



CHEMICAL SAFETY REPORT

Substance Name: [dihydrogen hexahydroxyplatinate](#)

EC Number: 257-471-2

CAS Number: 51850-20-5

Registrant's Identity: Predefined Legal entity



Table of Contents

Part A	9
1. SUMMARY OF RISK MANAGEMENT MEASURES	10
2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED	11
3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED	12
Part B	13
1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES	14
1.1. Name and other identifiers of the substance	14
1.2. Composition of the substance	14
1.3. Assessment entity information	15
1.4. Physicochemical properties	16
2. MANUFACTURE AND USES	20
2.1. Manufacture	20
2.2. Identified uses	20
3. CLASSIFICATION AND LABELLING	21
3.1. Classification and labelling according to CLP / GHS	21
4. ENVIRONMENTAL FATE PROPERTIES	24
4.1. Degradation	24
4.1.1. Abiotic degradation	24
4.1.1.1. Hydrolysis	24
4.1.1.2. Phototransformation/photolysis	24
4.1.1.2.1. Phototransformation in air	24
4.1.1.2.2. Phototransformation in water	24
4.1.1.2.3. Phototransformation in soil	24
4.1.2. Biodegradation	24
4.1.2.1. Biodegradation in water	24
4.1.2.1.1. Screening tests	24
4.1.2.1.2. Simulation tests (water and sediments)	25
4.1.2.1.3. Summary and discussion of biodegradation in water and sediment	25
4.1.2.2. Biodegradation in soil	25
4.2. Environmental distribution	25
4.2.1. Adsorption/desorption	25
4.2.2. Volatilisation	28
4.2.3. Distribution modelling	28
4.3. Bioaccumulation	28
4.3.1. Aquatic bioaccumulation	28
4.3.2. Terrestrial bioaccumulation	28
4.3.3. Summary and discussion of bioaccumulation	28
4.4. Secondary poisoning	28
5. HUMAN HEALTH HAZARD ASSESSMENT	29
5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)	29
5.1.1. Non-human information	29
5.1.2. Human information	29
5.1.3. Summary and discussion of toxicokinetics	29
5.2. Acute toxicity	33
5.2.1. Non-human information	33
5.2.1.1. Acute toxicity: oral	33
5.2.1.2. Acute toxicity: inhalation	34
5.2.1.3. Acute toxicity: dermal	34
5.2.1.4. Acute toxicity: other routes	34
5.2.2. Human information	35
5.2.3. Summary and discussion of acute toxicity	35
5.3. Irritation	36
5.3.1. Skin	36
5.3.1.1. Non-human information	36



5.3.1.2. Human information	38
5.3.2. Eye	38
5.3.2.1. Non-human information	38
5.3.2.2. Human information	38
5.3.3. Respiratory tract	38
5.3.3.1. Non-human information	38
5.3.3.2. Human information	38
5.3.4. Summary and discussion of irritation	39
5.4. Corrosivity	40
5.4.1. Non-human information	40
5.4.2. Human information	40
5.4.3. Summary and discussion of corrosion	40
5.5. Sensitisation	41
5.5.1. Skin	41
5.5.1.1. Non-human information	41
5.5.1.2. Human information	41
5.5.2. Respiratory system	41
5.5.2.1. Non-human information	41
5.5.2.2. Human information	42
5.5.3. Summary and discussion of sensitisation	42
5.6. Repeated dose toxicity	44
5.6.1. Non-human information	44
5.6.1.1. Repeated dose toxicity: oral	44
5.6.1.2. Repeated dose toxicity: inhalation	45
5.6.1.3. Repeated dose toxicity: dermal	45
5.6.1.4. Repeated dose toxicity: other routes	45
5.6.2. Human information	45
5.6.3. Summary and discussion of repeated dose toxicity	45
5.7. Mutagenicity	46
5.7.1. Non-human information	46
5.7.1.1. In vitro data	46
5.7.1.2. In vivo data	50
5.7.2. Human information	53
5.7.3. Summary and discussion of mutagenicity	53
5.8. Carcinogenicity	55
5.8.1. Non-human information	55
5.8.1.1. Carcinogenicity: oral	55
5.8.1.2. Carcinogenicity: inhalation	55
5.8.1.3. Carcinogenicity: dermal	56
5.8.1.4. Carcinogenicity: other routes	56
5.8.2. Human information	56
5.9. Toxicity for reproduction	56
5.9.1. Effects on fertility	56
5.9.1.1. Non-human information	56
5.9.1.2. Human information	57
5.9.2. Developmental toxicity	57
5.9.2.1. Non-human information	57
5.9.2.2. Human information	57
5.9.3. Summary and discussion of reproductive toxicity	57
5.10. Other effects	59
5.10.1. Non-human information	59
5.10.1.1. Neurotoxicity	59
5.10.1.2. Immunotoxicity	59
5.10.1.3. Specific investigations: other studies	59
5.10.1.4. Additional toxicological effects	59
5.10.2. Human information	59
5.11. Derivation of DNEL(s) and other hazard conclusions	59
5.11.1. Overview of typical dose descriptors for all endpoints	59
5.11.2. Selection of the DNEL(s) or other hazard conclusions for critical health effects	61
6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES	71



6.1. Explosivity	71
6.2. Flammability	71
6.3. Oxidising potential	72
7. ENVIRONMENTAL HAZARD ASSESSMENT	76
7.1. Aquatic compartment (including sediment)	76
7.1.1. Fish	76
7.1.1.1. Short-term toxicity to fish	76
7.1.1.2. Long-term toxicity to fish	77
7.1.2. Aquatic invertebrates	77
7.1.2.1. Short-term toxicity to aquatic invertebrates	77
7.1.2.2. Long-term toxicity to aquatic invertebrates	79
7.1.3. Algae and aquatic plants	79
7.1.4. Sediment organisms	83
7.1.5. Other aquatic organisms	83
7.2. Terrestrial compartment	83
7.2.1. Toxicity to soil macro-organisms	83
7.2.2. Toxicity to terrestrial plants	84
7.2.3. Toxicity to soil micro-organisms	84
7.2.4. Toxicity to other terrestrial organisms	84
7.3. Atmospheric compartment	84
7.4. Microbiological activity in sewage treatment systems	84
7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)	86
7.5.1. Toxicity to birds	86
7.5.2. Toxicity to mammals	86
7.6. PNEC derivation and other hazard conclusions	86
7.6.1. PNEC derivation and other hazard conclusions	86
8. PBT AND vPvB ASSESSMENT	91
8.1. Assessment of PBT/vPvB Properties	91
8.1.1. PBT/vPvB criteria and justification	91
8.1.2. Summary and overall conclusions on PBT or vPvB properties	91
8.2. Emission characterisation	91
9. EXPOSURE ASSESSMENT (and related risk characterisation)	92
9.0. Introduction	92
9.0.1. Overview on uses	92
9.0.2. Assessment entity groups	92
9.0.3. Introduction to the assessment for the environment	92
9.0.3.1. Tonnage	92
9.0.3.2. Scope and type of assessment for the environment	93
9.0.3.3. Fate and distribution parameters	93
9.0.3.4. Comments on assessment approach for the environment	94
9.0.3.5. Scope and type of assessment for man via environment	95
9.0.4. Introduction to the assessment for workers	95
9.0.4.1. Scope and type of assessment for workers	95
9.0.4.2. Comments on assessment approach for workers	95
9.0.5. Introduction to the assessment for consumers	96
9.1. Exposure scenario 1: Manufacture - Manufacture of the substance (as such)	97
9.1.1. Env CS 1: Manufacture of the substance (as such) ES 1.1 (ERC 1)	97
9.1.1.1. Conditions of use	97
9.1.1.2. Releases	98
9.1.1.3. Exposure and risks for the environment and man via the environment	99
9.1.2. Env CS 2: Manufacture of the substance (as such) ES 1.2 (ERC 1)	99
9.1.2.1. Conditions of use	99
9.1.2.2. Releases	100
9.1.2.3. Exposure and risks for the environment and man via the environment	100
9.1.3. Worker CS 3: Raw material handling of dry/dusty materials (PROC 26)	100
9.1.3.1. Conditions of use	101
9.1.3.2. Exposure and risks for workers	101
9.1.4. Worker CS 4: Raw material handling of non to low dusty platinum substances (PROC 21)	102
9.1.4.1. Conditions of use	102



9.1.4.2. Exposure and risks for workers	103
9.1.5. Worker CS 5: Raw material handling of liquid platinum substances (PROC 8b, PROC 9)	104
9.1.5.1. Conditions of use	104
9.1.5.2. Exposure and risks for workers	105
9.1.6. Worker CS 6: Raw material handling of platinum substances in fully contained systems (PROC 1)	105
9.1.6.1. Conditions of use	105
9.1.6.2. Exposure and risks for workers	106
9.1.7. Worker CS 7: Sampling/Evaluation of solid platinum substances (PROC 15)	106
9.1.7.1. Conditions of use	107
9.1.7.2. Exposure and risks for workers	107
9.1.8. Worker CS 8: Sampling/Evaluation of liquid platinum substances (PROC 15)	108
9.1.8.1. Conditions of use	108
9.1.8.2. Exposure and risks for workers	109
9.1.9. Worker CS 9: Wet processing in fully contained systems (PROC 1)	110
9.1.9.1. Conditions of use	110
9.1.9.2. Exposure and risks for workers	110
9.1.10. Worker CS 10: Wet processing in not fully contained systems (PROC 2, PROC 3; PROC 4; PROC 5)	111
9.1.10.1. Conditions of use	111
9.1.10.2. Exposure and risks for workers	112
9.1.11. Worker CS 11: Separation/Filtration in fully contained systems (PROC 1)	113
9.1.11.1. Conditions of use	113
9.1.11.2. Exposure and risks for workers	113
9.1.12. Worker CS 12: Separation/Filtration of non to low dusty platinum substances (PROC 2, PROC 3; PROC 4)	114
9.1.12.1. Conditions of use	114
9.1.12.2. Exposure and risks for workers	115
9.1.13. Worker CS 13: Separation/Filtration of liquid platinum substances (PROC 2, PROC 3; PROC 4)	115
9.1.13.1. Conditions of use	116
9.1.13.2. Exposure and risks for workers	116
9.1.14. Worker CS 14: Washing/Drying in fully contained systems (PROC 1)	117
9.1.14.1. Conditions of use	117
9.1.14.2. Exposure and risks for workers	118
9.1.15. Worker CS 15: Washing/Drying of non to low dusty platinum substances (PROC 2, PROC 3; PROC 4)	118
9.1.15.1. Conditions of use	119
9.1.15.2. Exposure and risks for workers	119
9.1.16. Worker CS 16: Washing/Drying of liquid platinum substances (PROC 2, PROC 3)	120
9.1.16.1. Conditions of use	120
9.1.16.2. Exposure and risks for workers	121
9.1.17. Worker CS 17: Calcination in fully contained systems (PROC 1)	121
9.1.17.1. Conditions of use	121
9.1.17.2. Exposure and risks for workers	122
9.1.18. Worker CS 18: Calcination in partly enclosed systems (PROC 22)	123
9.1.18.1. Conditions of use	123
9.1.18.2. Exposure and risks for workers	123
9.1.19. Worker CS 19: Milling/Grinding/Sieving (PROC 1)	124
9.1.19.1. Conditions of use	124
9.1.19.2. Exposure and risks for workers	125
9.1.20. Worker CS 20: Packaging/Filling of dry/dusty platinum substances (PROC 26) ..	125
9.1.20.1. Conditions of use	125
9.1.20.2. Exposure and risks for workers	126
9.1.21. Worker CS 21: Packaging/Filling of non to low dusty platinum substances (PROC 21)	127
9.1.21.1. Conditions of use	127
9.1.21.2. Exposure and risks for workers	128



9.1.22. Worker CS 22: Packaging/Filling of liquid platinum substances (PROC 8b, PROC 9)	128
9.1.22.1. Conditions of use	129
9.1.22.2. Exposure and risks for workers	129
9.1.23. Worker CS 23: Packaging/Filling in fully contained systems (PROC 1)	130
9.1.23.1. Conditions of use	130
9.1.23.2. Exposure and risks for workers	131
9.1.24. Worker CS 24: Cleaning and maintenance: vacuum cleaning (PROC 26)	131
9.1.24.1. Conditions of use	132
9.1.24.2. Exposure and risks for workers	132
9.1.25. Worker CS 25: Cleaning and maintenance: wet cleaning (PROC 8a)	133
9.1.25.1. Conditions of use	133
9.1.25.2. Exposure and risks for workers	134
9.2. Exposure scenario 2: Use at industrial sites - Use as an intermediate	135
9.2.1. Env CS 1: Use as an intermediate ES 2.1 (ERC 6a)	135
9.2.1.1. Conditions of use	135
9.2.1.2. Releases	136
9.2.1.3. Exposure and risks for the environment and man via the environment	136
9.2.2. Env CS 2: Use as an intermediate ES 2.2 (ERC 6a)	137
9.2.2.1. Conditions of use	137
9.2.2.2. Releases	137
9.2.2.3. Exposure and risks for the environment and man via the environment	138
9.2.3. Worker CS 3: Handling of solutions or low dusty material and reaction (PROC 3, PROC 15; PROC 26; PROC 4; PROC 5; PROC 8b; PROC 9)	138
9.2.3.1. Conditions of use	138
9.2.3.2. Exposure and risks for workers	139
9.2.4. Worker CS 4: Fully contained process (PROC 1)	140
9.2.4.1. Conditions of use	140
9.2.4.2. Exposure and risks for workers	140
9.2.5. Worker CS 5: Reaction process (furnace operation) (PROC 22)	141
9.2.5.1. Conditions of use	141
9.2.5.2. Exposure and risks for workers	142
9.2.6. Worker CS 6: Wet cleaning (PROC 8a)	142
9.2.6.1. Conditions of use	142
9.2.6.2. Exposure and risks for workers	143
9.2.7. Worker CS 7: Vacuum cleaning (PROC 26)	143
9.2.7.1. Conditions of use	144
9.2.7.2. Exposure and risks for workers	144
10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE	146
10.1. Human health	146
10.1.1. Workers	146
10.1.2. Consumer	146
10.2. Environment (combined for all emission sources)	146
10.2.1. All uses (regional scale)	146
10.2.1.1. Total releases	146
10.2.2. Regional assessment	146
10.2.3. Local exposure due to all widespread uses	147
10.2.4. Local exposure due to combined uses at a site	147
Annexes	148
1. Annex: References	149
2. Annex: Information on Test Material	153
3. Annex: Mode of action / Human relevance Framework	160



