = 40) **Supportive exposure (not used for RC):** 9.24 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 7.3
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #22 (GSD=7.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Pt monitoring database including RPE with APF = 40 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 6 ; GSD: 0.3
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #22 (GSD=7.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 40.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of the use of appropriate gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2. Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.21. Worker CS 21: Packaging/Filling of non to low dusty platinum substances (PROC 21)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.21.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: Low *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances are always handled in at least partly contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (see the dermal exposure pattern below).	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.21.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.28. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.04 µg/m³ (Measured data: Analogous data including RPE with APF = 10) **Supportive exposure (not used for RC):** 0.38 µg/m³ (Measured data: Analogous data)	Risk adequately controlled

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt raw material handling
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 10 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt raw material handling
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 10.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.22. Worker CS 22: Packaging/Filling of liquid platinum substances (PROC 8b, PROC 9)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.22.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low *It is noted that spraying operations are not covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation*	

	Method
A minimum efficiency of 80 % has to be assured.	
• Level of containment: Partly contained systems *Platinum substances are always handled in at least partly-contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (see the dermal exposure pattern below).	
• Removal of residuals: Splashes *Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.22.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.29. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.04 µg/m³ (Measured data: Analogous data including RPE with APF = 10) **Supportive exposure (not used for RC):** 0.38 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt raw material handling
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the

Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 10 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt raw material handling
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 10.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level (< 1µg/kg bw/day) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.23. Worker CS 23: Packaging/Filling in fully contained systems (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.23.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant (fully contained systems)*	
• Maximum emission potential of the substance: Unknown *Not relevant (fully contained systems)*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• Potential for contamination *Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.*	

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.23.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.30. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.01 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: All
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the “Methodology applied in the Occupational Exposure Scenarios for Platinum Substances” document.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 12
Explanation: The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.24. Worker CS 24: Cleaning and maintenance: vacuum cleaning (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.24.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid *Dusty residuals*	
• Maximum emission potential of the substance: High *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Removal of residuals: Dusty residuals *A highly efficient vacuum cleaner is to be used. No direct manual removal of dust. Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.* *Workplaces are to be cleaned before any maintenance work starts.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.24.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.31. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.07 µg/m³ (Measured data: Pt monitoring database including RPE with APF = 40)	Risk adequately controlled

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
		Supportive exposure (not used for RC): 2.96 µg/m³ (Measured data: Pt monitoring database)	
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.01 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 5.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Pt monitoring database including RPE with APF = 40 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 5.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 40.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NNE in consideration of the use of appropriate gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.25. Worker CS 25: Cleaning and maintenance: wet cleaning (PROC 8a)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.1.25.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Removal of residuals: Splashes *Removal of residuals is considered to be part of regular work.* *Splashes are to be removed immediately, before drying. Please refer to the introduction*	

	Method
for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry. *Workplaces are to be cleaned before any maintenance work starts.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.1.25.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.32. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.07 µg/m³ (Measured data: Pt monitoring database including RPE with APF = 40) **Supportive exposure (not used for RC):** 2.96 µg/m³ (Measured data: Pt monitoring database)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.29 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 5.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Pt monitoring database including RPE with APF = 40 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 5.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 40.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni

Dermal exposure, long term systemic dose: Number of measured data points: 17
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDE in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2. Exposure scenario 2: Use at industrial sites - Use as an intermediate

Sector of use: SU 9: Manufacture of fine chemicals; SU 14: Manufacture of basic metals, including alloys

Environment contributing scenario(s):		
CS 1	Use as an intermediate ES 1.1	ERC 6a
CS 2	Use as an intermediate ES 1.2	ERC 6a
Worker contributing scenario(s):		
CS 3	Handling of medium/high dusty materials	PROC 26
CS 4	Handling of low dusty materials	PROC 26
CS 5	Handling of solutions and reaction	PROC 3, PROC 15; PROC 4; PROC 5; PROC 8b; PROC 9
CS 6	Fully contained process	PROC 1
CS 7	Reaction process (furnace operation)	PROC 22
CS 8	Hot powder production	PROC 27a
CS 9	Wet powder production	PROC 27b
CS 10	Wet cleaning	PROC 8a
CS 11	Vacuum cleaning	PROC 26

9.2.1. Env CS 1: Use as an intermediate ES 1.1 (ERC 6a)

Assessment entity group used for the assessment of this contributing scenario: Pt dissolved for ENV RA