List of Tables

1.1. Substance identity	14
1.2. Constituents (Dihydrogen hexahydroxyplatinate - Registration boundary conditions)	15
1.3. Impurities (Dihydrogen hexahydroxyplatinate - Registration boundary conditions)	15
1.4. Constituents (Dihydrogen hexahydroxyplatinate)	15
1.5. Impurities (Dihydrogen hexahydroxyplatinate)	15
1.6. Physicochemical properties	16
3.1. Classification and labelling according to CLP / GHS for physicochemical properties	21
3.2. Classification and labelling according to CLP / GHS for health hazards	22
3.3. Classification and labelling according to CLP / GHS for environmental hazards	22
4.1. Studies on adsorption/desorption	25
5.1. Studies on acute toxicity after oral administration	33
5.2. Studies on skin irritation	36
5.3. Studies on eye irritation	38
5.4. Studies on skin sensitisation	41
5.5. Studies on repeated dose toxicity after oral administration	44
5.6. In vitro genotoxicity studies:	46
5.7. In vivo genotoxicity studies	50
5.8. Studies on fertility	56
5.9. Studies on developmental toxicity	57
5.10. Available dose-descriptor(s) per endpoint as a result of its hazard assessment	59
5.11. Hazard conclusions for workers	61
5.12. Hazard conclusions for the general population	67
6.1. Information on flammability	71
6.2. Information on oxidising potential	72
7.1. Short-term effects on fish	76
7.2. Short-term effects on aquatic invertebrates	77
7.3. Long-term effects on aquatic invertebrates	79
7.4. Effects on algae and aquatic plants	79
7.5. Effects on soil macro-organisms	83
7.6. Effects on terrestrial arthropods	84
7.7. Effects on micro-organisms	84
7.8. Hazard assessment conclusion for the environment	86
9.1. Assessment entity groups	92
9.2. Tonnage for assessment	92
9.3. Type of risk characterisation required for the environment	93
9.4. Substance key phys-chem and fate properties	93
9.5. Type of risk characterisation required for workers	95
9.6. Local releases to the environment	98
9.7. Exposure concentrations and risks for the environment and man via the environment	99
9.8. Local releases to the environment	100
9.9. Exposure concentrations and risks for the environment and man via the environment	100
9.10. Exposure concentrations and risks for workers	101
9.11. Exposure concentrations and risks for workers	103
9.12. Exposure concentrations and risks for workers	105
9.13. Exposure concentrations and risks for workers	106
9.14. Exposure concentrations and risks for workers	107
9.15. Exposure concentrations and risks for workers	109
9.16. Exposure concentrations and risks for workers	110
9.17. Exposure concentrations and risks for workers	112
9.18. Exposure concentrations and risks for workers	113
9.19. Exposure concentrations and risks for workers	115
9.20. Exposure concentrations and risks for workers	116
9.21. Exposure concentrations and risks for workers	118
9.22. Exposure concentrations and risks for workers	119
9.23. Exposure concentrations and risks for workers	121



9.24. Exposure concentrations and risks for workers	122
9.25. Exposure concentrations and risks for workers	124
9.26. Exposure concentrations and risks for workers	125
9.27. Exposure concentrations and risks for workers	126
9.28. Exposure concentrations and risks for workers	128
9.29. Exposure concentrations and risks for workers	129
9.30. Exposure concentrations and risks for workers	131
9.31. Exposure concentrations and risks for workers	132
9.32. Exposure concentrations and risks for workers	134
9.33. Local releases to the environment	136
9.34. Exposure concentrations and risks for the environment and man via the environment	136
9.35. Local releases to the environment	137
9.36. Exposure concentrations and risks for the environment and man via the environment	138
9.37. Exposure concentrations and risks for workers	139
9.38. Exposure concentrations and risks for workers	140
9.39. Exposure concentrations and risks for workers	142
9.40. Exposure concentrations and risks for workers	143
9.41. Exposure concentrations and risks for workers	144
10.1. Total releases to the environment per year from all life cycle stages	146
10.2. Predicted regional exposure concentrations (Regional PEC) and risks for the environment	147



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

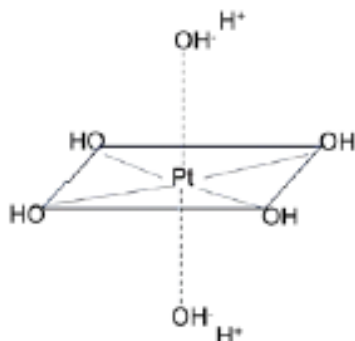
1.1. Name and other identifiers of the substance

The substance [dihydrogen hexahydroxyplatinate](#) 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:	257-471-2
EC name:	dihydrogen hexahydroxyplatinate
CAS number (EC inventory):	51850-20-5
CAS number:	51850-20-5
IUPAC name:	hexahydroxyplatinate(2-)
Molecular formula:	H ₆ O ₆ Pt.2H
Molecular weight range:	297.129

Structural formula:



1.2. Composition of the substance

Overall information on composition:

Composition	Related composition(s)	Related assessment entity
Dihydrogen hexahydroxyplatinate - Registration boundary conditions (boundary composition of the substance)		dihydrogen hexahydroxyplatinate Pt dissolved
Dihydrogen hexahydroxyplatinate (legal entity composition of the substance)		dihydrogen hexahydroxyplatinate

Name: Dihydrogen hexahydroxyplatinate - 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 (Dihydrogen hexahydroxyplatinate - Registration boundary conditions)

Constituent	Typical concentration	Concentration range	Remarks
dihydrogen hexahydroxyplatinate EC no.: 257-471-2	>99 % (w/w)	>=99 - <=100 % (w/w)	

Table 1.3. Impurities (Dihydrogen hexahydroxyplatinate - 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: Dihydrogen hexahydroxyplatinate

(legal entity composition of the substance)

State/form: solid: particulate/powder

Degree of purity: % (w/w)

Description: Mono-constituent substance

Table 1.4. Constituents (Dihydrogen hexahydroxyplatinate)

Constituent	Typical concentration	Concentration range	Remarks
dihydrogen hexahydroxyplatinate EC no.: 257-471-2	% (w/w)	% (w/w)	

Table 1.5. Impurities (Dihydrogen hexahydroxyplatinate)

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
dihydrogen hexahydroxyplatinate	Assessment entity composition: The composition(s) for this assessment



	entity is the one listed in section 1.2 (Composition of the Substance)
Pt dissolved	<p>Assessment entity composition: platinum EC no.: 231-116-1 Additional information:</p> <p>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]⁰ as 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.</p> <p>More details are provided in the Read Across Justification Document, attached in IUCLID Section 13.</p>

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 reliable peer reviewed handbook and so can be considered reliable and suitable for use as the key study for this endpoint. At 20°C and 1013 hPa dihydrogen hexahydroxyplatinate is an inorganic solid of yellow needles.	At 20°C and 1013 hPa dihydrogen hexahydroxyplatinate is an inorganic solid of yellow needles.	dihydrogen hexahydroxyplatinate Pt dissolved
Melting / freezing point	145°C at 101.3 kPa Walker & White (2011) study is a GLP complaint, guideline study considered suitable for use as the key study for this endpoint. The decomposition temperature of dihydrogen hexahydroxyplatinate is approximately 145 °C with no definitive signs of melting below 450°C The CRC Handbook (Lide, 2008) is a reliable peer reviewed handbook and so can be considered reliable	Dihydrogen hexahydroxyplatinate decomposes before it melts. The decomposition temperature is ~ 145°C	dihydrogen hexahydroxyplatinate Pt dissolved



Dihydrogen hexahydroxyplatinate

	and suitable for use as the supporting study for this endpoint. The decomposition temperature is 100 °C.		
Relative density	Potthoff (2011) is a guideline study which is considered suitable for use as the key study for this endpoint. The density of dihydrogen hexahydroxyplatinate is 4.08 - 4.12 g/cm ³ at 25°C	The density of dihydrogen hexahydroxyplatinate is 4.08 - 4.12 g/cm ³ at 25°C.	dihydrogen hexahydroxyplatinate
Granulometry	<p>Walker & White (2011) is a GLP compliant, guideline study considered suitable for use as the key study for this endpoint. The proportion of Dihydrogen hexahydroxyplatinate < 100 µm was 62.1 %.</p> <p>The dustiness of Dihydrogen hexahydroxyplatinate was tested in a modified Heubach procedure according to the guideline DIN 55992-1:2006. The study is non-GLP, but follows a standard guideline and is considered to be reliable. The total dustiness of Dihydrogen hexahydroxyplatinate was determined to be 261.47 mg/g. The inhalable fraction was 188.35 mg/g, the thoracic fraction was 124.2 mg/g and the respirable fraction was 48.26 mg/g. The Mass Median Aerodynamic Diameter (MMAD) was 12.34 µm with Geometric Standard Deviation of 2.94 µm.</p>	In an OECD 110 Granulometry (Screening Test) the proportion of Dihydrogen hexahydroxyplatinate <100 µm was 62.1 %.	
Vapour pressure	0Pa at 20°C HHPA is an inorganic non volatile substance. A very low value has been included for the exposure assessment.		dihydrogen hexahydroxyplatinate Pt dissolved
Water solubility	10mg/L at The water solubility of hexahydroxyplatonic acid is < 10 mg/L (Gregory 2014). The result is taken from a published paper and is	The water solubility of hexahydroxyplatonic acid is < 10 mg/L.	dihydrogen hexahydroxyplatinate Pt dissolved



	rated Klimisch 2 as it was conducted according to guideline but was not GLP compliant and some methodological details were not reported.		
Autoflammability / self-ignition temperature	Walker & White (2011) is a GLP compliant, guideline study which is considered suitable for use as the key study for this endpoint. Dihydrogen hexahydroxyplatinate showed no signs of self-ignition or self-heating throughout the test. Michael-Schulz (2012) is a guideline experimental study that is not GLP compliant, but is otherwise adequate for assessment. On the basis of the test results, dihydrogen hexahydroxyplatinate is not a self-heating substance.	Dihydrogen hexahydroxyplatinate is not classified as a self-heating substance under Division 4.2 as it showed no signs of self-ignition or self-heating throughout the test.	
Flammability	non flammable Walker & White (2011) is a GLP compliant, guideline study considered suitable for use as the key study for this endpoint. Dihydrogen hexahydroxyplatinate (hydrated solid) is not classified as a flammable solid under Division 4.1. Michael-Schulz (2012) is a guideline experiment study that is not GLP compliant, but is otherwise adequate for assessment. On the basis of the test results, dihydrogen hexahydroxyplatinate is not a flammable solid.	Dihydrogen hexahydroxyplatinate is not classified as a flammable solid under Division 4.1.	
Oxidising properties	no Michael-Schulz (2012) is a guideline experimental study and is not GLP compliant, but is otherwise adequate for assessment. On the basis of the test results and according to the criteria specified in the Regulation (EC) No 1272/2008 (CLP-/GHS-Regulation) dihydrogen hexahydroxyplatinate is not an oxidising solid.	Dihydrogen hexahydroxyplatinate is not an oxidising solid according to the criteria specified in the Regulation (EC) No 1272/2008 (CLP-/GHS-Regulation).	

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 'Remark' - Dihydrogen hexahydroxyplatinate is an inorganic substance that forms a crystal lattice. Upon heating, it decomposes at ~145 °C. It is scientifically not plausible that dihydrogen hexahydroxyplatinate 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. Dihydrogen hexahydroxyplatinate 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 dihydrogen hexahydroxyplatinate, 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.

Based on the test results and structure of the substance, dihydrogen hexahydroxyplatinate is not classified for physico-chemical endpoints.



2. MANUFACTURE AND USES

2.1. Manufacture

No information available on manufacture.

2.2. Identified uses

No information available on identified uses.



3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Substance: [Dihydrogen hexahydroxyplatinate](#)

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 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:			data conclusive but not sufficient for classification
----------------------	--	--	---

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:			data conclusive but not sufficient for classification
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 Irrit. 2	H319: Causes serious eye irritation.	
Respiratory sensitisation:			data conclusive but not sufficient for classification
Skin sensitisation:			data conclusive but not sufficient for classification
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 conclusive but not sufficient for classification
Carcinogenicity:			data lacking
Specific target organ toxicity – single exposure:			data conclusive but not sufficient for classification
Specific target organ toxicity – repeated exposure:			data conclusive but not sufficient for classification

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):	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: 1			
M-Factor chronic: 1			
Hazardous to the ozone layer:			data conclusive but not sufficient for classification



Labelling

Signal word: Warning

Hazard pictogram:

GHS07: exclamation mark



GHS09: environment



Hazard statements:

H319: Causes serious eye irritation.

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.

P264: Wash ... thoroughly after handling.

P273: Avoid release to the environment.

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

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

P337+P313: If eye irritation persists: Get medical advice/attention.

P391: Collect spillage.

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
<p>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: Dihydrogen hexahydroxyplatinate 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.</p>		
<p>adsorption / desorption, other - Determination of sediment Kd values batch equilibrium method Laboratory study, no guideline followed</p>	<p>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:</p>	<p>2 (reliable with restrictions) supporting study experimental study</p> <p>Test material Pt(IV), Form: gas under pressure: refrigerated liquefied gas (full information in Annex II).</p> <p>Reference Turner A, Crussell M, Millward G, Cobelo-Garcia A, Fisher A 2006</p>
<p>adsorption / desorption, other - Determination of sediment Kd values</p>	<p>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:</p>	<p>2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate)</p> <p>Test material Pt(IV), Form: gas under pressure: refrigerated liquefied gas (full information in Annex II).</p> <p>Reference</p>
<p>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: Dihydrogen hexahydroxyplatinate 3. ANALOGUE APPROACH JUSTIFICATION For risk assessment purposes, total measured platinum concentrations in the environment are used in order to assess environmental exposure. The</p>		



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: Dihydrogen hexahydroxyplatinate 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 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:

Dihydrogen hexahydroxyplatinate 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 oral absorption figure of 0.5% is proposed.

Although exposure by the inhalation route is anticipated to be low, based on limited experimental data inhalation absorption is potentially extensive. In line with ECHA guidance, a conservative assumption of 100% inhalation absorption is proposed.

Significant bioavailability after dermal exposure is unlikely, notably as demonstrated by experimental dermal penetration data (human in vitro studies) for a closely-related surrogate. A value of 10% dermal absorption is proposed.

Once absorbed, distribution and excretion are expected to be rapid, with little or no bioaccumulation anticipated. 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 (%): 10

Absorption rate - inhalation (%): 100

Additional information:

Absorption



Limited data indicate that absorption of soluble platinum compounds is very low following oral exposure. Seventy-one fasted male rats were administered a dose of radiolabelled ^{191}Pt (as PtCl_4) 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 $\text{Pt}(\text{SO}_4)_2$ 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 a mixture of soluble platinum salts (mainly diammonium hexachloroplatinate) at calculated mean air concentrations of 1.7 and 0.15 $\mu\text{g Pt}/\text{m}^3$, respectively, urinary platinum 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 platinum measurements in rats following an acute inhalation of radiolabelled Pt, PtO_2 , PtCl_4 or $\text{Pt}(\text{SO}_4)_2$ (particle diameter around 1 μm) indicated only small fractions of the administered dose were absorbed, even for the two soluble salts (Moore et al., 1975a).

Particle size distribution (PSD) data, as measured by simple sieving, indicate that a significant proportion (62.1%) of the compound is $<100 \mu\text{m}$ (Walker and White, 2011b). Dustiness testing, a more energetic PSD measurement, with the compound returned a mass median aerodynamic diameter (MMAD) value of 12.3 μm (Selck and Parr, 2011). In agreement with the granulometry data, an MMAD value $<100 \mu\text{m}$ indicates that a significant proportion of the substance is likely to be inhalable. However, respiratory tract deposition modelling with the dustiness data yielded output values of 66.4, 1.10 and 2.40% for the nasopharyngeal (head), tracheobronchial (TB) and pulmonary regions of the respiratory tract, respectively. This indicates that little airborne substance ($<4\%$) will be deposited in the lower regions of the human respiratory tract, i.e. the TB or pulmonary regions via oronasal normal augmented breathing.

Most of the inhaled fraction is likely to be retained in the head region and therefore would be cleared by ingestion, along with that deposited in the TB region, and oral bioavailability will again predominantly determine systemic uptake. Around 2% is likely capable of reaching the alveoli. Thus, inhalation will not be a significant route of exposure.



While it is very unlikely that dihydrogen hexahydroxyplatinate 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 dihydrogen hexahydroxyplatinate were identified. The low water solubility (<10 mg/L; Gregory, 2014) suggests that the substance may be able to cross the lipid-rich environment of the stratum corneum to a “low to moderate” extent, indicating that the appropriate default value for dermal absorption is 100% in this case (ECHA, 2014). However, 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]. In contrast, 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). Furthermore, there is no evidence that dihydrogen hexahydroxyplatinate causes skin irritation (which could facilitate a greater degree of dermal uptake).

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, care must be taken not to overestimate the dermal absorption potential of dihydrogen hexahydroxyplatinate, considering its relatively low water solubility (and thus its potential to penetrate the stratum corneum). With particular reference to the Franken et al. studies, and considering the lack of evidence of skin irritation, a value of 10% dermal absorption is proposed.

Distribution/Metabolism

Once absorbed, distribution of hydrogen and hexahydroxyplatinate ions throughout the body is expected based on a relatively low molecular weight (~300 g/mol).

In Moore’s study (1975b), platinum was found in the liver and kidney of rats gavaged with radiolabelled-PtCl₄, although levels in other organs were not significantly above background. Other investigators have detected platinum 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 (and Bioaccumulation)

In rats given gavage doses of radiolabelled-platinum compounds, absorbed platinum was found to be predominantly excreted in the faeces, with only a small amount excreted in the urine. (Moore et al., 1975b).



Given that oral absorption was so low, faecal excretion of unabsorbed platinum during the first 1-2 days after administration contributed substantially to the detected levels (US EPA, 2009). Most of the radiolabelled platinum in rats administered a range of salts by inhalation appeared in the faeces (Moore et al., 1975a), presumably reflecting mucociliary clearance and a lack of significant absorption from the gastrointestinal tract (US EPA, 2009).

“Total net gastrointestinal excretion was extremely high”, with less than 1% of the administered dose retained after 3 days (Moore et al., 1975b). Similarly, clearance of radiolabelled platinum after inhalation exposure to platinum metal and various (soluble and insoluble) platinum salts was rapid (20-40% retained after 1 day; approximately 10-15% after 4 days) (Moore et al., 1975a). Accordingly, dihydrogen hexahydroxyplatinate is considered to have only a low potential for bioaccumulation.

Conclusion

Experimental data suggest that dihydrogen hexahydroxyplatinate 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 (based on respiratory tract deposition modelling data), based on limited experimental data absorption could be extensive. A high dermal bioavailability is unlikely.

Absorption values of 0.5%, 100% and 10% are proposed for the oral, inhalation and dermal routes, respectively, and are considered health-precautionary for use in the calculation of DNEL values.

References (for which an ESR has not been created in IUCLID):

ECHA (2012). European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health. Reference: ECHA-2010-G-19-EN. Version 2.1. November 2012.http://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf

ECHA (2014). European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Chapter R.7c: endpoint specific guidance. Version 2.0. November 2014.

Franken A, Eloff FC, du Plessis J, Badenhorst CJ, Jordaan A and Du Plessis JL (2014). In vitro permeation of platinum and rhodium through Caucasian skin. *Toxicology in Vitro* 28, 1396-1401.

Franken A, Eloff FC du Plessis J, Badenhorst CJ and Du Plessis JL (2015). In vitro permeation of platinum through African and Caucasian skin. *Toxicology Letters* 232, 566-572.



ICMM (2007). International Council on Mining & Metals. Health risk assessment guidance for metals. September 2007.

Lown BA, Morganti JB, Stineman CH, D'Agostino RB and Massaro EJ (1980). Tissue organ distribution and behavioral effects of platinum following acute and repeated exposure of the mouse to platinum sulfate. *Environmental Health Perspectives* 34, 203-212.

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.

Moore W, Hysell D, Hall L, Campbell K and Stara J (1975b). Preliminary studies on the toxicity and metabolism of palladium and platinum. *Environmental Health Perspectives* 10, 63-71.

Moore W, Jr, Hysell D, Crocker W and Stara J (1975c). Biological fate of a single administration of ¹⁹¹Pt in rats following different routes of exposure. *Environmental Research* 9, 152-158.

Schierl R, Fries HG, van de Weyer C and Fruhmann G (1998). Urinary excretion of platinum from platinum industry workers. *Occupational and Environmental Medicine* 55, 138-140.

US EPA (2009). United States Environmental Protection Agency. Toxicological review of halogenated platinum salts and platinum compounds in support of summary information on the Integrated Risk Information System (IRIS). January 2009 Draft. EPA/635/R-08/018. https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=513625

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] (HsdCpb: WU) male/female oral: gavage according to OECD Guideline 401 (Acute Oral Toxicity) [before 2002] ; according to EEC Guideline 92/32/EEC	LD0: >2150 mg/kg bw (male/female) based on: (test mat.) (CL not applicable) LD50: >2150 mg/kg bw (male/female) based on: (test mat.) (CL not applicable)	1 (reliable without restriction) key study experimental study Test material 52438-26-3 / 52438-26-3 / 257-921-8; Hexahydroxoplatinu



		m(IV) acid, (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: other justification

Justification: see 'Remark' - In accordance with Column 2 of REACH Annex VIII, this study does not need to be conducted as human exposure via inhalation of aerosols, particles or droplets of an inhalable size is unlikely. Particle size distribution (PSD) data, as measured by simple sieving, indicate that a significant proportion (62.1%) of the compound is <100 µm (Walker and White, 2011b). Dustiness testing, a more energetic PSD measurement, with the compound returned a mass median aerodynamic diameter (MMAD) value of 12.3 µm (Selck and Parr, 2011). In agreement with the granulometry data, an MMAD value <100 µm indicates that a significant proportion of the substance is likely to be inhalable. However, respiratory tract deposition modelling with the dustiness data yielded output values of 66.4, 1.10 and 2.40% for the nasopharyngeal (head), tracheobronchial (TB) and pulmonary regions of the respiratory tract, respectively. Hence, little airborne substance (<4%) is expected to deposit in the lower regions of the human respiratory tract, i.e. the TB or pulmonary regions via oronasal normal augmented breathing. Most of the inhaled fraction is likely to be retained in the head region and could be coughed or sneezed out of the body or swallowed, with systemic uptake being determined predominantly by oral bioavailability. Around 2% is likely capable of reaching the alveoli. Thus, inhalation will not be a significant route of exposure. 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 'Remarks' - No acute dermal toxicity data are available for dihydrogen hexahydroxyplatinate. In accordance with Column 2 of REACH Annex VIII, this study does not need to be conducted as the substance does not meet the criteria for classification as acute toxicity or STOT SE by the oral route. The existing in vivo skin sensitisation study (Dearman & Kimber, 2011), albeit limited in its assessment of general systemic toxicity, indicates 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, dihydrogen hexahydroxyplatinate is a crystalline powder (CRC, 2008a) and skin contact during production and/or use is expected to be very low. Second, dihydrogen hexahydroxyplatinate is classified for eye irritation, so appropriate safety labelling, personal protection and RMMs/OCs are required to protect the eyes and skin (e.g. "wear protective gloves/clothing" and "wash hands thoroughly after handling"). These will ensure that the potential for skin exposure is reduced. 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 a last resort. Consequently, no further testing is considered justified.

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:

In a guideline GLP study, the acute oral LD50 value of hexahydroxoplatinum(IV) acid was determined to exceed 2150 mg/kg bw (limit test) in rats (Berthold, 1995a).

No relevant acute dermal or inhalation toxicity data were identified.

Value used for CSA:

Acute oral toxicity:

no adverse effect observed

Acute dermal toxicity:

no study available

Acute inhalation toxicity:

no study available

Additional information:

No relevant human acute toxicity data were identified.

In a well-conducted acute oral toxicity test, conducted in accordance with OECD Test Guideline 401 and to GLP, HsdCpb: WU rats (5/sex) were gavaged with hexahydroxoplatinum(IV) acid (as a suspension in aqueous carboxymethyl cellulose) at a limit dose of 2150 mg/kg bw and observed for 14 days. Transient clinical signs of stilted gait and sunken sides were apparent in some animals. No deaths were observed within the observation period. The oral LD50 (and indeed the LD0) was therefore determined to exceed 2150 mg/kg bw in male and female rats (Berthold, 1995a)

No acute inhalation toxicity data were identified. However, the compound is not expected to reach the lungs in appreciable quantities (based on respiratory tract deposition modelling data). Thus, inhalation will not be a significant route of exposure.

Similarly, no acute dermal toxicity data were identified. However, 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 toxicity study in rats, dihydrogen hexahydroxyplatinate does not require classification for acute oral toxicity 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
<p>human [other species] (Reconstructed human epidermis model (see details below))</p> <p>Coverage: Applied evenly to the epidermal surface before the application of 10 ul NaCl solution. (in vitro cell culture)</p> <p>Vehicle: physiological saline according to OECD Guidelines for Testing of Chemicals, Section 4, No. 431, "In Vitro Skin Corrosion: Human Skin Model" adopted 13 April 2004 ; according to Commission Regulation (EC) No 440/2008, Annex Part B, B.40Bis: "IN VITRO SKIN CORROSION: HUMAN SKIN MODEL TEST", Official Journal of the European Union No. L142, dated May 31st, 2008.</p> <p>The reconstructed human epidermis model EPISKIN-SM is designed to predict and classify the corrosive potential of chemicals, by measuring its cytotoxic effect, as reflected in the MTT [3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide, Thiazolyl blue; CAS number 298-93-1] assay, on the EPISKIN reconstituted human epidermis. This method is approved by international regulatory agencies as a replacement for the identification of irritants / corrosives in the in vivo Rabbit skin assay (OECD 404) and is specifically approved as a replacement for the in vivo skin corrosivity test within OECD 431. It is based on the experience that corrosive</p>	<p>Non-corrosive to skin - Criteria used for interpretation of results: not specified other:</p> <p>Value: 82 (- Basis: mean Cell/tissue viability. Time point: 4 hours.</p> <p>Reversibility: other: Not applicable.</p> <p>Remarks: Score is a percentage (%) of negative control. Mean relative viability <=35% the test substance is considered to be corrosive to skin.. (migrated information))</p>	<p>1 (reliable without restriction) key study experimental study</p> <p>Test material hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, (full information in Annex II).</p> <p>Reference Kiss I 2012</p>



chemicals show cytotoxic effects following short-term exposure of the stratum corneum of the epidermis.		
<p>human [other species] (Reconstructed human epidermis model (see details below))</p> <p>Coverage: Applied evenly to the epidermal surface following the application of 10 ul distilled water to this surface (in vitro cell culture)</p> <p>Vehicle: water - distilled according to OECD Guidelines for Testing of Chemicals, Section 4, No. 439, "In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method" adopted 22 July 2010 ; according to EpiSkin™ SOP, Version 1.8 (February 2009), ECVAM Skin Irritation Validation Study: Validation of the EpiSkin™ test method 15 min - 42 hours for the prediction of acute skin irritation of chemicals.</p> <p>Available at: [http://ecvam.jrc.ec.europa.eu] ; according to IN VITRO SKIN IRRITATION: RECONSTRUCTED HUMAN EPIDERMIS MODEL TEST in relation to Regulation (EC) No 440/2008 (as amended) and Regulation (EC) No 1907/2006 on REACH (Annex III, B.46). The test is designed to predict and classify the skin irritant potential of chemicals according to chemical safety regulations, using the reconstructed human epidermis model EPISKIN-SM and parameters related to skin irritation. EPISKIN-SM is a three-dimensional human skin model comprising a reconstructed epidermis with a functional stratum corneum. Its use for skin irritation testing involves topical application of test materials to the surface of the epidermis, and the subsequent assessment of their effects on cell viability. Cell viability determination is based on cellular mitochondrial dehydrogenase activity, measured by MTT reduction and conversion into a blue formazan salt that is quantitatively measured after extraction from tissues. The reduction of cell viability in treated tissues is compared to negative controls and expressed as a %. The % reduction in viability is used to predict the irritation potential. The EPISKIN-SM has been found scientifically valid for reliably predicting no label and R38 (irritant) substances in respect to the previous EU classification scheme and has been confirmed in April 2009 by ESAC for use</p>	<p>not classified - Migrated information</p> <p>Criteria used for interpretation of results:</p> <p>EU</p> <p>other:</p> <p>Value: 82 (- Basis: mean Cell/tissue viability. Time point: 42 hours.</p> <p>Reversibility: other: Not applicable.</p> <p>Remarks: Score is a percentage (%) of negative control. Mean relative viability <=50% the test substance is considered to be irritant to skin.. (migrated information))</p>	<p>1 (reliable without restriction)</p> <p>key study</p> <p>experimental study</p> <p>Test material</p> <p>Hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, (full information in Annex II).</p> <p>Reference</p> <p>Kiss I 2012</p>



under the UN GHS system as “applicable to all authorities”. It is approved by international regulatory agencies as a replacement for the identification of irritants/corrosives in the in vivo rabbit skin assay(OECD 404).		
---	--	--

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

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 EEC Guideline 92/32/EEC	not classified - Migrated information Criteria used for interpretation of results: EU Irritation index (mean) 6 of max. 110 (Time point: 1, 24, 48 and 72 hours post-application) Not applicable	2 (reliable with restrictions) key study experimental study Test material 52438-26-3 / 52438-26-3 / 257-921-8; Hexahydroxoplatinum (IV) acid, (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 in vitro EpiSkin assays conducted in accordance with OECD Test Guidelines 431 and 439 (corrosion and irritation, respectively) and to GLP, dihydrogen hexahydroxyplatinate was considered to be non-corrosive and non-irritating to skin (Kiss, 2012a, b).

In an OECD Test Guideline 405 in vivo eye irritation study, conducted to GLP, hexahydroxoplatinum(IV) acid produced some transient irritation following instillation of the test material (0.1 ml) into one eye of each of 3 rabbits (Berthold, 1995b).

No relevant respiratory tract irritation data were identified.

Value used for CSA:

Skin irritation / corrosion: no adverse effect observed (not irritating) Eye irritation: adverse effect observed (irritating) Respiratory irritation: no study available

Additional information:

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

Dihydrogen hexahydroxyplatinate was tested for skin corrosion potential in an in vitro reconstructed human epidermis model (EpiSkin assay) conducted in accordance with OECD Test Guideline 431, and to GLP. EpiSkin is a three-dimensional human skin model comprising a reconstructed epidermis with a functional stratum corneum. Its use for skin corrosivity testing involves the topical application of test materials to the surface of the skin, and the subsequent assessment of their effects on cell viability. Cytotoxicity is expressed as the reduction of mitochondrial dehydrogenase activity measured by formazan production from MTT. The reduction of cell viability in treated tissues is compared to negative controls and expressed as a %. If the resulting mean relative viability is less than 35% of the negative control, the test substance is considered to be corrosive to skin. Following a 4-hr incubation with the test substance, the test system skin cell viability was calculated to be greater than 35% (the average was 82% and the range was 72 -89%), and it was therefore considered to be non-corrosive to skin (Kiss, 2012a). Under the conditions of this assay, dihydrogen hexahydroxyplatinate does not require classification for skin corrosion according to EU CLP criteria (EC 1272/2008).

Subsequently, dihydrogen hexahydroxyplatinate was tested for skin irritation potential in a further EpiSkin assay conducted in accordance with OECD Test Guideline 439, and to GLP. The assay designed to assess skin irritation is highly similar to the analogous assay for corrosivity. In this assay, if the mean relative viability (as adjusted for intrinsic colour) is less than or equal to 50% of the negative control, the test substance is considered to be irritant to skin. Following a 15-minute exposure to the test substance, the test system skin cell viability was calculated to be greater than 50% (the average was 82% and the range was 74 -88%), and it was therefore considered to be non-irritating to skin (Kiss, 2012b). Under the conditions of this assay, dihydrogen



hexahydroxyplatinate does not require classification for skin irritation according to EU CLP criteria (EC 1272/2008).

In an in vivo eye irritation study carried out in accordance with OECD Test Guideline 405, and to GLP, a 0.1 ml aliquot of undiluted hexahydroxoplatinum(IV) acid was instilled into the conjunctival sac of each of three male White Russian rabbits. 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, 24, 48 and 72 hours. One animal was observed after an additional 24 hours. Corneal opacity, effects on the iris and conjunctival redness, chemosis and discharge were scored according to the Draize numerical scale. No corneal effects (opacity) were observed in any animal. Effects on the iris were seen in one animal at 1 hour (slight circumcorneal hyperemia), and in another animal at 24 and 48 hours (moderate circumcorneal hyperemia). Effects on the conjunctiva were seen in all animals. Notably, in one animal, these were moderate/severe, with maximum scores for discharge and redness reported for at least one time point within the observation period. Indeed, the maximum observed score for conjunctival chemosis (swelling) in this animal was 3 (of a maximum of 4 achievable on the Draize scale). All effects on the iris and conjunctivae were, however, fully reversible within 4 days. The primary irritation index calculated for all animals was 6 (out of 110). The study authors considered the substance to be non-irritant to rabbit eyes (Berthold, 1995b). Based on the severe irritation observed in one of the tested animals, it is prudent to classify the test item as an eye irritant (category 2), according to EU CLP criteria (EC 1272/2008).