9.2.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 30 tonnes/year *74.7 tonnes dipotassium hexachloroplatinate (30 tonnes Pt metal equivalent); 90P from sector data*
• Daily use amount at site: <= 0.091 tonnes/day *Based on 330 days per year (50P from sector data)*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 57.1%]
• Discharge rate of STP: >= 3E3 m3/day
• Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the platinum content of the waste is elevated enough, internal or external recovery/recycling should be considered.* *Fraction of daily/annual use expected in waste: 0%* *Appropriate waste codes: 06 04 05*, 06 05 02*, 10 07 01, 10 07 02, 10 07 03, 10 07 05, 10 08 16, 15 02 02*, 16 01 18, 16 08 01, 16 08 06*, 16 08 07*, 19 08 06*, 20 01 40* *Suitable disposal: Hazardous waste produced during the manufacture and downstream use is sent to a recycler only marginal amounts are sent to a landfill or an incinerator. Waste containing platinum is recycled for almost a 100%* *A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2016)*
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 9.3E4 m3/day

• Discharge to: Freshwater only

Fate (release percentage) in the biological sewage treatment plant

The biological STP is site specific and the releases to the various compartments have been set by the assessor for some assessment entities. They are distributed in the following way:

Assessment entities	Pt(IV) dissolved
Release to water	42.9%
Release to air	0%
Release to sludge	57.1%
Release degraded	0%

Explanation for Pt(IV) dissolved:
Based on European STP monitoring programme. Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Platinum Group Metals in Industrial Effluent during Sewage Treatment. In: Abstracts Book of the SETAC Europe 26th Annual Meeting – 22-26 May 2016, Nantes, France, Society of Environmental Toxicology and Chemistry

9.2.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.33. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pt(IV) dissolved	Estimated release factor	**Release factor before on site RMM:** 1.19E-3% **Release factor after on site RMM:** 1.19E-3% **Local release rate:** 1.08E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99 % (sector data) Release factor after on-site treatment: 11.9 g/T (50P from sector data)
Air	Pt(IV) dissolved	Estimated release factor	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 2.73E-3 kg/day **Explanation:** Treatment of air emissions by wet scrubbers and filters (e.g. fabric, bag, HEPA). Release factor after on-site treatment: 30 g/T (10% of SpERC RF for 'Manufacture of metal compounds')
Non agricultural soil	Pt(IV) dissolved	Estimated release factor	**Release factor after on site RMM:** 0%

9.2.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.34. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Fresh water	Pt(IV) dissolved	**Local PEC:** 4.74E-6 mg/L RCR = 0.034	Final RCR = 0.034

Protection target	Assessment entity	Exposure concentration	Risk quantification
Sediment (freshwater)	Pt(IV) dissolved	**Local PEC:** 8.84E-3 mg/kg dw RCR = 0.034	Final RCR = 0.034
Sewage Treatment Plant	Pt(IV) dissolved	**Local PEC:** 1.55E-4 mg/L RCR = 6.59E-4	Final RCR < 0.01
Agricultural soil	Pt(IV) dissolved	**Local PEC:** 1.22E-3 mg/kg dw RCR = 0.234	Final RCR = 0.234

9.2.2. Env CS 2: Use as an intermediate ES 1.2 (ERC 6a)

Assessment entity group used for the assessment of this contributing scenario: Pt dissolved for ENV RA

9.2.2.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 30 tonnes/year *74.7 tonnes dipotassium hexachloroplatinate (30 tonnes Pt metal equivalent); 90P from sector data*
• Daily use amount at site: <= 0.091 tonnes/day *Based on 330 days per year (50P from sector data)*
Conditions and measures related to biological sewage treatment plant
• Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the platinum content of the waste is elevated enough, internal or external recovery/recycling should be considered.* *Fraction of daily/annual use expected in waste: 0%* *Appropriate waste codes: 06 04 05*, 06 05 02*, 10 07 01, 10 07 02, 10 07 03, 10 07 05, 10 08 16, 15 02 02*, 16 01 18, 16 08 01, 16 08 06*, 16 08 07*, 19 08 06*, 20 01 40* *Suitable disposal: Hazardous waste produced during the manufacture and downstream use is sent to a recycler only marginal amounts are sent to a landfill or an incinerator. Waste containing platinum is recycled for almost a 100%* *A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2016)*
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 3E6 m3/day
• Discharge to: Freshwater only
• Discharge rate of effluent: >= 3E3 m3/day

9.2.2.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.35. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pt(IV) dissolved	Estimated release factor	**Release factor before on site RMM:** 1.19E-3% **Release factor after on site RMM:** 1.19E-3% **Local release rate:** 1.08E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99 % (sector data)

Release	Assessment entity	Release estimation method	Explanations
			Release factor after on-site treatment: 11.9 g/T (50P from sector data)
Air	Pt(IV) dissolved	Estimated release factor	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 2.73E-3 kg/day **Explanation:** Treatment of air emissions by wet scrubbers and filters (e.g. fabric, bag, HEPA). Release factor after on-site treatment: 30 g/T (10% of SpERC RF for 'Manufacture of metal compounds')
Non agricultural soil	Pt(IV) dissolved	Estimated release factor	**Release factor after on site RMM:** 0%