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 reliable in vitro skin irritation study, there is no requirement to classify dihydrogen hexahydroxyplatinate for skin irritation under EU CLP criteria (EC 1272/2008).

Based on the results of the available and reliable in vivo eye irritation study (severe irritation observed in one of the tested animals), it is prudent to classify the test item as an eye irritant (category 2), 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
mouse (Balb/c [mouse]) not specified skin sensitisation: in vivo (LLNA) The primary aim of the study was to evaluate the allergenic potential of the test substance and to determine its ability to cause allergic sensitization of the respiratory tract. Following analysis of lymphocyte proliferation using a standard local lymph node assay (LLNA) protocol cytokine fingerprinting was undertaken to explore respiratory sensitizing potential. Repeated topical exposure of BALB/c strain mice to chemical respiratory allergens, or contact allergens, has been shown to provoke characteristic cytokine secretion profiles consistent with the divergent activation of discreet T cell subpopulations. Cytokine profiles were compared with the recognised respiratory sensitizers Trimellitic anhydride (TMA) and Ammonium hexachloroplatinate (AHCP), as well as the known contact sensitizer 2,4-Dinitrochlorobenzene (DNCB) and the non-sensitizer Tetraammine platinum dichloride (TPC).	not sensitising - Migrated information Criteria used for interpretation of results: expert judgment Stimulation index: (See results, below) disintegrations per minute (DPM): (Full details on results are presented below under Any other information on results incl. tables)	2 (reliable with restrictions) key study experimental study Test material 52438-26-3 / 52438-26-3 / 257-921-8; Hexahydroxyplatinate acid, Form: solid - liquid: suspension (full information in Annex II). Reference Dearman RJ and Kimber I 2011

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.

5.5.1.2. Human information

No relevant information available.

5.5.2. Respiratory system

5.5.2.1. Non-human information

No relevant information available.



5.5.2.2. Human information

No relevant information available.

5.5.3. Summary and discussion of sensitisation

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

Skin sensitisation

A modified LLNA, combined with a detailed cytokine fingerprinting assay, was used to assess allergenic potential of dihydrogen hexahydroxyplatinate compared to a number of known respiratory-, contact-, and non-sensitisers. Although dihydrogen hexahydroxyplatinate at high concentrations (40% and 80% HHPA in DMF gave a Stimulation Index (SI) of 5.4 and 5.7, respectively) demonstrated a mild sensitisation response (based on $SI > 3$), the more sophisticated cytokine fingerprinting assay indicated that it was not a significant skin (or respiratory) sensitiser (Dearman and Kimber, 2011).

Value used for CSA: no adverse effect observed (not sensitising)

Additional information:

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

Repeated topical exposure of BALB/c strain mice to chemical contact allergens has been shown to provoke characteristic cytokine secretion profiles consistent with the divergent activation of discrete T cell subpopulations (Dearman et al., 1998; 2002).

Dihydrogen hexahydroxyplatinate was subjected to a modified LLNA, combined with a detailed cytokine fingerprinting assay, to evaluate its allergenic potential. Mice (4/group) received a 25 μ L application of HHPA (concentrations of 40% or 80% HHPA in DMF, or DMF alone) on the dorsum of both ears on three consecutive days. Five days after the initiation of treatment, cell proliferation in the local lymph nodes was measured by incorporation of radiolabelled thymidine. Subsequently, a standard 13-day cytokine fingerprinting assay was undertaken, involving mice (3/group) exposed to 80% HHPA in DMF. Additional groups of mice were treated with ammonium hexachloroplatinate (AHCP) (a respiratory sensitising platinum salt; positive control), tetraammineplatinum dichloride (TPC) (a non-sensitising platinum salt; negative control), as well as the reference respiratory allergen trimellitic anhydride (TMA) or the reference contact allergen 2,4-dinitrochlorobenzene (DNCB). Animals received 50 μ L of test chemical on both shaved flanks on day 0 and day 5, followed by a further dose of 25 μ L of chemical on the dorsum of both ears on days 10, 11 and 12. In the LLNA, the observed Stimulation Index (SI) values were 5.4 and 5.7 at 40 and 80%, respectively, demonstrating a mild sensitisation response. However, the more sophisticated detailed cytokine fingerprinting assay indicated that the test material was not a significant skin sensitiser. Type 1 and type 2 cytokine profiles were compared with those of the known respiratory sensitisers TMA and AHCP, the contact sensitiser DNCB, and the known non-sensitiser TPC. HHPA failed to stimulate vigorous type 2 cytokine production, indicating a lack of respiratory sensitising potential, and demonstrated a cytokine profile similar to that of the non-sensitiser TPC. Type 1 cytokine IFN-gamma was below the limit of detection, and IL-12 was not elevated above normal background values, based on historical vehicle controls (Dearman and Kimber, 2011). The results of this scientifically valid approach fit with current industrial experience to date.

It is concluded, based on the available experimental data, and industrial experience to date, that dihydrogen hexahydroxyplatinate does not represent a significant skin sensitisation hazard.



Although it is not considered necessary to repeat the LLNA, it is recommended that a lack of skin sensitising potential be confirmed using a standard in vivo assay for skin sensitisation using guinea-pigs, following current international guidelines.

References

Dearman RJ et al. (2002). Cytokine fingerprinting of chemical allergens: species comparisons and statistical analyses. *Food and Chemical Toxicology* 40, 1881 -1892.

Dearman RJ et al. (1998). Selective induction of type 2 cytokines following topical exposures of mice to platinum salts. *Food and Chemical Toxicology* 36, 199 -207.

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

Respiratory sensitisation

Value used for CSA: no study available
Additional information:

At present there is no validated or widely accepted standard test protocol to detect respiratory allergenicity of low molecular weight compounds. No sensitisation data involving inhalation exposure of experimental animals are available for dihydrogen hexahydroxyplatinate. A new study was not conducted as it is not a REACH Standard Information Requirement. Nevertheless, a good-quality and scientifically-acceptable study involving dermal exposure of mice is available for dihydrogen hexahydroxyplatinate, providing results which are considered suitable and sufficiently valid to form the basis of a preliminary assessment of respiratory sensitisation.

Repeated topical exposure of BALB/c strain mice to chemical respiratory allergens has been shown to provoke characteristic cytokine secretion profiles consistent with the divergent activation of discrete T cell subpopulations (Dearman et al., 1998; 2002).

Dihydrogen hexahydroxyplatinate was subjected to a modified LLNA, combined with a detailed cytokine fingerprinting assay, to evaluate its allergenic potential, particularly with regard to its ability to cause sensitisation of the respiratory tract. The cytokine profiles were compared with the recognised respiratory sensitisers TMA and AHCP, as well as the platinum substance TPC, considered to be a non-sensitiser to the respiratory tract based on occupational study data. Detailed cytokine fingerprinting indicated that it was not a significant respiratory sensitiser, demonstrating a cytokine profile similar to that of TPC (Dearman and Kimber, 2011). The results of this scientifically valid approach fit with current industrial experience to date.

It is concluded, based on the available experimental data, and industrial experience to date, that dihydrogen hexahydroxyplatinate does not represent a significant respiratory sensitisation hazard.



References

Dearman RJ et al. (2002). Cytokine fingerprinting of chemical allergens: species comparisons and statistical analyses. *Food and Chemical Toxicology* 40, 1881 -1892.

Dearman RJ et al. (1998). Selective induction of type 2 cytokines following topical exposures of mice to platinum salts. *Food and Chemical Toxicology* 36, 199 -207.

Justification for classification or non classification:

Based on the results of the detailed cytokine profiling analysis on dihydrogen hexahydroxyplatinate in mice, and compared with the results for a number of known respiratory-, contact-, and non-sensitisers, it is concluded that dihydrogen hexahydroxyplatinate is not a significant skin or respiratory tract sensitiser and that non-classification is justified under EU CLP criteria (EU 1272/2008). The results of this assessment fit with current industrial experience of handling this substance.

It is proposed that a lack of significant skin sensitising potential could be confirmed using a standard in vivo assay for sensitisation using guinea-pigs. Results from such a study would add to the LLNA and cytokine fingerprinting data described above.

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 5.5. 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 - combined repeated dose and reproduction / developmental screening (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	NOAEL: 1000 mg/kg bw/day (actual dose received) (male/female) based on: (test mat.) No general systemic effects seen at highest tested dose	1 (reliable without restriction) key study experimental study Test material hexahydroxyplatinat e(2-) / 51850-20-5 / 257-471-2, Form: solid: particulate/powder - migrated information: powder (full information in Annex II).



the day before sacrifice (from test day 41 for the first sacrificed females to test day 58 for the last sacrificed female). (Once daily.) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)		Reference Hansen B 2015
--	--	--

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 422 combined repeated dose and reproductive/developmental toxicity screening study in rats, involving the gavage administration of dihydrogen hexahydroxyplatinate for at least 35 days, no clinical signs of toxicity or any adverse pathological or histopathological effects were observed. The study NOAEL was the highest tested dose (1000 mg/kg bw/day) (Hansen, 2015).

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):

no adverse effect observed
(NOAEL: 1000mg/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.

In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, CD rats (12/sex/group) were orally administered dihydrogen hexahydroxyplatinate by stomach tube (gavage) at doses of 0, 100, 300 or 1000 mg/kg bw/day. Males were dosed for 35 days (2 weeks pre-mating, during the mating period and for approximately 2 weeks post-mating). Females were dosed for 14 days pre-mating, through mating, gestation and up to post-partum day 3 (test day 41-58). Daily administration of dihydrogen hexahydroxyplatinate by oral gavage to CD rats did not result in test item related mortality clinical signs of toxicity or neurological observations, or changes in the body weight, food/water consumption, haematology or clinical chemistry parameters at dose levels of up to 1000 mg/kg bw/day during the treatment period. There were no adverse treatment-related changes in organ weights, or following macroscopic examination and histopathology for the adult animals of either sex. On this basis, a study NOAEL of 1000 mg/kg bw/day was established (Hansen, 2015).

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. The compound is not expected to reach the lungs in appreciable quantities (based on respiratory tract deposition modelling data). Thus, inhalation will not be a significant route of exposure. Similarly, skin contact during production and/or use is expected to be negligible. As the oral route of exposure is considered the most appropriate, repeated dose toxicity studies were not carried out for the dermal or inhalation routes.

Justification for classification or non classification:

No adverse systemic effects were seen in a reliable repeated dose toxicity study (combined with a reproductive/developmental screening assay) following gavage administration of rats for at least 35 days. As such, classification of dihydrogen hexahydroxyplatinate as STOT-RE is not required, according to EU CLP criteria (EC 1272/2008).

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

5.7. 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 5.6. In vitro genotoxicity studies:

Method	Results	Remarks
bacterial reverse mutation assay [in vitro]	Test results:	1 (reliable without



<p>gene mutation study in bacteria] (in vitro gene mutation study in bacteria - Type of genotoxicity: gene mutation)</p> <p>S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 (main study (Experiments 1 and 2)) (with and without met. act.)</p> <p>S. typhimurium TA 98, TA 100 and TA 102 (range-finding study) (with and without met. act.)</p> <p>Test concentrations: Range-finding study: 0, 5, 15.8, 50, 158.1, 500, 1581 or 5000 µg/plate Main study: Experiment 1: 0, 5, 15.8, 50, 158.1, 500, 1581 or 5000 µg/plate Experiment 2: 0, 156.3, 312.5, 625, 1250, 2500 or 5000 µg/plate</p> <p>Positive control substance(s): 2-nitrofluorene</p> <p>Positive control substance(s): sodium azide</p> <p>Positive control substance(s): 9-aminoacridine</p> <p>Positive control substance(s): mitomycin C</p> <p>Positive control substance(s): benzo(a)pyrene</p> <p>Positive control substance(s): 2-aminoanthracene</p> <p>according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria]</p>	<p>positive - in Experiments 1 and 2 for S. typhimurium TA 98 [bacteria]; met. act.: with</p> <p>genotoxicity: positive - in Experiments 1 and 2 cytotoxicity: no cytotoxicity vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid</p> <p>Test results: positive - in Experiments 1 and 2 for S. typhimurium TA 98 [bacteria]; met. act.: without</p> <p>genotoxicity: positive - in Experiments 1 and 2 cytotoxicity: no cytotoxicity vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid</p> <p>Test results: positive - in Experiments 1 and 2 for S. typhimurium TA 100 [bacteria]; met. act.: with</p> <p>genotoxicity: positive - in Experiments 1 and 2 cytotoxicity: no cytotoxicity vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid</p> <p>Test results: positive - in Experiments 1 and 2 for S. typhimurium TA 100 [bacteria]; met. act.: without</p> <p>genotoxicity: positive - in Experiments 1 and 2 cytotoxicity: no cytotoxicity vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid</p> <p>Test results: positive - in Experiments 1 and 2 for S. typhimurium TA 102 [bacteria]; met. act.: with</p> <p>genotoxicity: positive - in Experiments 1 and 2 cytotoxicity: cytotoxicity - in Experiment 1 at 5000 µg/plate vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid</p> <p>Test results: ambiguous - statistically significant increase in revertants in Experiments 1 and 2, but not clearly concentration-related or reproducible for S. typhimurium TA 102 [bacteria]; met. act.: without</p> <p>genotoxicity: ambiguous - statistically significant increase in revertants in Experiments 1 and 2, but not clearly concentration-related or reproducible cytotoxicity: no cytotoxicity vehicle controls valid: valid</p>	<p>restriction) key study experimental study</p> <p>Test material hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid - liquid: suspension (full information in Annex II).</p> <p>Reference Mc Garry S 2013</p>
---	---	--



	<p>negative controls valid: not examined positive controls valid: valid</p> <p>Test results: positive - in Experiment 2, with pre-incubation for <i>S. typhimurium</i> TA 1535 [bacteria]; met. act.: with genotoxicity: positive - in Experiment 2, with pre-incubation cytotoxicity: in Experiment 1 from 500 or 1581 µg/plate vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid</p> <p>Test results: ambiguous - statistically significant increase in revertants in Experiment 2, but not clearly concentration-related or reproducible for <i>S. typhimurium</i> TA 1535 [bacteria]; met. act.: without genotoxicity: ambiguous - statistically significant increase in revertants in Experiment 2, but not clearly concentration-related or reproducible cytotoxicity: in Experiment 1 from 500 or 1581 µg/plate vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid</p> <p>Test results: negative for <i>S. typhimurium</i> TA 1537 [bacteria]; met. act.: with genotoxicity: negative cytotoxicity: no vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid</p> <p>Test results: negative for <i>S. typhimurium</i> TA 1537 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: in Experiment 2, at 5000 µg/plate vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid</p> <p>Remarks: all strains/cell types tested - Migrated from field 'Test system'.</p>	
in vitro mammalian cell micronucleus test [in vitro cytogenicity / micronucleus study] (in vitro cytogenicity / micronucleus study - Type of genotoxicity: chromosome aberration) Chinese hamster Ovary (CHO)	<p>Test results: ambiguous - frequency of micronuclei statistically significantly higher than control, but within normal range except one culture at 70 µg/ml, for which MNBN cell incidence exceeded the</p>	1 (reliable without restriction) key study experimental study Test material



<p>[mammalian cell line] (with and without met. act.) Test concentrations: Range-finding study 1: 0 or 0.9-250 µg/ml Range-finding study 2: 0 or 10.1-1000 µg/ml Main study: 0 or 10-800 µg/ml Concentrations assessed in main study: 3-hr (with and without S-9): 0, 20, 40, 70 or 100 µg/ml 24-hr (without S-9): 0, 10, 20, 40 or 70 µg/ml</p> <p>Positive control substance(s): mitomycin C</p> <p>Positive control substance(s): cyclophosphamide</p> <p>Positive control substance(s): vinblastine</p> <p>according to OECD Guideline 487 (In Vitro Mammalian Cell Micronucleus Test)</p>	<p>normal range for Chinese hamster Ovary (CHO) [mammalian cell line]; met. act.: without</p> <p>genotoxicity: ambiguous - frequency of micronuclei statistically significantly higher than control, but within normal range except one culture at 70 µg/ml, for which MNBN cell incidence exceeded the normal range cytotoxicity: cytotoxicity - 9, 10, 19 and 26% for selected test concentrations (20, 40, 70 and 100 µg/ml, respectively). Higher levels of cytotoxicity seen at higher concentrations</p> <p>vehicle controls valid: valid negative controls valid: valid positive controls valid: valid</p> <p>Test results: positive - significantly increased incidence of micronuclei seen at each test concentration for Chinese hamster Ovary (CHO) [mammalian cell line]; met. act.: with</p> <p>genotoxicity: positive - significantly increased incidence of micronuclei seen at each test concentration cytotoxicity: cytotoxicity - 8, 19, 34 and 43% for selected test concentrations (20, 40, 70 and 100 µg/ml, respectively). Higher levels of cytotoxicity seen at higher concentrations</p> <p>vehicle controls valid: valid negative controls valid: valid positive controls valid: valid</p> <p>Test results: not determined - no significant increase in micronuclei relative to controls, but positive control not valid for Chinese hamster Ovary (CHO) [mammalian cell line]; met. act.: without</p> <p>genotoxicity: not determined - no significant increase in micronuclei relative to controls, but positive control not valid cytotoxicity: cytotoxicity - 6, 6, 12 and 12% for selected test concentrations (10, 20, 40 and 70 µg/ml, respectively). Higher levels of cytotoxicity seen at higher concentrations</p> <p>vehicle controls valid: valid negative controls valid: valid positive controls valid: not valid</p> <p>Remarks: all strains/cell types tested - Migrated from field 'Test system'. Remarks: 3-hour treatment</p>	<p>hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid - liquid: suspension (full information in Annex II).</p> <p>Reference Lloyd M 2014</p>
--	---	---

Data waiving



Information requirement: In vitro genotoxicity: (in vitro gene mutation study in mammalian cells)

Reason: study scientifically not necessary / other information available

Justification: an in vitro gene mutation study in mammalian cells does not need to be conducted because a positive result was found in in vitro gene mutation study in bacteria [study scientifically not necessary / other information available] ; an in vitro gene mutation study in mammalian cells does not need to be conducted because a positive result was found in in vitro micronucleus study [study scientifically not necessary / other information available] ; see 'Remark' - No mammalian cell gene mutation data are available for dihydrogen hexahydroxyplatinate. Irrespective of the result of any hypothetical gene mutation test, the observation of mutagenic activity in bacterial cells (McGarry, 2013) and cytogenicity in mammalian cells (Lloyd, 2014) necessitates the consideration of further in vivo testing. Related platinum compounds have also demonstrated a general tendency to induce genotoxicity in vitro, though the available, if somewhat limited, dataset suggests that such findings might not be relevant in vivo and hence a similar lack of classification for mutagenicity is proposed for these compounds. Additional in vivo testing of other platinates has been proposed to clarify the relevance of the in vitro findings. Consequently, it is considered unnecessary to conduct further in vitro testing on dihydrogen hexahydroxyplatinate. Instead, further in vivo genotoxicity testing has been performed.

5.7.1.2. In vivo data

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

Table 5.7. 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 500mg/kg bw/day (actual dose received) 1000mg/kg bw/day (actual dose received) 2000mg/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 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. (male) toxicity: no effects vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Liver: no statistically significant increase in % tail intensity. (male) toxicity: not examined vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Glandular stomach: no statistically significant increase in % tail intensity. (male) toxicity: not examined vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Duodenum: no statistically significant increase in % tail intensity. (male) toxicity: not examined vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:	1 (reliable without restriction) key study experimental study Test material Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, (full information in Annex II). Reference Eurlings IMJ 2020
Justification for type of information: An EPMF member company received an official request from the Korean		



<p>authorities to perform the in vivo mutagenicity assay with hexahydroxyplatinate, compound with 2-aminoethanol(1:2) (CAS 68133-90-4), ahead of the formal testing proposal approval by ECHA. The requested experimental information is in line with the assay submitted in the TP for this substance. The deadline given by the Korean authorities was however much tighter than the anticipated date of receiving the final decision on the TP. Therefore, the in vivo mutagenicity testing with this substance has been initiated in the EU prior to receiving the final decision on the TP. In the attached document (translation from Korean and anonymised), a justification for initiating the in vivo muta testing upon official request from an non-EU authority (i.e. request outside EU-REACH), ahead of receiving the final decision on the TP. More information is available upon request.</p>		
<p>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</p> <p>500mg/kg bw/day (actual dose received)</p> <p>1000mg/kg bw/day (actual dose received)</p> <p>2000mg/kg bw/day (actual dose received)</p> <p>Cyclophosphamide. - Route of administration: Gavage. - Doses / concentrations: A single dose of 19 mg/kg bw, dissolved in physiological saline. according to OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) [in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus]</p>	<p>Genotoxicity: negative (male) toxicity: no effects vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:</p>	<p>1 (reliable without restriction) key study experimental study</p> <p>Test material Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, (full information in Annex II).</p> <p>Reference Eurlings IMJ 2020</p>
<p>Justification for type of information: An EPMF member company received an official request from the Korean authorities to perform the in vivo mutagenicity assay with hexahydroxyplatinate, compound with 2-aminoethanol(1:2) (CAS 68133-90-4), ahead of the formal testing proposal approval by ECHA. The requested experimental information is in line with the assay submitted in the TP for this substance. The deadline given by the Korean authorities was however much tighter than the anticipated date of receiving the final decision on the TP. Therefore, the in vivo mutagenicity testing with this substance has been initiated in the EU prior to receiving the final decision on the TP. In the attached document (translation from Korean and anonymised), a justification for initiating the in vivo muta testing upon official request from an non-EU authority (i.e. request outside EU-REACH), ahead of receiving the final decision on the TP. More information is available upon request.</p>		
<p>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</p> <p>500mg/kg bw/day (actual dose received)</p> <p>1000mg/kg bw/day (actual dose received)</p> <p>2000mg/kg bw/day (actual dose received)</p>	<p>Genotoxicity: negative - Kidney: no statistically significant increase in % tail intensity. (male) toxicity: no effects vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:</p> <p>Genotoxicity: negative - Liver: no statistically significant increase in % tail intensity. (male) toxicity: not examined vehicle controls valid: valid negative controls valid:</p>	<p>1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate)</p> <p>Test material hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid: particulate/powder - migrated</p>



<p>Ethyl methanesulphonate. - Route of administration: Gavage. - Doses / concentrations: 200 mg/kg bw, dissolved in physiological saline, administered twice. according to OECD Guideline 489 (In vivo Mammalian Alkaline Comet Assay) [in vivo mammalian cell study: DNA damage and/or repair]</p>	<p>positive controls valid: valid Remark: Genotoxicity: negative - Glandular stomach: no statistically significant increase in % tail intensity. (male) toxicity: not examined vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Duodenum: no statistically significant increase in % tail intensity. (male) toxicity: not examined vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:</p>	<p>information: powder (full information in Annex II). Reference Eurlings IMJ 2020</p>
<p>Justification for type of information: For the group of hexahydroxyplatinate(IV) substances, it is proposed that, in aqueous solution and in biological media (e.g. gastric fluid), the cations (hydrogen or 2-aminoethanol) dissociate, leaving the core hexahydroxyplatinate(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 hexahydroxyplatinate(IV) complex is anticipated to occur in vivo. The 2-aminoethanol, acting as counter-ion of one group member, contributes to the effects observed for selected mammalian endpoints like irritation, repeated dose toxicity and reproductive toxicity. However, no contribution of 2-aminoethanol is expected for the mutagenicity endpoint. The mutagenicity test data should be considered equally applicable to each of the two group members. More details on this read-across approach are provided in IUCLID Section 13.</p>		
<p>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 500mg/kg bw/day (actual dose received) 1000mg/kg bw/day (actual dose received) 2000mg/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 OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) [in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus]</p>	<p>Genotoxicity: negative (male) toxicity: no effects vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:</p>	<p>1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate) Test material Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid (full information in Annex II). Reference Eurlings IMJ 2020</p>
<p>Justification for type of information: For the group of hexahydroxyplatinate(IV) substances, it is proposed that, in aqueous solution and in biological media (e.g. gastric fluid), the cations (hydrogen or 2-aminoethanol) dissociate, leaving the core hexahydroxyplatinate(IV) complex as the common product and toxicologically-active species. It should be noted that this represents a chemical transformation and not a “biotransformation”;</p>		



no metabolism of the hexahydroxyplatinate(IV) complex is anticipated to occur in vivo. The 2-aminoethanol, acting as counter-ion of one group member, contributes to the effects observed for selected mammalian endpoints like irritation, repeated dose toxicity and reproductive toxicity. However, no contribution of 2-aminoethanol is expected for the mutagenicity endpoint. The mutagenicity test data should be considered equally applicable to each of the two group members. 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):

In a good-quality Ames assay, conducted according to GLP and OECD Test Guideline 471, dihydrogen hexahydroxyplatinate displayed evidence of mutagenicity when tested in five *Salmonella typhimurium* strains (TA98, TA100, TA102, TA1535 and TA1537), in the presence and absence of a rat liver metabolic activation (S9) system (McGarry, 2013).

In an in vitro mammalian cell micronucleus test, conducted according to GLP and OECD Test Guideline 487, dihydrogen hexahydroxyplatinate induced micronuclei in cultured Chinese hamster ovary (CHO) cells following treatment with metabolic activation (S9). Weak evidence for inducing micronuclei was seen in the absence of S9 (Lloyd, 2014).

No mammalian cell gene mutation data are available for dihydrogen hexahydroxyplatinate. Further in vitro testing is considered unnecessary in the light of the performed in vivo genotoxicity testing.

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 dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, 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 500, 1000 or 2000 mg/kg bw/day of the test item on three consecutive days. 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 evidence of an increase in the incidence of micronucleated polychromatic erythrocytes. There was no increase in % tail intensity in the liver, glandular stomach, kidney or duodenum (Eurlings, 2020). As such, and as platinum was detected in the plasma of the test animals, the test item was considered to be non-genotoxic in vivo.

The data were considered relevant for dihydrogen hexahydroxyplatinate via read-across (cfr. IUCLID section 13).



Value used for CSA (genetic toxicity in vivo): Genetic toxicity: no study available

Justification for classification or non classification

Based on the existing data set, dihydrogen hexahydroxyplatinate 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).

Additional information:

No studies conducted in humans were identified.

Dihydrogen hexahydroxyplatinate was assessed for mutagenicity in a bacterial reverse mutation (Ames) assay performed to GLP, and according to OECD Guideline 471. Triplicate cultures of *Salmonella typhimurium* strains TA98, TA100, TA102, TA1535 and TA1537 were tested with and without the addition of a mammalian (rat liver) metabolic activation (S9) system in two separate experiments. In the first experiment, agar containing the test substance at up to 5000 µg/plate was incubated with the bacterial strains for 3 days. The second experiment, also using concentrations of up to 5000 µg/plate, included an additional 20-minute pre-incubation step for cultures of TA1535 and TA1537 in the presence of S9. There was significant evidence of mutagenicity in strains TA98 and TA100, with and without S9, and TA1535 and TA102 in the presence of S9 only. The lowest concentration producing a statistically significant increase in the number of revertant colonies was 50 µg/plate (for TA100, with S9). Cytotoxicity was observed at high concentrations in some of the test plates. Vehicle and positive controls performed as expected. Under the conditions of this assay, dihydrogen hexahydroxyplatinate was mutagenic to *S. typhimurium*, with and without metabolic activation (McGarry, 2013).

In an in vitro GLP study, conducted in accordance with OECD Test Guideline 487 (in vitro mammalian cell micronucleus test), dihydrogen hexahydroxyplatinate was tested for its ability to induce chromosome damage in the form of micronuclei. Following two range-finding studies, Chinese hamster ovary (CHO) cells were treated with the test substance (in 1% methyl cellulose) for 3 hours (with a 21-hr recovery phase) in the presence and absence of rat liver (S9) metabolic activation, or for 24 hr in the absence of S9 alone. The maximum assessed concentrations, limited by precipitation of the test material, were 100 and 70 µg/ml for cells treated for 3 and 24 hr, respectively. For the 3-hr treatment in the presence of S-9, there was clear evidence of chromosome damage from the lowest tested concentration (20 µg/ml). In the absence of S9, results were ambiguous – statistically significantly higher incidences of micronuclei were observed relative to the vehicle control, but incidences were generally within the normal historical control range. The results from the 24-hour continuous treatment were not considered reliable; no significant genotoxicity was seen for the test substance or for the positive control. Nevertheless, results from the 3-hour treatment were considered sufficient to conclude that dihydrogen hexahydroxyplatinate is clastogenic under the conditions of this assay (Lloyd, 2014).

In a combined in vivo micronucleus test and Comet assay in rats, dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, administered by gavage at doses of 500, 1000 or 2000 mg/kg bw/day for three days did not cause an increased incidence of micronucleated polychromatic erythrocytes. Treatment also gave no evidence of DNA damage in the liver, kidney, glandular stomach or duodenum when assessed by the Comet procedure. As such, the test item was considered to be non-genotoxic in vivo (Eurlings, 2020). These data are considered valid for dihydrogen hexahydroxyplatinate via a read-across approach (cfr. IUCLID Section 13).

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 (DECOS, 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 (DECOS, 2008). Limited experimental data on carcinogenicity for other platinum compounds give no evidence of activity that would meet classification criteria (DECOS, 2008; SCOEL, 2011).

Following 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) and the unclear in vivo relevance of these in vitro findings, a combined in vivo micronucleus test and Comet assay in rats (with dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol) did not cause an increased incidence of micronucleated polychromatic erythrocytes and gave no evidence of DNA damage in the liver, kidney, glandular stomach or duodenum when assessed by the Comet procedure (Eurlings, 2020).

References

DECOS (2008). Dutch Expert Committee on Occupational Standards. Platinum and Platinum Compounds. Health-based recommended occupational exposure limit. Gezondheidsraad, 2008/12OSH. <https://www.gezondheidsraad.nl/en/publications/gezonde-arbeidsomstandigheden/platinum-and-platinum-compounds-health-based-recommended>

EMA (2008). European Medicines Agency. Guideline on the specification limits for residues of metal catalysts or metal reagents. Committee for Medicinal Products for Human Use (CHMP). EMEA/CHMP/SWP/4446/2000. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003586.pdf

SCOEL (2011). Recommendation from the Scientific Committee on Occupational Exposure Limits for platinum and platinum compounds. SCOEL/SUM/150. <http://ec.europa.eu/social/BlobServlet?docId=7303&langId=en>

WHO (1991). World Health Organization. Platinum. International Programme on Chemical Safety. Environmental Health Criteria 125. <http://www.inchem.org/documents/ehc/ehc/ehc125.htm#SectionNumber:7.4>

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 5.8. Studies on fertility

Method	Results	Remarks
rat (Crj: CD(SD) [rat]) male/female toxicity to reproduction [deactivated phrase] - other: combined repeated dose and reproduction / developmental screening oral: gavage Doses / Concentrations: 100 mg/kg bw/day Basis: actual ingested Doses / Concentrations: 300 mg/kg bw/day Basis: actual ingested Doses / Concentrations: 1000 mg/kg bw/day Basis: actual ingested 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 58 for the last sacrificed female). (Once daily.) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	First parental generation (P0) NOAEL (PO) 1000 mg/kg bw/day (actual dose received) (male/female) based on: No general systemic or reproductive effects seen at highest tested dose F1 generation NOAEL : 1000 mg/kg bw/day (actual dose received) (male/female) based on: No general systemic effects seen in the F1 generation at 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 hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid: particulate/powder - migrated information: powder (full information in Annex II). Reference Hansen B 2015

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 5.9. 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 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 58 for the last sacrificed female). (Once daily.) according to OECD Guideline 422 (Combined repeated dose and reproduction / developmental screening)	Maternal animals: NOAEL: 1000 mg/kg bw/day (actual dose received) based on: (test mat.) Fetuses: Fetal abnormalities not specified NOAEL: 1000 mg/kg bw/day (actual dose received) based on: (test mat.) Overall developmental toxicity: not specified Lowest effective dose / concentration: Relation to maternal toxicity:	1 (reliable without restriction) key study experimental study Test material hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid: particulate/powder - migrated information: powder (full information in Annex II). Reference Hansen B 2015

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 422 combined repeated dose and reproductive/developmental toxicity screening study in rats, involving the gavage administration of dihydrogen hexahydroxyplatinate for at least 35 days (including 2-weeks pre-mating and throughout mating), no effects on any measured reproductive or fertility parameters were observed. The systemic and reproductive NOAEL was the highest tested dose (1000 mg/kg bw/day) (Hansen, 2015).