9.2.2.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.36. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Fresh water	Pt(IV) dissolved	**Local PEC:** 3.83E-7 mg/L RCR = 2.73E-3	Final RCR < 0.01
Sediment (freshwater)	Pt(IV) dissolved	**Local PEC:** 7.14E-4 mg/kg dw RCR = 2.73E-3	Final RCR < 0.01
Agricultural soil	Pt(IV) dissolved	**Local PEC:** 1.22E-3 mg/kg dw RCR = 0.234	Final RCR = 0.234

9.2.3. Worker CS 3: Handling of medium/high dusty materials (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.2.3.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Exterior exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	

	Method
• Level of containment: Partly contained systems *Platinum substances have to be handled in at least partly-contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (see the dermal exposure pattern below).	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.2.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.37. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.09 µg/m³ (Measured data: Analogous data including RPE with APF = 40) **Supportive exposure (not used for RC):** 3.63 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers raw material handling
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 3.7
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #01 (GSD=3.7) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 40 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers raw material handling
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 3.7
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #01 (GSD=3.7) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 40.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.4. Worker CS 4: Handling of low dusty materials (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.2.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: Low *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Exterior exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Containment due to physical form *The physical form of the platinum substance may be considered as some containment considerably reducing emissions. Platinum substances have to be handled in at least partly-contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (see the dermal exposure pattern below).	
• Removal of residuals: Dusty residuals	

	Method
Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.2.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.38. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.04 µg/m³ (Measured data: Analogous data including RPE with APF = 10) **Supportive exposure (not used for RC):** 0.38 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers raw material handling
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 10 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers raw material handling
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 10.

Analogous data (Ni) for dipotassium hexachloroplatinate:

Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.5. Worker CS 5: Handling of solutions and reaction (PROC 3, PROC 15; PROC 4; PROC 5; PROC 8b; PROC 9)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.2.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low *It is noted that spraying operations are not covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances are always handled in at least partly-contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (see the dermal exposure pattern below).	
• Removal of residuals: Splashes *Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the	

	Method
earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.2.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.39. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.07 µg/m³ (Measured data: Analogous data including RPE with APF = 10) **Supportive exposure (not used for RC):** 0.68 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers wet processing
Inhalation exposure, long term concentration: Number of measured data points: 21 ; GSD: 2.5
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #09 (GSD=2.5) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 10 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers wet processing
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #09 (GSD=2.5) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 10.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level (< 1µg/kg bw/day) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.6. Worker CS 6: Fully contained process (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.2.6.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant (fully contained systems)*	
• Maximum emission potential of the substance: Unknown *Not relevant (fully contained systems)*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• Potential for contamination *Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.*	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.2.6.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.40. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.01 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers separation/filtration
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 12
Explanation: The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.7. Worker CS 7: Reaction process (furnace operation) (PROC 22)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.2.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant*	
• Maximum emission potential of the substance: Low *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Maximum process temperature: °C *Below melting point*	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Integrated exhaust ventilation* *A minimum efficiency of 90 % has to be assured.*	
• Level of containment: Partly contained systems	

	Method
Platinum substances have to be handled in at least partly enclosed systems. The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (see the dermal exposure pattern below).	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.2.7.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.41. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.07 µg/m³ (Measured data: Analogous data including RPE with APF = 20) **Supportive exposure (not used for RC):** 1.35 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers calcination
Inhalation exposure, long term concentration: Number of measured data points: 4 ; GSD: 2.6
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #17 (GSD=2.6) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 20 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers calcination
Inhalation exposure, long term concentration: Number of measured data points: 4 ; GSD: 2.6
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #17 (GSD=2.6) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 20.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level (<1µg/kg bw/day) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.8. Worker CS 8: Hot powder production (PROC 27a)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.2.8.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Molten *Molten / powder (already other substance)*	
• Maximum emission potential of the substance: Medium *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Maximum process temperature: °C *Slightly above melting point*	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Integrated exhaust ventilation* *A minimum efficiency of 90 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances have to be handled in at least partly-contained systems with only limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (see the dermal exposure pattern below).	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be*	

	Method
blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.2.8.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.42. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.07 µg/m³ (Measured data: Analogous data including RPE with APF = 20) **Supportive exposure (not used for RC):** 1.35 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers calcination
Inhalation exposure, long term concentration: Number of measured data points: 4 ; GSD: 2.6
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #17 (GSD=2.6) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 20 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers calcination
Inhalation exposure, long term concentration: Number of measured data points: 4 ; GSD: 2.6
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #17 (GSD=2.6) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 20.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni

Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level (<1µg/kg bw/day) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.9. Worker CS 9: Wet powder production (PROC 27b)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.2.9.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Various	
• Maximum emission potential of the substance: Low *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances have to be handled in at least partly enclosed systems. The level of containment should be as high as possible, easy maintenance should be allowed by system design.*	
• Level of automation: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (see the dermal exposure pattern below).	
• Removal of residuals: Dusty residuals *Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	

	Method
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.2.9.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.43. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.05 µg/m³ (Measured data: Analogous data including RPE with APF = 20) **Supportive exposure (not used for RC):** 1.04 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers separation/filtration
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 3.4
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #12 (GSD=3.4) taken from the Pt monitoring database from the “Methodology applied in the Occupational Exposure Scenarios for Platinum Substances” document.

Analogous data including RPE with APF = 20 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers separation/filtration
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 3.4
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #12 (GSD=3.4) taken from the Pt monitoring database from the “Methodology applied in the Occupational Exposure Scenarios for Platinum Substances” document and including RPE with APF = 20.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level (<1µg/kg bw/day) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.10. Worker CS 10: Wet cleaning (PROC 8a)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.2.10.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Removal of residuals: Splashes *Removal of residuals is considered to be part of regular work.* *Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.* *Workplaces are to be cleaned before any maintenance work starts.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.2.10.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.44. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.07 µg/m³ (Measured data: Analogous data including RPE with APF = 40) **Supportive exposure (not used for RC):** 2.96 µg/m³ (Measured data: Analogous	Risk adequately controlled

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
		data)	
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.29 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers cleaning and maintenance
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 5.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 40 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers cleaning and maintenance
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 5.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 40.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 17
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDE in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.11. Worker CS 11: Vacuum cleaning (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: Dipotassium hexachloroplatinate for OCC RA

9.2.11.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid *Dusty residuals*	
• Maximum emission potential of the substance: High *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Removal of residuals: Dusty residuals *A highly efficient vacuum cleaner is to be used. No direct manual removal of dust.*	

	Method
Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry. *Workplaces are to be cleaned before any maintenance work starts.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded. Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.*	

9.2.11.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.45. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloroplatinate	0.07 µg/m³ (Measured data: Analogous data including RPE with APF = 40) **Supportive exposure (not used for RC):** 2.96 µg/m³ (Measured data: Analogous data)	Risk adequately controlled
Dermal, systemic, long term	dipotassium hexachloroplatinate	0.01 mg/kg bw/day (Measured data: Analogous data (Ni))	Risk adequately controlled

Remarks on measured exposure:

Analogous data for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers cleaning and maintenance
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 5.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data including RPE with APF = 40 for dipotassium hexachloroplatinate:
Identity of the substance used: ClPt manufacturers cleaning and maintenance
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 5.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document and including RPE with APF = 40.

Analogous data (Ni) for dipotassium hexachloroplatinate:
Identity of the substance used: Ni
Dermal exposure, long term systemic dose: Number of measured data points: 7
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NNE in consideration of the use of appropriate gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, systemic, long term, Inhalation, systemic, acute, Inhalation, local, long term, Inhalation, local, acute, Dermal, systemic, long term, Dermal, systemic, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

This chapter describes why a separate risk characterisation related to combined exposure is not required.
Combined exposure may result from any of the following scenarios:

1. Multiple platinum substances handled in parallel at the same workplace,
2. More than just a single contributing occupational exposure scenario relevant for an individual worker,
3. Workers that are also exposed to platinum substances in their free time are not considered relevant as soluble platinum substances are not available for consumers.

These scenarios are considered below:
1. Multiple platinum substances handled in parallel at the same workplace
Exposure monitoring data were obtained from a number of workplaces where platinum and/or platinum substances are manufactured or used in parallel. Any samples are analysed for their soluble platinum content rather than for the content of the respective platinum substance. Thus, measured soluble platinum levels are intrinsically reflective of any potential parallel exposure to multiple soluble platinum substances and are not only relevant for a single platinum substance. An exposure assessment based on such monitoring data can therefore be considered to include an assessment for any platinum substance handled in parallel.
2. More than just a single contributing occupational exposure scenario relevant for an individual worker
For aggregated exposure resulting from the applicability of more than just a single contributing worker scenario in a single work shift, it is noted that all exposure levels were derived for a full-shift exposure time and a safe use was demonstrated for each contributing scenario. Thus, by demonstrating safe use for individual contributing scenarios it is assured that a combination of activities within a single shift, could not lead to any adverse effect.

10.1.2. Consumer

Not relevant.