Value used for CSA (route: oral):

no adverse effect observed (NOAEL): 1000mg/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.

In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, CD rats (12/sex/group) were orally administered dihydrogen hexahydroxyplatinate by stomach tube (gavage) at doses of 0, 100, 300 or 1000 mg/kg bw/day. Males were dosed for 35 days (2 weeks pre-mating, during the mating period and for approximately 2 weeks post-mating). Females were dosed for 14 days pre-mating, through mating, gestation and up to post-partum day 3 (test day 41-58). There were no reported changes to reproductive parameters (including number of corpora lutea, implantation sites, number of pups, fertility and gestation indices, birth index and pre- and post-implantation losses). The systemic and reproductive NOAEL was the highest tested dose (1000 mg/kg bw/day) (Hansen, 2015).

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 422 combined repeated dose and reproductive/developmental toxicity screening study in rats, involving the gavage administration of dihydrogen hexahydroxyplatinate for at least 35 days (including, for females, throughout mating, gestation and up to post-natal day 3), no signs of developmental toxicity or any adverse effects on pups were observed. The study NOAEL for developmental toxicity/embryotoxicity was the highest tested dose (1000 mg/kg bw/day) (Hansen, 2015).

Value used for CSA (route: oral):

no adverse effect observed (NOAEL): 1000mg/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.



In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, CD rats (12/sex/group) were orally administered dihydrogen hexahydroxyplatinate by stomach tube (gavage) at doses of 0, 100, 300 or 1000 mg/kg bw/day. Males were dosed for 35 days (2 weeks pre-mating, during the mating period and for approximately 2 weeks post-mating). Females were dosed for 14 days pre-mating, through mating, gestation and up to post-partum day 3 (test day 41-58). There were no reported clinical signs of toxicity in the dams, and no gross pathological changes to the pups that were attributed to treatment. The study NOAEL for developmental toxicity was the highest tested dose (1000 mg/kg bw/day) (Hansen, 2015).

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

Justification for classification or non classification:

No adverse effects on reproductive parameters (sexual function or fertility) or development of offspring were seen in a reliable guideline combined repeated dose toxicity study and reproductive/developmental toxicity screening study with dihydrogen hexahydroxyplatinate. As such, classification 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 5.10. 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	no adverse effect observed
Acute toxicity	dermal	no study available
Acute toxicity	inhalation	no study available
Irritation / Corrosivity	skin	no adverse effect observed (not irritating)
Irritation / Corrosivity	eye	adverse effect observed (irritating)
Irritation / Corrosivity	resp. tract	no study available
Sensitisation	skin	no adverse effect observed (not sensitising)
Sensitisation	resp. tract	no study available
Repeated dose toxicity	oral	no adverse effect observed (NOAEL): 1000mg/kg bw/day (subacute; rat [common rodent species])
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 adverse effect observed
Reproductive toxicity: effects on fertility	oral	no adverse effect observed (NOAEL): 1000mg/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): 1000mg/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 5.11. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.31mg/m ³	repeated dose toxicity (Oral)
Inhalation	Systemic effects - Acute	no hazard identified	
Inhalation	Local effects - Long-term	no hazard identified	
Inhalation	Local effects - Acute	no hazard identified	
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.43mg/kg bw/day	repeated dose toxicity (Oral)
Dermal	Systemic effects - Acute	no hazard identified	
Dermal	Local effects - Long-term	no hazard identified	
Dermal	Local effects - Acute	no hazard identified	
Eyes	Local effects	low hazard (no threshold derived)	

Inhalation Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEC

Overall Assessment Factor: 75

AF for dose response relationship: 1 (Default ECHA AF; NOAEL from a well-conducted combined repeated-dose with reproductive/developmental toxicity screening study, conducted by the oral route; the highest dose was set at 1000 mg/kg bw/day)

AF for difference in duration of exposure: 6 (Default ECHA AF for subacute (28-day) to chronic extrapolation.)

AF for interspecies differences (allometric scaling): 1 (Default ECHA AF for rat for toxicokinetic differences in metabolic rate (allometric scaling) is not required)

AF for other interspecies differences: 2.5 (Default ECHA AF for remaining toxicokinetic differences (not related to metabolic rate) and toxicodynamic differences)

AF for intraspecies differences: 5 (Default ECHA AF for (healthy) worker)

AF for the quality of the whole database: 1 (Default ECHA AF; the human health effects data are reliable and consistent, and confidence in the database is high.)

AF for remaining uncertainties: 1 (Not required)

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

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEL

Overall Assessment Factor: 75

AF for dose response relationship: 1 (Default ECHA AF; NOAEL from a well-conducted combined repeated-dose with reproductive/developmental toxicity screening study, conducted by the oral route; the highest dose was set at 1000 mg/kg bw/day)

AF for difference in duration of exposure: 6 (Default ECHA AF for subacute (28-day) to chronic extrapolation.)

AF for interspecies differences (allometric scaling): 1 (Default ECHA AF for rat for toxicokinetic differences in metabolic rate (allometric scaling) is not required)

AF for other interspecies differences: 2.5 (Default ECHA AF for remaining toxicokinetic differences (not related to metabolic rate) and toxicodynamic differences)

AF for intraspecies differences: 5 (Default ECHA AF for (healthy) worker)

AF for the quality of the whole database: 1 (Default ECHA AF; the human health effects data are reliable and consistent, and confidence in the database is high.)

AF for remaining uncertainties: 1 (Not required)

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 of humans or laboratory animals to dihydrogen hexahydroxyplatinate are available, route-to-route extrapolation to calculate an inhalation DNEL from a combined repeated-dose with reproductive/developmental toxicity screening by the oral route was considered a suitable alternative method (particularly as first pass effects are not expected to be significant for an inorganic compound).

In the combined study, conducted according to OECD Test Guideline (TG) 422 and GLP, rats (12/sex/group) received dihydrogen hexahydroxyplatinate (in corn oil) by gavage at doses of 0, 100, 300 or 1000 mg/kg bw/day. Males were dosed from test days 1-35 (inclusive), while 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 58 for the last sacrificed female). There were no reported test-item-related effects on body weight, food/water consumption, haematological and clinical chemistry parameters, or on the organs subjected to gross or histopathological examination. Likewise, there were no differences in the measured reproductive parameters, and no gross pathological changes to the pups that were attributed to treatment. Thus, the NOAEL for systemic, reproductive and developmental toxicity was set at 1000 mg/kg bw/day, the highest dose tested (Hansen, 2015). This equates to a NOAEL of 652.14 mg/kg bw/day when expressed as elemental platinum based on MWt ratios[1].

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 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).

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 dihydrogen hexahydroxyplatinate, the corrected inhalatory NOAEC (worker, 8 h exposure/day) = oral NOAEL*(1/sRV[rat])*(ABS[oral-rat]/ABS[inh-human]) *(sRV[human]/wRV) = 1000 mg/kg bw/day*(1/0.38 m³/kg bw/day)*(0.5/100)*(6.7 m³ [8h]/10 m³ [8h]) = 8.82 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 = 8.82*4 = 35.26 mg/m³.

Application of the assessment factors (overall AF 75, described above) to this corrected inhaled NOAEC gives a systemic long-term inhalation DNEL for dihydrogen hexahydroxyplatinate of 0.47 mg/m³, which equates to an elemental platinum exposure of 0.31 mg/m³ (306.6 µg/m³).

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 dihydrogen hexahydroxyplatinate. In a guideline (OECD TG 401) acute oral toxicity study in rats (5/sex/group), an LD₅₀ value >2150 mg/kg bw was reported for dihydrogen hexahydroxyplatinate (referred to in the study report as "hexahydroxoplatinum(IV) acid", with CAS RN 52438-26-3)[2]. There were no deaths or other clinical signs of toxicity within a 14-day observation period (Berthold, 1995a). It was concluded that dihydrogen hexahydroxyplatinate does not require classification for its acute oral toxicity.

"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). However, dihydrogen hexahydroxyplatinate is not classified for acute toxicity according to CLP, so a qualitative assessment is not required.



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

There are no data in relation to respiratory tract irritation or sensitisation of dihydrogen hexahydroxyplatinate in humans or laboratory animals; the compound is not considered a significant skin (or respiratory) sensitiser based on a cytokine fingerprinting assay in mice (Dearman and Kimber, 2011). Consequently, no worker-DNELs for long-term or acute local effects in the respiratory tract have been calculated. Further, dihydrogen hexahydroxyplatinate is not considered a skin irritant.

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

As no relevant data on effects of repeated dermal exposure of humans or laboratory animals to dihydrogen hexahydroxyplatinate are available, route-to-route extrapolation to calculate a dermal DNEL from a combined repeated-dose with reproductive/developmental toxicity screening study by the oral route was considered a suitable alternative method (particularly as first pass effects are not expected to be significant for an inorganic compound). This study has been described in detail above [“Hazard via inhalation route: systemic effects following long-term exposure”] (Hansen, 2015).

The oral NOAEL of 1000 mg/kg bw/day, based on the lack of adverse general systemic, reproductive or developmental effects, was taken as the health-precautionary critical point of departure for calculating the long-term systemic dermal DNEL for dihydrogen hexahydroxyplatinate. This equates to a NOAEL of 652.14 mg/kg bw/day for elemental platinum (based on MWt ratios).

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 et al., 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 soluble platinum salt, 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 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.

In the absence of high-quality data for dermal absorption, default guidance allows for the estimation of dermal absorption based on other relevant available information (mainly water solubility, molecular weight and log Pow) and expert judgement. Dihydrogen hexahydroxyplatinate is reported to have aqueous solubility of



<10 mg/L (Gregory, 2014), and therefore may be able to cross the lipid-rich environment of the stratum corneum to a “low to moderate” extent. Guidance on the health risk assessment of metals indicates that considerations based on physico-chemical properties do not apply to these substances (“as inorganic compounds require dissolution involving dissociation to metal cations prior to being able to penetrate skin by diffusive mechanisms”) (ICMM, 2007).

Experimental dermal penetration data (human in vitro studies) for a chloroplatinate substance indicated about 5-8% dermal absorption. Therefore, an assumption of 100% uptake seems to be unduly conservative. It is deemed suitably health precautionary to take forward the lower of the two ECHA default values for dermal absorption, 10%, for the safety assessment of dihydrogen hexahydroxyplatinate.

Dose descriptor starting point (after route to route extrapolation) = $\text{NOAEL} * (\text{ABS}[\text{oral-rat}] / \text{ABS}[\text{der-human}])$
= $1000 \text{ mg/kg bw/day} * (0.5\% / 10\%) = 50 \text{ mg/kg bw/day}$.

Application of the assessment factors (overall AF 75) described above to this corrected dermal NOAEL gives a systemic long-term dermal DNEL for dihydrogen hexahydroxyplatinate of 0.67 mg/kg bw/day, which equates to a platinum exposure of 0.43 mg/kg bw/day.

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

Although hexahydroxyplatinate (CAS RN 52438-26-3) at high concentration demonstrated a mild proliferative response using a conventional Local Lymph Node Assay (LLNA) approach (40% and 80% HHPA in DMF gave a Stimulation Index (SI) of 5.4 and 5.7, respectively), the more sophisticated detailed cytokine fingerprinting assay indicated that it was not a significant skin (or respiratory) sensitiser, demonstrating a cytokine profile similar to that of the recognised non-sensitiser tetraammine platinum dichloride (TPC). While this study was well-conducted and reported, and appears scientifically reliable, it was not conducted according to GLP or OECD Test Guideline 429 (Dearman and Kimber, 2011).

Two in vitro EPISKIN studies of dihydrogen hexahydroxyplatinate’s skin corrosion/irritation potential have been carried out.

In the first study, conducted according to OECD Test Guideline 431, 20 mg of the solid test material was applied to the surface of a reconstructed human epidermis, followed by 10 µL sodium chloride solution. Exposure lasted 4 hours, after which time the viability of the exposed cells was determined by the MTT assay to be 82% of the negative control cells. As a mean cell viability of $\leq 35\%$ of the negative control is required for a test substance to be considered corrosive, dihydrogen hexahydroxyplatinate was considered to be non-corrosive to skin (Kiss, 2012a).

In a follow-up study, conducted according to OECD Test Guideline 439, 20 mg of the solid test material was applied to the surface of a reconstructed human epidermis immediately following the application of 10 µL distilled water (to ensure good contact with the epidermis). After 15 minutes’ exposure, the cells were washed and incubated in a “maintenance medium” for 42 hours. The viability of the exposed cells was again determined



by the MTT assay, with viability reported to be 82% of the negative control cells. As a mean cell viability of $\leq 50\%$ of the negative control is required for a test substance to be considered irritating, dihydrogen hexahydroxyplatinate was considered to be non-irritant to skin (Kiss, 2012b).

The evidence from studies on dihydrogen hexahydroxyplatinate indicates that classification as a skin irritant or skin sensitiser, according to the CLP regulation, is not required.

Hazard for the eyes

Dihydrogen hexahydroxyplatinate (referred to in the study report as “hexahydroxoplatinum(IV) acid, with CAS RN 52438-26-3”) was instilled into the eyes of 3 New Zealand white rabbits in a well-reported study conducted in accordance with OECD Test Guideline 405 and to GLP. Effects on the iris were seen in one animal at 1 hour (slight circumcorneal hyperemia), and in another animal at 24 and 48 hours (moderate circumcorneal hyperemia). Effects on the conjunctiva were seen in all animals. Notably, in one animal, these were moderate/severe, with maximum scores for discharge and redness reported for at least one time point within the observation period. Indeed, the maximum observed score for conjunctival chemosis (swelling) in this animal was 3 (of a maximum of 4 on the Draize scale). All effects on the iris and conjunctivae were, however, fully reversible within 4 days. No corneal effects (opacity) were observed in any animal. The primary irritation index calculated for all animals was 6, indicating that the substance would be “non-irritant” if graded using a modified method according to Gilman et al. (as the study report has done) (Berthold, 1995b).

Given the pronounced variability between the scores in the animals tested, and the severity of the effects observed, it is considered health precautionary to adopt a Category 2 classification for dihydrogen hexahydroxyplatinate according to the EU CLP Regulation (EC 1272/2008). Accordingly, it is placed in the low hazard band for effects on the eye, and the appropriate RMMs and OCs in Table E3-1 of ECHA (2012b) should be considered.

[1]MWts: Pt metal, 195.08 g mol⁻¹; Dihydrogen hexahydroxyplatinate, 299.14 g mol⁻¹

[2]According to ChemIDPlus, the CAS in this study report corresponds to “diaquatetrahydroxyplatinum”. The name dihydrogen hexahydroxyplatinate (synonyms hexahydroxoplatinum(IV) acid and hexahydroxyplatonic acid) corresponds to CAS 51850-20-5. This apparent discrepancy within the study report between CAS and name is inconsequential as these are equivalent from a toxicological perspective.