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

10.2.1.1. Total releases

The total releases to the environment from all the exposure scenarios covered are presented in the table below. This is the sum of the releases to the environments from all exposure scenarios addressed.
Where there is more than one contributing scenario for the environment for a given exposure scenario, the highest release per route across all the contributing scenarios within the use has been taken into account as the release for the use (both for the regional and the exposure due to all the widespread uses). This may lead to overestimation of the PEC.

Table 10.1. Total releases to the environment per year from all life cycle stages

Release route	Assessment entity	Total releases per year
Water	Pt(IV) dissolved	0.714 kg/year
Air	Pt(IV) dissolved	1.8 kg/year
Soil	Pt(IV) dissolved	0 kg/year

10.2.2. Regional assessment

The regional predicted environmental concentration (PEC regional) and the related risk characterisation ratios when a PNEC is available are presented in the table below. The exposure to man via the environment from regional exposure and the related risk characterisation ratios are also provided (when relevant). The exposure concentration for human via inhalation is equal to the PEC air.

The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 10.2. Predicted regional exposure concentrations (Regional PEC) and risks for the environment

Protection target	Assessment entity	Regional PEC	Risk characterisation
Fresh water	Pt(IV) dissolved	**Regional PEC:** 3.18E-8 mg/L (estimated by External EUSES calculation 2.1.2) RCR = 2.27E-4 **Supportive exposure (not used for RC):** 4.27E-8 mg/L	Final RCR < 0.01
Sediment (freshwater)	Pt(IV) dissolved	**Regional PEC:** 1.59E-4 mg/kg dw RCR = 6.1E-4	Final RCR < 0.01
Marine water	Pt(IV) dissolved	**Regional PEC:** 4.26E-9 mg/L RCR = 3.04E-4	Final RCR < 0.01
Sediment (marine water)	Pt(IV) dissolved	**Regional PEC:** 1.59E-5 mg/kg dw RCR = 6.08E-4	Final RCR < 0.01
Agricultural soil	Pt(IV) dissolved	**Regional PEC:** 9.46E-4 mg/kg dw (Measured data: GEMAS) RCR = 0.181 **Supportive exposure (not used for RC):** 4.71E-6 mg/kg dw	Final RCR = 0.181

Remarks on risk characterisation for regional concentrations:

All exposure scenarios detailed in this document include estimates of background concentrations of total platinum in fresh and marine waters and sediments (calculated using the EUSES model and an assumption of 50 % of the continental tonnage being manufactured and used in one region). Measured regional background concentrations of platinum in soil are taken from the GEMAS database.

10.2.3. Local exposure due to all widespread uses

Not relevant as there are not several widespread uses covered in this CSR.

10.2.4. Local exposure due to combined uses at a site

The ES for manufacturing and industrial intermediate use is based on a sector-wide approach based on monitoring data for total platinum and considering ALL forms of platinum processed at these sites.

Annexes

1. Annex: References

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2. Annex: Information on Test Material

Test material: **Platinum (IV)**
Form:

Composition type: Constituent	**Reference substance:** Platinum (IV) EC no.: CAS no: IUPAC name: Platinum (IV)	**Concentration range:**

Details on test material: Plasma emission standard, in 1 M HCl Source: BDH

Test material: **Pt(IV)**
Form: **gas under pressure: refrigerated liquefied gas**

Composition type: Constituent	**Reference substance:** Pt(IV) EC no.: CAS no: IUPAC name: Pt(IV)	**Concentration range:**

Details on test material: 10000 ppm Pt(IV) plasma emission standard in 1.2 M HCl Source: BDH

Test material: **Platinum (IV)**
Form:

Composition type: Constituent	**Reference substance:** Platinum (IV) EC no.: CAS no: IUPAC name: Platinum (IV)	**Concentration range:**

Details on test material: H2PtCl3in 7 % HCl, 1000 ppm ICP-OES standards (CertiPur, Merck)

Test material: **dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: 240-979-3 CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Potassiumhexachloroplatinate(IV) - Substance type: - Physical state: Powder - Analytical purity: >99.9% - Impurities (identity and concentrations): - Composition of test material, percentage of components: - Isomers composition: - Purity test date: - Lot/batch No.: 8833 / June 23, 1994 - Expiration date of the lot/batch: - Stability under test conditions: According to sponsor, the test substance was stable throughout the experimental period - Storage condition of test material: Closed container in refrigerator - Other:

Test material: **Sodium hexachloroplatinate**
Form: **solid: crystalline**

Composition type: Constituent	**Reference substance:** Sodium hexachloroplatinate EC no.: CAS no: IUPAC name: Sodium hexachloroplatinate	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Sodium chloroplatinate - Substance type: orange crystalline solid - Physical state: solid - Lot/batch No.: 031003

Test material: **Dipotassium hexachloroplatinate**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: 240-979-3	**Concentration range:**

	CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	

Test material: **diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: 240-973-0 CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Ammonium hexachloroplatinate - Substance type: yellow powder - Physical state: solid - Lot/batch No.: 57662

Test material: **dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: 240-979-3 CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Potassiumhexachloroplatinate(IV) - Substance type: - Physical state: Powder - Analytical purity: >99.9% - Impurities (identity and concentrations): - Composition of test material, percentage of components: - Isomers composition: - Purity test date: - Lot/batch No.: 8833 / June 23, 1994 - Expiration date of the lot/batch: - Stability under test conditions: According to information from sponsor, test substance stable throughout experimental period - Storage condition of test material: Closed container in refrigerator - Other:

Test material: **Ammonium hexachloroplatinate IV**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** Ammonium hexachloroplatinate IV EC no.: CAS no: IUPAC name: Ammonium hexachloroplatinate IV	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Ammonium hexachloroplatinate - Substance type: yellow powder - Physical state: solid - Lot/batch No.: no data

Test material: **Disodium hexachloroplatinate hexahydrate; Na2[PtCl6].6H2O**
Form: **not specified**

Composition type: Constituent	**Reference substance:** Disodium hexachloroplatinate hexahydrate EC no.: CAS no: IUPAC name: Disodium hexachloroplatinate hexahydrate	**Concentration range:**
Composition type: Constituent	**Reference substance:** Na2[PtCl6].6H2O EC no.: CAS no: IUPAC name: Na2[PtCl6].6H2O	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Disodium hexachloroplatinate - Molecular formula (if other than submission substance): Na2[PtCl6].6H2O - Molecular weight (if other than submission substance): 561.9 g/mol - Smiles notation (if other than submission substance): [Pt+4]([Cl-])([Cl-])([Cl-])([Cl-])([Cl-])[Cl-].[Na+].[Na+] (dehydrated form) - InChl (if other than submission substance):

1S/6ClH.2Na.Pt/h6*1H;;;/q;;;;;;2*+1;+4/p-6 (dehydrated form) - Structural formula attached as image file (if other than submission substance): see Fig. (dehydrated form) - Substance type: Technical product - Physical state: No data - Analytical purity: No data - Lot/batch No.: No data - Stability under test conditions: No data - Storage condition of test material: No data - Other: supplied by Degussa AG (Hanau, Germany)

Test material: **Ammonium hexachloroplatinate IV**
Form: **dissolved in DMSO**

Composition type: Constituent	**Reference substance:** Ammonium hexachloroplatinate IV EC no.: CAS no: IUPAC name: Ammonium hexachloroplatinate IV	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Ammonium hexachloroplatinate IV - Molecular formula (if other than submission substance): Cl6-Pt.2H4-N - Molecular weight (if other than submission substance): 444 g/mol - Smiles notation (if other than submission substance): Pt+4]([Cl-])([Cl-])([Cl-])([Cl-])([Cl-])[Cl-].[NH4+].[NH4+] - InChl (if other than submission substance): InChI=1S/6ClH.2H3N.Pt/h6*1H;2*1H3;/q;;;;;;;;+4/p-4 - Structural formula attached as image file (if other than submission substance): see Fig. - Substance type: Technical product - Physical state: No data - Analytical purity: 99.99% - Impurities (identity and concentrations): No data - Purity test date: No data - Lot/batch No.: No data - Stability under test conditions: No data - Storage condition of test material: No data - Other: Source Aldrich Chemical Co., Gillingham, UK

Test material: **Sodium hexachloroplatinate; disodium hexachloroplatinate(2-) / 16923-58-3 / 240-983-5; hexachloroplatinic acid / 16941-12-1 / 241-010-7**
Form:

Composition type: Constituent	**Reference substance:** hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: hexachloroplatinic acid	**Concentration range:**
Composition type: Constituent	**Reference substance:** Sodium hexachloroplatinate EC no.: CAS no: IUPAC name: Sodium hexachloroplatinate	**Concentration range:**
Composition type: Constituent	**Reference substance:** disodium hexachloroplatinate EC no.: 240-983-5 CAS no: 16923-58-3 IUPAC name: disodium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: Hexachloroplatinic acid CAS# 16941-12-1 Sodium hexachloroplatinate CAS# 16923-58-3

Test material: **hexachloroplatinic acid / 16941-12-1 / 241-010-7**
Form:

Composition type: Constituent	**Reference substance:** hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: hexachloroplatinic acid	**Concentration range:**

Details on test material: CAS 16941-12-1

Test material: **Potassium hexachloroplatinate; dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-**

3
Form:

Composition type: Constituent	**Reference substance:** Potassium hexachloroplatinate EC no.: CAS no: IUPAC name: Potassium hexachloroplatinate	**Concentration range:**
Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: 240-979-3 CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: Presumably exposure was mostly to potassium hexachloroplatinate, but this was not explicitly stated; workers were said to be exposed to “platinum salts”. In the factory, dissolved “platinum” from catalysts is processed to make potassium hexachloroplatinate powder, which is further processed to make metallic platinum and platinum-containing catalysts.