Table 5.12. 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	low 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 dihydrogen hexahydroxyplatinate. In all uses with potential consumer exposure due to service life of articles, dihydrogen hexahydroxyplatinate 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 dihydrogen hexahydroxyplatinate has not been performed as the registered substance is manufactured/imported/marketed at <100 tpa and is not classified as STOT-RE 1 or 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: Dihydrogen hexahydroxyplatinate

Related composition: Dihydrogen hexahydroxyplatinate - 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 equivalent or similar to EC No 1272/2008 Method N.1 of the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, fifth revised edition 2009	Evaluation of results: non flammable - Migrated information 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 51820-20-5; Dihydrogen hexahydroxyplatinate (hydrated solid), Form: not specified (full information in Annex II). Reference Walker JA, White DF 2011
flammable solids according to UN-Test N.1, UN Recommendations on the Transport of Dangerous Goods, Tests and Criteria, fifth revised edition, 2009.	Evaluation of results: non flammable - Migrated information Study results: Flammable gasses (lower and upper explosion limits): Aerosols: Flammable solids: burning rate test: preliminary screening test (Hexahydroxy platinic acid could not be ignited with the gas burner.	2 (reliable with restrictions) supporting study experimental study Test material hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: Solid (full information in



	Heating time was 2 minutes) Pyrophoric solids: Pyrophoric liquid: Self-heating substances/mixtures: Substances/ mixture which in contact with water emit flammable gases:	Annex II). Reference Michael-Schultz H 2012
--	---	--

Discussion

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

Flammability

Key value for chemical safety assessment: Flammability: non flammable

Dihydrogen hexahydroxyplatinate is not classified as a flammable solid under Division 4.1.

Additional information:

Walker & White (2011) is a GLP compliant, guideline study considered suitable for use as the key study for this endpoint. Dihydrogen hexahydroxyplatinate (hydrated solid) is not classified as a flammable solid under Division 4.1. Michael-Schulz (2012) is a guideline experiment study that is not GLP compliant, but is otherwise adequate for assessment. On the basis of the test results, dihydrogen hexahydroxyplatinate is not a flammable solid.

Flash Point

No relevant information available.

Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: Dihydrogen hexahydroxyplatinate

Related composition: Dihydrogen hexahydroxyplatinate - 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

6.3. Oxidising potential

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

Table 6.2. Information on oxidising potential

Method	Results	Remarks
oxidising solids Contact with: powdered cellulose (min) according to UN-Test O.1, UN Recommendations on the Transport of Dangerous Goods, Tests and Criteria, fifth revised edition, 2009.	Evaluation of results: no oxidising properties - Migrated information Test results: Oxidising solids: 1:1 sample-to-cellulose ratio: burning rate: 225.6 s (t1 result. 1:1 ratio of test item:cellulose (% by mass); Mean burning times of test mixture; 225.6 s, n = 5) 4:1 sample-to-cellulose ratio: burning rate: >240 s (t2 result. 4:1 ratio of test item:cellulose (% by mass); Mean	2 (reliable with restrictions) key study experimental study Test material Hexahydroxy Platonic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: Solid (full



		burning times of test mixture; > 240 s, n = 5)						information in Annex II).
		Remarks:						Reference
		Hexahydroxy Platinic Acid (2.23/090212/01)						Michael-Schultz H 2012
		The sample was used as delivered.						
Mi xt ur e rat io sa m ple : cel lul os e [by ma ss]	Bu rni ng ti me [s]	M ea n bu rni ng ti me [s]						
	1: 1 1	> 24 0	> 24 0	2 14 .8	2 24 .0	2 09 .4	t1 : 22 5. 6	
Bu rn- off wi th fla me s an d for ma tio n of sm ok e								
	4. 1 1	> 24 0	> 24 0	> 24 0	> 24 0	> 24 0	t2: > 24 0	
B ur								



	n-off with flames						
	Reference mixtures (measured 14 September 2011)						
	Ratios of potassium bromate : Cellulose [by mass]	Burn- ing time [s]	Mean burning times [s]				
3:7	126.0	132	114.2	134.0	135.0	R1 : 127.9	
	Burn-off with yellow flames						

Discussion



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

Dihydrogen hexahydroxyplatinate is not an oxidising solid according to the criteria specified in the Regulation (EC) No 1272/2008 (CLP-/GHS-Regulation).

Value used for CSA:

Oxidising properties: no

Additional information:

Michael-Schulz (2012) is a guideline experimental study and is not GLP compliant, but is otherwise adequate for assessment. On the basis of the test results and according to the criteria specified in the Regulation (EC) No 1272/2008 (CLP-/GHS-Regulation) dihydrogen hexahydroxyplatinate is not an oxidising solid.

Classification according to GHS

Name: Dihydrogen hexahydroxyplatinate

Related composition: Dihydrogen hexahydroxyplatinate - 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



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 Biagiante-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 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



		<p>Test material Hexachloroplatinic acid (hydrate) / 26023-84-7, (full information in Annex II).</p> <p>Reference Okamoto A et al 2015</p>
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	<p>2 (reliable with restrictions) key study experimental study</p> <p>Test material Hexachloroplatinic acid, Form: Resin (full information in Annex II).</p> <p>Reference Zimmermann S et al 2017</p>

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	<p>2 (reliable with restrictions) key study experimental study</p> <p>Test material Hexachloroplatinic acid, (full information in Annex II).</p> <p>Reference Biesinger KE, Christensen GM 1972</p>

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
<p>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]</p>	<p>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)</p>	<p>1 (reliable without restriction) key study experimental study</p> <p>Test material Hexahydroxyplatonic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid: crystalline (full information in Annex II).</p> <p>Reference Wenzel A 2014</p>
<p>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)</p>	<p>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)</p>	<p>1 (reliable without restriction) key study experimental study</p> <p>Test material 16941-12-1 / 241-010-7, Form: liquid (full information in Annex II).</p> <p>Reference Pawlowski S and Wydra V 2005</p>



	<p>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</p>	
<p>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)</p>	<p>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</p>	<p>1 (reliable without restriction) key study experimental study</p> <p>Test material 16941-12-1 / 241-010-7, Form: solid (full information in Annex II).</p> <p>Reference Mead C, Mullee DM 2001</p>
<p>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]</p>	<p>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 = .045 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 =</p>	<p>1 (reliable without restriction) key study experimental study</p> <p>Test material Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, (full information in Annex II).</p> <p>Reference Wenzel A 2016</p>



	<p>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.)</p>	
<p>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)</p>	<p>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)</p>	<p>2 (reliable with restrictions) key study experimental study</p> <p>Test material Platinum(IV) chloride, (full information in Annex II).</p> <p>Reference Sorensen S et al 2016</p>
<p>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)</p>	<p>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)</p>	<p>2 (reliable with restrictions) key study experimental study</p> <p>Test material Platinum(IV) chloride, (full information in Annex II).</p> <p>Reference</p>



		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 Hexahydroxyplatonic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid: crystalline (full information in Annex II). Reference Muckle M 2014



	<p>EC50 (3h): >1000 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration</p> <p>EC50 (3h): >648 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration</p>	
<p>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)</p>	<p>EC10 (3h): 2.35 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 2.15 - 2.55 mg/L)</p> <p>NOEC (3h): 3.2 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate</p> <p>NOEC (3h): 1.26 mg/L element - Pt (nominal) based on: inhibition of total respiration</p> <p>NOEC (3h): 10 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration</p> <p>NOEC (3h): 3.92 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration</p> <p>EC10 (3h): 6 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 5.5 - 6.5 mg/L)</p> <p>EC10 (3h): 8.2 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 6.0 - 11 mg/L)</p> <p>EC10 (3h): 3.21 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 2.35 - 4.31 mg/L)</p> <p>EC50 (3h): 103 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 96 - 110 mg/L)</p> <p>EC50 (3h): 40.33 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 37.58 - 43.065 mg/L)</p> <p>EC50 (3h): 83 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 76 - 91 mg/L)</p> <p>EC50 (3h): 32.49 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 29.75 - 35.63 mg/L)</p>	<p>1 (reliable without restriction) key study experimental study</p> <p>Test material Hexachloroplatinic acid, Form: Resin (full information in Annex II).</p> <p>Reference Muckle M 2015</p>
<p>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</p>	<p>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.)</p> <p>NOEC (3h): 60 mg/L test mat. (nominal) based on: inhibition of total respiration (Without ATU.)</p> <p>NOEC (3h): 10.29 mg/L element - Pt (nominal) based on: inhibition of total</p>	<p>1 (reliable without restriction) key study experimental study</p> <p>Test material Dihydrogen hexahydroxyplatinat e, compound with 2-</p>



Test)	<p>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.)</p>	<p>amino-ethanol, Form: liquid (full information in Annex II).</p> <p>Reference Muckle M 2016</p>
-------	--	--

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 hexahydroxyplatinate 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 respesiate 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.**

	Molecular formula	MW	Pt (wt%)	Classification using category data	Classification using substance specific data						
				Acute ERV (µg Tl/L)	Chronic ERV (µg Tl/L)	Aq Acute classif	Aq Chron classif	Acute ERV (µg Tl/L)	Chronic ERV (µg Tl/L)	Aq Acute classif	Aq Chron classif
Diammonium hexachloroplatinate	(NH ₄) ₂ [PtCl ₆]	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	K ₂ [PtCl ₆]	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	H ₂ [PtCl ₆]	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	H ₂ [Pt(OH) ₆]	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-C ₂ H ₄ -NH ₃) ₂ Pt(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 $>0.01 \leq 0.1$ 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 $>0.1 \leq 1$ 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-1 for 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 $>0.01 \leq 0.1$ 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 $>0.1 \leq 1$ 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 $>0.1 \leq 1$ 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:

dihydrogen hexahydroxyplatinate. View the assessment entity table in chapter 1.3 [here](#);

Pt 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	<ul style="list-style-type: none">100% Pt dissolved	Relevant for the assessment of contributing scenarios for: - Environment and Man via environment Method for calculating the RCR across the AEs: Summed RCR
HHPA for OCC RA	<ul style="list-style-type: none">100% dihydrogen hexahydroxyplatinate	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 2.1 (ERC 6a)		0.091	30
	- Use as an intermediate ES 2.2 (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 dissolved	Quantitative	PNEC aqua (freshwater) = 0.14 µg/L
Sediment (freshwater)	Pt dissolved	Quantitative	PNEC sediment (freshwater) = 0.261 mg/kg sediment dw
Marine water	Pt dissolved	Quantitative	PNEC aqua (marine water) = 0.014 µg/L
Sediment (marine water)	Pt dissolved	Quantitative	PNEC sediment (marine water) = 0.026 mg/kg sediment dw
Sewage Treatment Plant	Pt dissolved	Quantitative	PNEC STP = 235 µg/L
Air	Pt dissolved	Not needed	No hazard identified
Agricultural soil	Pt dissolved	Quantitative	PNEC soil = 5.23E-3 mg/kg soil dw
Predator's prey (freshwater)	Pt dissolved	Not needed	No potential for bioaccumulation
Predator's prey (marine water)	Pt dissolved	Not needed	No potential for bioaccumulation
Top predator's prey (marine water)	Pt dissolved	Not needed	No potential for bioaccumulation
Predator's prey (terrestrial)	Pt 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 dissolved
Molecular weight	≥ 195.0
Molecular weight used for the assessment	195.0
Melting point at 101 325 Pa	145 °C
Vapour pressure	1E-12 Pa at 20 °C
Water solubility	10 mg/L
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-	3.27



Substance property	Pt dissolved
water in raw sewage sludge)	
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

Caution: The exposure estimates have been obtained with EUSES although the following parameter(s) is/are outside the boundaries of the EUSES model:

- Vapour pressure (of assessment entities Pt dissolved)

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 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: dihydrogen hexahydroxyplatinate.

The fractions reported in the above table have been set by the assessor for some assessment entities.

Explanation for Pt 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.

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	dihydrogen hexahydroxyplatinate	Quantitative	DNEL (Derived No Effect Level) = 0.31 mg/m ³
	Systemic effects - acute	dihydrogen hexahydroxyplatinate	Not needed	No hazard identified
	Local effects - long term	dihydrogen hexahydroxyplatinate	Not needed	No hazard identified
	Local effects - acute	dihydrogen hexahydroxyplatinate	Not needed	No hazard identified
Dermal	Systemic effects - long term	dihydrogen hexahydroxyplatinate	Quantitative	DNEL (Derived No Effect Level) = 0.43 mg/kg bw/day
	Systemic effects - acute	dihydrogen hexahydroxyplatinate	Not needed	No hazard identified
	Local effects - long term	dihydrogen hexahydroxyplatinate	Not needed	No hazard identified
	Local effects - acute	dihydrogen hexahydroxyplatinate	Not needed	No hazard identified
Eye	Local effects	dihydrogen hexahydroxyplatinate	Qualitative	Low hazard (no threshold derived)

9.0.4.2. Comments on assessment approach for workers

**Assessment approach related to toxicological hazard:**

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) contaminated 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).

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 not part of this assessment 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.

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.

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	Calcination in fully contained systems	PROC 1
CS 18	Calcination in partly enclosed systems	PROC 22
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:

Hexachloroplatinic acid solution is mixed with sodium hydroxide solution and boiled to form a solution of sodium hexahydroxyplatinate. This is then treated with acetic acid to precipitate hexahydroxyplatinate which is then filtered 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 <i>46.0 tonnes dihydrogen hexahydroxyplatinate (30 tonnes Pt metal equivalent); 90P from sector data</i>



<ul style="list-style-type: none"> Daily use amount at site: ≤ 0.091 tonnes/day <i>Based on 330 days per year (50P from sector data)</i>
Conditions and measures related to biological sewage treatment plant
<ul style="list-style-type: none"> Biological STP: Site specific [Effectiveness Water: 57.1%] Discharge rate of STP: $\geq 3E3$ m³/day Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
<ul style="list-style-type: none"> Particular considerations on the waste treatment operations: No (low amount) <i>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.</i> <i>Fraction of daily/annual use expected in waste: 0%</i> <i>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</i> <i>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%</i> <i>A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2016)</i>
Other conditions affecting environmental exposure
<ul style="list-style-type: none"> Receiving surface water flow rate: $\geq 9.3E4$ 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 dissolved
Release to water	42.9%
Release to air	0%
Release to sludge	57.1%
Release degraded	0%

Explanation for Pt 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 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 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 dissolved	Estimated release factor	Release factor after on site RMM: 0% Explanation: No direct emissions to soil.

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 dissolved	Local PEC: 4.74E-6 mg/L RCR = 0.034	Final RCR = 0.034
Sediment (freshwater)	Pt dissolved	Local PEC: 8.84E-3 mg/kg dw RCR = 0.034	Final RCR = 0.034
Sewage Treatment Plant	Pt dissolved	Local PEC: 1.55E-4 mg/L RCR = 6.59E-4	Final RCR < 0.01
Agricultural soil	Pt 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)
<ul style="list-style-type: none"> Annual use amount at site: <= 30 tonnes/year <i>46.0 tonnes dihydrogen hexahydroxyplatinate (30 tonnes Pt metal equivalent); 90P from sector data</i> Daily use amount at site: <= 0.091 tonnes/day <i>Based on 330 days per year (50P from sector data)</i>
Conditions and measures related to biological sewage treatment plant
<ul style="list-style-type: none"> Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)
<ul style="list-style-type: none"> Particular considerations on the waste treatment operations: No (low amount) <i>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.</i> <i>Fraction of daily/annual use expected in waste: 0%</i> <i>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</i> <i>Suitable disposal: Hazardous waste produced during the manufacture and downstream use is sent to a</i>



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: $\geq 3E6$ m ³ /day
• Discharge to: Freshwater only
• Discharge rate of effluent: $\geq 3E3$ m ³ /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 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 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 dissolved	Estimated release factor	Release factor after on site RMM: 0% Explanation: No direct emissions to soil.