Test material: **Chloroplatinates & Tetaammine platinum dichloride (TPC)**
Form: **Airborne [possibly particulate matter]**

Composition type: Constituent	**Reference substance:** Chloroplatinates & Tetaammine platinum dichloride (TPC) EC no.: CAS no: IUPAC name: Chloroplatinates & Tetaammine platinum dichloride (TPC)	**Concentration range:**

Test material: **Chloroplatinum salts (as soluble platinum)**
Form: **Airborne [possible total dust as opposed to inhalable fraction]**

Composition type: Constituent	**Reference substance:** Chloroplatinum salts (as soluble platinum) EC no.: CAS no: IUPAC name: Chloroplatinum salts (as soluble platinum)	**Concentration range:**

Details on test material: Soluble platinum

Test material: **diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: 240-973-0 CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): diammonium hexachloroplatinate. - Substance type: organometallic. - Physical state: solid. - Analytical purity: salt assumed 100% pure. - Impurities (identity and concentrations): total metallic impurities (excluding Na) < 0.1%; sodium 0.2%. - Composition of test material, percentage of components: 37.99% w/w platinum. - Isomers composition: not applicable. - Purity test date: 01 July 2013. - Lot/batch No.: UZ0129-1. - Expiration date of the lot/batch: 5 years from the date of manufacture [01 July 2018] if packaging is intact and material is stored under described conditions. - Stability under test conditions: as above. - Storage condition of test material: At +10degC to +25degC, in a tightly closed container, protected from direct sunlight.

Test material: **Potassium hexachloroplatinate (IV); dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** Potassium hexachloroplatinate (IV) EC no.: CAS no: IUPAC name: Potassium hexachloroplatinate (IV)	**Concentration range:**
Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: 240-979-3 CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**

Test material: **dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form: **In [presumably aqueous] solution**

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: 240-979-3 CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: Potassium hexachloroplatinate (CAS 16921-30-5) Purchased from Chemical Procurement Labs, Inc. Stored in the dark; CAS not provided.

Test material: **K2PtCl6; Potassium hexachloroplatinate; dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: 240-979-3 CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Potassium hexachloroplatinate EC no.: CAS no: IUPAC name: Potassium hexachloroplatinate	**Concentration range:**
Composition type: Constituent	**Reference substance:** K2PtCl6 EC no.: CAS no: IUPAC name: K2PtCl6	**Concentration range:**

Test material: **dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: 240-979-3 CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: Dipotassium hexachloroplatinate (CAS 16921-30-5) dissolved in distilled water

Test material: **Potassium hexachloroplatinate; dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: 240-979-3 CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Potassium hexachloroplatinate EC no.: CAS no: IUPAC name: Potassium hexachloroplatinate	**Concentration range:**

Test material: **dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: 240-979-3 CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): K2PtCl6(IV); CAS RN 16921-30-5

Test material: **dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: 240-979-3 CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Label: Dipotassium hexachloroplatinate - Physical description: Yellow solid - Batch number: 10410 - Storage and Handling: stored at room temperature in the dark

Test material: **hexachloroplatinic acid / 16941-12-1 / 241-010-7**
Form: **not specified**

Composition type: Constituent	**Reference substance:** hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: hexachloroplatinic acid	**Concentration range:**

Test material: **85392-65-0 / 286-924-7; Tetraammonium decachloro-mu-oxodiruthenate (4-)**
Form:

Composition type: Constituent	**Reference substance:** Tetraammonium decachloro-mu-oxodiruthenate(4-) EC no.: 286-924-7 CAS no: 85392-65-0 IUPAC name: Tetraammonium decachloro-mu-oxodiruthenate(4-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Tetraammonium decachloro-mu-	**Concentration range:**

	oxodiruthenate (4-) EC no.: CAS no: IUPAC name: Tetraammonium decachloro-mu-oxodiruthenate (4-)	

Details on test material: - Physical description: Black powder - Batch Number RHV315 - Storage and Handling: stored at room temperature in the dark

Test material: **16941-12-1 / 241-010-7**
Form: **liquid**

Composition type:	**Reference substance:**	**Concentration range:**
Constituent	Hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	

Details on test material: - Colour/form: orange liquid - Density: 2.069 g/mL

Test material: **Dihydrogen hexahydroxyplatinate, compound with 2-amino-ethanol**
Form: **liquid**

Composition type:	**Reference substance:** dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) EC no.: 268-717-3 CAS no: 68133-90-4 IUPAC name: dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2)	**Concentration range:**
Constituent		

Test material: **Hexachloroplatinic acid; 16941-12-1 / 241-010-7**
Form:

Composition type:	**Reference substance:**	**Concentration range:**
Constituent	Hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	

Details on test material: - Name of test material (as cited in study report): Dihydrogen hexachloroplatinate (CAS 16941-12-1) - Analytical purity: “Of the highest purity commercially available” in Japan.

Test material: **16941-12-1 / 241-010-7**
Form: **solid**

Composition type:	**Reference substance:**	**Concentration range:**
Constituent	Hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	

Test material: **Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**
Form: **solid**

Composition type:	**Reference substance:**	**Concentration range:**
Constituent	Hexahydroxyplatinic Acid EC no.: CAS no: IUPAC name: Hexahydroxyplatinic Acid	

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate EC no.: 257-471-2 CAS no: 51850-20-5 IUPAC name: hexahydroxyplatinate(2-)	**Concentration range:**

Details on test material: - Physical state: Yellow crystal needles - Stability under test conditions: Stable under normal conditions - Storage condition of test material: Room temperature (15-30 °C)

Test material: **Platinate(2-), hexachloro-, diammonium; diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form: **solid**

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: 240-973-0 CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Platinate(2-), hexachloro-, diammonium EC no.: CAS no: IUPAC name: Platinate(2-), hexachloro-, diammonium	**Concentration range:**

Details on test material: - Physical state: Yellow crystalline powder - Stability under test conditions: Stable under normal conditions - Storage condition of test material: Protected from direct sunlight in a dry and well-ventilated area at 15-30 °C

Test material: **Dihydrogen hexahydroxyplatinate, compound with 2-amino-ethanol**
Form: **liquid**

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) EC no.: 268-717-3 CAS no: 68133-90-4 IUPAC name: dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2)	**Concentration range:**

Test material: **Hexachloroplatinic acid (hydrate) / 26023-84-7**
Form:

Composition type: Constituent	**Reference substance:** Hexachloroplatinic acid (hydrate) EC no.: CAS no: 26023-84-7 IUPAC name: Hexachloroplatinic acid (hydrate)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Hexachloroplatinum(IV)-solution - Substance type: - Physical state: liquid - Analytical purity: - Impurities (identity and concentrations): - Composition of test material, percentage of components: 25% Pt - Isomers composition: - Purity test date: 2003-08-08 - Lot/batch No.: 2700/76-03 - Expiration date of the lot/batch: 31 July 2004 - Stability under test conditions: not stated - Storage condition of test material: room temperature; opaque plastic bottle - Other:

Test material: **Hexachloroplatinic acid**
Form: **Resin**

Composition type: Constituent	**Reference substance:** Hexachloroplatinic acid EC no.: 241-010-7	**Concentration range:**

	CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	

Test material: **Hexachloroplatinic acid**
Form:

Composition type: Constituent	**Reference substance:** hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: hexachloroplatinic acid	**Concentration range:**

Test material: **Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**
Form: **solid: crystalline**

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate EC no.: 257-471-2 CAS no: 51850-20-5 IUPAC name: hexahydroxyplatinate(2-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Hexahydroxyplatinic Acid EC no.: CAS no: IUPAC name: Hexahydroxyplatinic Acid	**Concentration range:**

Test material: **Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol**
Form:

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) EC no.: 268-717-3 CAS no: 68133-90-4 IUPAC name: dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2)	**Concentration range:**

Test material: **Platinum(IV) chloride**
Form:

Composition type: Constituent	**Reference substance:** Platinum(IV) chloride EC no.: CAS no: 13454-96-1 IUPAC name: Tetrachloroplatinum	**Concentration range:**

Test material: **Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**
Form: **solid: crystalline**

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate EC no.: 257-471-2 CAS no: 51850-20-5 IUPAC name: hexahydroxyplatinate(2-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Hexahydroxyplatinic Acid	**Concentration range:**

	EC no.: CAS no: IUPAC name: Hexahydroxyplatinic Acid	

3. Annex: Mode of action / Human relevance Framework

Section 5.6.3: Repeated dose toxicity
Detailed information on mode of action / Human relevance framework:

No data identified.

Section 5.7.3: Genetic toxicity
Detailed information on mode of action / Human relevance framework:

No data identified.

Section 5.9.3: Toxicity to reproduction
Detailed information on mode of action / Human relevance framework:

No data identified.