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 dissolved	Local PEC: 3.83E-7 mg/L RCR = 2.74E-3	Final RCR < 0.01
Sediment (freshwater)	Pt dissolved	Local PEC: 7.14E-4 mg/kg dw RCR = 2.74E-3	Final RCR < 0.01
Agricultural soil	Pt 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: HHPA 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 <i>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.</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Exterior exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Partly contained systems <i>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.</i>	
• 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 <i>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.</i>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	3.63 µg/m ³ (Measured data: Analogous data) RCR = 0.012	Final RCR = 0.012
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 0.07	Final RCR = 0.07
Combined routes, systemic, long-term			Final RCR = 0.081

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

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.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA 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 <i>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.</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Exterior exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Containment due to physical form	



	Method
<i>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.</i>	
• 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 <i>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.</i>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	0.38 µg/m ³ (Measured data: Analogous data) RCR = 1.23E-3	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 0.07	Final RCR = 0.07
Combined routes, systemic, long-term			Final RCR = 0.071

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

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 (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA for OCC RA

9.1.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid <i>Solution, suspension</i>	
• Maximum emission potential of the substance: Very low <i>It is noted that spraying operations are not covered in this assessment.</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Partly contained systems <i>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.</i>	
• 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 <i>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.</i>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	



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	dihydrogen hexahydroxyplatinate	0.38 µg/m ³ (Measured data: Analogous data) RCR = 1.23E-3	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 2.33E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

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 (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA for OCC RA

9.1.6.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown <i>Not relevant (fully contained systems)</i>	
• Maximum emission potential of the substance: Unknown <i>Not relevant (fully contained systems)</i>	
• 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	



	Method
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• Potential for contamination <i>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.</i>	
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%] <i>Precautionary measure as gloves are not needed to demonstrate safe use.</i>	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	0.01 µg/m ³ (Measured data: Pt monitoring database) RCR = 3.23E-5	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 9.3E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate:

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 dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA 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 <i>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.</i>	
• 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: - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Partly contained systems <i>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.</i>	
• 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 <i>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.</i>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	3.25 µg/m ³ (Measured data: Analogous data) RCR = 0.01	Final RCR = 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	0.3 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 0.698	Final RCR = 0.698
Combined routes, systemic, long-term			Final RCR = 0.708

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

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.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA for OCC RA

9.1.8.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid <i>Solution, suspension</i>	
• Maximum emission potential of the substance: Very low <i>It is noted that spraying operations are not covered in this assessment.</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Containment due to physical form <i>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</i>	



	Method
<i>possible, easy maintenance should be allowed by system design.</i>	
<ul style="list-style-type: none"> 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). 	
<ul style="list-style-type: none"> Removal of residuals: Splashes <i>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.</i> 	
<ul style="list-style-type: none"> Dermal pattern of use: Non-dispersive use 	
<ul style="list-style-type: none"> Dermal pattern of exposure control: Direct handling 	
<ul style="list-style-type: none"> Dermal contact level: Intermittent 	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> 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%] 	
<ul style="list-style-type: none"> Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i> 	
<ul style="list-style-type: none"> Respiratory protection: No [Effectiveness Inhalation: 0%] 	

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	dihydrogen hexahydroxyplatinate	0.08 µg/m ³ (Measured data: Analogous data) RCR = 2.58E-4	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 0.07	Final RCR = 0.07
Combined routes, systemic, long-term			Final RCR = 0.07

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

Identity of the substance used: ClPt

Inhalation exposure, long term concentration: Number of measured data points: 2 ; GSD: 5.1

Explanation: The estimated exposure level represents the maximum value multiplied with 1.5 of the exposure distribution for estimate #06 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA for OCC RA

9.1.9.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown <i>Not relevant (fully contained systems)</i>	
• Maximum emission potential of the substance: Unknown <i>Not relevant (fully contained systems)</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• 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 <i>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.</i>	
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%] <i>Precautionary measure as gloves are not needed to demonstrate safe use.</i>	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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,	dihydrogen	0.01 µg/m ³ (Measured data: Pt monitoring)	Final RCR < 0.01



Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
long term	hexahydroxyplatinate	database) RCR = 3.23E-5	
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 9.3E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate:

Identity of the substance used: All

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 dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA for OCC RA

9.1.10.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid <i>Solution, suspension</i>	
• Maximum emission potential of the substance: Very low <i>It is noted that spraying operations are not covered in this assessment.</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Partly contained systems <i>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.</i>	
• Level of automation: As high as possible to reduce potential for exposure. This is	



	Method
inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (see the dermal exposure pattern below).	
<ul style="list-style-type: none"> Removal of residuals: Splashes <i>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.</i> 	
<ul style="list-style-type: none"> Dermal pattern of use: Non-dispersive use 	
<ul style="list-style-type: none"> Dermal pattern of exposure control: Non-direct handling 	
<ul style="list-style-type: none"> Dermal contact level: Intermittent 	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> 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%] 	
<ul style="list-style-type: none"> Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i> 	
<ul style="list-style-type: none"> Respiratory protection: No [Effectiveness Inhalation: 0%] 	

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	dihydrogen hexahydroxyplatinate	56.13 µg/m ³ (Measured data: Pt monitoring database) RCR = 0.181	Final RCR = 0.181
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 2.33E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.183

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate:

Identity of the substance used: sol Pt

Inhalation exposure, long term concentration: Number of measured data points: 4 ; GSD: 16.7

Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #10 (GSD=16.7) taken from the Pt monitoring database from the “Methodology applied in the Occupational Exposure Scenarios for Platinum Substances” document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.



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: HHPA for OCC RA

9.1.11.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown <i>Not relevant (fully contained systems)</i>	
• Maximum emission potential of the substance: Unknown <i>Not relevant (fully contained systems)</i>	
• 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: - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• 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 <i>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.</i>	
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%] <i>Precautionary measure as gloves are not needed to demonstrate safe use.</i>	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	0.01 µg/m ³ (Measured data: Pt monitoring database) RCR = 3.23E-5	Final RCR < 0.01



Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 9.3E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate:

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 dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA 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 <i>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.</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Exterior exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Containment due to physical form <i>The physical form of the platinum substance may be considered as some containment considerably reducing emissions. Soluble platinum substances may be handled in not enclosed systems. The level of containment should be as high as possible, easy maintenance should be allowed by system design.</i>	



	Method
<ul style="list-style-type: none"> Removal of residuals: Dusty residuals <i>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.</i> 	
<ul style="list-style-type: none"> Dermal pattern of use: Non-dispersive use 	
<ul style="list-style-type: none"> Dermal pattern of exposure control: Direct handling 	
<ul style="list-style-type: none"> Dermal contact level: Extensive 	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> 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%] 	
<ul style="list-style-type: none"> Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i> 	
<ul style="list-style-type: none"> Respiratory protection: No [Effectiveness Inhalation: 0%] 	

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	dihydrogen hexahydroxyplatinate	65.84 µg/m ³ (Measured data: Pt monitoring database) RCR = 0.212	Final RCR = 0.212
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	0.29 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 0.674	Final RCR = 0.674
Combined routes, systemic, long-term			Final RCR = 0.887

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate:

Identity of the substance used: sol Pt

Inhalation exposure, long term concentration: Number of measured data points: 2 ; GSD: 4.8

Explanation: The estimated exposure level represents the maximum value multiplied with 1.5 of the exposure distribution for estimate #15 (GSD=4.8) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA for OCC RA

9.1.13.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid <i>Solution, suspension</i>	
• Maximum emission potential of the substance: Very low <i>It is noted that spraying operations are not covered in this assessment.</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Exterior exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Containment due to physical form <i>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.</i>	
• Removal of residuals: Splashes <i>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.</i>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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,	dihydrogen	65.84 µg/m ³ (Measured data: Pt monitoring)	Final RCR = 0.212



Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
long term	hexahydroxyplatinate	database) RCR = 0.212	
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 2.33E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.215

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate:

Identity of the substance used: sol Pt

Inhalation exposure, long term concentration: Number of measured data points: 2 ; GSD: 4.8

Explanation: The estimated exposure level represents the maximum value of the exposure distribution multiplied with 1.5 for estimate #15 (GSD=4.8) taken from the Pt monitoring database from the “Methodology applied in the Occupational Exposure Scenarios for Platinum Substances” document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA for OCC RA

9.1.14.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown <i>Not relevant (fully contained systems)</i>	
• Maximum emission potential of the substance: Unknown <i>Not relevant (fully contained systems)</i>	
• 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: - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• 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	



	Method
<ul style="list-style-type: none"> Potential for contamination <i>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.</i> 	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> 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%] <i>Precautionary measure as gloves are not needed to demonstrate safe use.</i> 	
<ul style="list-style-type: none"> Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i> 	
<ul style="list-style-type: none"> Respiratory protection: No [Effectiveness Inhalation: 0%] 	

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	dihydrogen hexahydroxyplatinate	0.01 µg/m ³ (Measured data: Pt monitoring database) RCR = 3.23E-5	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 9.3E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate:

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 dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA 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 <i>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.</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Partly contained systems <i>The level of containment should be as high as possible, easy maintenance should be allowed by system design.</i>	
• Removal of residuals: Dusty residuals <i>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.</i>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	65.84 µg/m ³ (Measured data: Analogous data) RCR = 0.212	Final RCR = 0.212
Dermal, systemic,	dihydrogen	0.03 mg/kg bw/day (Measured data:	Final RCR = 0.07



Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
long term	hexahydroxyplatinate	Analogous data (Ni) RCR = 0.07	
Combined routes, systemic, long-term			Final RCR = 0.282

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

Identity of the substance used: sol Pt Separation/Filtration

Inhalation exposure, long term concentration: Number of measured data points: 2 ; GSD: 4.8

Explanation: The estimated exposure level represents the maximum value multiplied with 1.5 of the exposure distribution for estimate #15 (GSD=4.8) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA for OCC RA

9.1.16.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid <i>Solution, suspension</i>	
• Maximum emission potential of the substance: Very low <i>It is noted that spraying operations are not covered in this assessment.</i>	
• 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: <i>- Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Partly contained systems <i>The level of containment should be as high as possible, easy maintenance should be allowed by system design.</i>	
• Removal of residuals: Splashes <i>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.</i>	
• Dermal pattern of use: Non-dispersive use	



	Method
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	65.84 µg/m ³ (Measured data: Analogous data) RCR = 0.212	Final RCR = 0.212
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 2.33E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.215

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

Identity of the substance used: sol Pt Separation/Filtration

Inhalation exposure, long term concentration: Number of measured data points: 2 ; GSD: 4.8

Explanation: The estimated exposure level represents the maximum value of the exposure distribution multiplied with 1.5 for estimate #15 (GSD=4.8) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

9.1.17. Worker CS 17: Calcination in fully contained systems (PROC 1)

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

9.1.17.1. Conditions of use

	Method
Product (article) characteristics	



	Method
• Physical form of substance: Unknown <i>Not relevant (fully contained systems)</i>	
• Maximum emission potential of the substance: Unknown <i>Not relevant (fully contained systems)</i>	
• 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 <i>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.</i>	
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%] <i>Precautionary measure as gloves are not needed to demonstrate safe use.</i>	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	0.01 µg/m ³ (Measured data: Pt monitoring database) RCR = 3.23E-5	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 9.3E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate:

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 dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

9.1.18. Worker CS 18: Calcination in partly enclosed systems (PROC 22)

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

9.1.18.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• 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 <i>Below melting point</i>	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: <i>- Integrated exhaust ventilation A minimum efficiency of 84 % has to be assured.</i>	
• Level of containment: Partly contained systems	
• Removal of residuals: Dusty residuals <i>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.</i>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	160 µg/m ³ (MEASE 1) RCR = 0.516	Final RCR = 0.516
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 2.33E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.518

Remarks on measured exposure:

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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

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

9.1.19.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown <i>Not relevant (fully contained systems)</i>	
• Maximum emission potential of the substance: Unknown <i>Not relevant (fully contained systems)</i>	
• 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: <i>- Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.</i>	
• 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 <i>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.</i>	



	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> 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%] <i>Precautionary measure as gloves are not needed to demonstrate safe use.</i> 	
<ul style="list-style-type: none"> Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i> 	
<ul style="list-style-type: none"> Respiratory protection: No [Effectiveness Inhalation: 0%] 	

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	dihydrogen hexahydroxyplatinate	0.01 µg/m ³ (Measured data: Pt monitoring database) RCR = 3.23E-5	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 9.3E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate:

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 dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA for OCC RA

9.1.20.1. Conditions of use

	Method
Product (article) characteristics	



	Method
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Exterior exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Partly contained systems <i>The level of containment should be as high as possible, easy maintenance should be allowed by system design.</i>	
• 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 <i>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.</i>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	128.1 µg/m ³ (Measured data: Pt monitoring database) RCR = 0.413	Final RCR = 0.413



Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 0.07	Final RCR = 0.07
Combined routes, systemic, long-term			Final RCR = 0.483

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate:

Identity of the substance used: sol Pt

Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 5.3

Explanation: The estimated exposure level represents the maximum value of the exposure distribution multiplied with 1.5 for estimate #24 (GSD=5.3) taken from the Pt monitoring database from the “Methodology applied in the Occupational Exposure Scenarios for Platinum Substances” document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA 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 <i>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.</i>	
• 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: - <i>Generic local exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Partly contained systems <i>The level of containment should be as high as possible, easy maintenance should be allowed by system design.</i>	
• 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).	



	Method
<ul style="list-style-type: none"> Removal of residuals: Dusty residuals <i>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.</i> 	
<ul style="list-style-type: none"> Dermal pattern of use: Non-dispersive use 	
<ul style="list-style-type: none"> Dermal pattern of exposure control: Direct handling 	
<ul style="list-style-type: none"> Dermal contact level: Intermittent 	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> 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%] 	
<ul style="list-style-type: none"> Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i> 	
<ul style="list-style-type: none"> Respiratory protection: No [Effectiveness Inhalation: 0%] 	

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	dihydrogen hexahydroxyplatinate	0.38 µg/m ³ (Measured data: Analogous data) RCR = 1.23E-3	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	0.03 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 0.07	Final RCR = 0.07
Combined routes, systemic, long-term			Final RCR = 0.071

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

Identity of the substance used: ClPt, sol Pt

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 (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA for OCC RA

9.1.22.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid <i>Solution, suspension</i>	
• Maximum emission potential of the substance: Very low <i>It is noted that spraying operations are not covered in this assessment.</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Partly contained systems <i>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.</i>	
• 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 <i>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.</i>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	0.38 µg/m ³ (Measured data: Analogous data) RCR = 1.23E-3	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 2.33E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

Identity of the substance used: ClPt, sol Pt

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 (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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: HHPA for OCC RA

9.1.23.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown <i>Not relevant (fully contained systems)</i>	
• Maximum emission potential of the substance: Unknown <i>Not relevant (fully contained systems)</i>	
• 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: - <i>Generic local exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i>	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	



	Method
• Dermal contact level: None	
• Potential for contamination <i>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.</i>	
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%] <i>Precautionary measure as gloves are not needed to demonstrate safe use.</i>	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	0.01 µg/m ³ (Measured data: Pt monitoring database) RCR = 3.23E-5	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	4E-3 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 9.3E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate:

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 dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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



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

9.1.24.1. Conditions of use

	Method
Product (article) characteristics	
<ul style="list-style-type: none"> Physical form of substance: Solid <i>Dusty residuals</i> 	
<ul style="list-style-type: none"> Maximum emission potential of the substance: High <i>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.</i> 	
<ul style="list-style-type: none"> Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%] 	
Amount used (or contained in articles), frequency and duration of use/exposure	
<ul style="list-style-type: none"> Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%] 	
Technical and organisational conditions and measures	
<ul style="list-style-type: none"> Removal of residuals: Dusty residuals <i>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.</i> 	
<ul style="list-style-type: none"> Dermal pattern of use: Non-dispersive use 	
<ul style="list-style-type: none"> Dermal pattern of exposure control: Non-direct handling 	
<ul style="list-style-type: none"> Dermal contact level: Extensive 	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> 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%] 	
<ul style="list-style-type: none"> Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i> 	
<ul style="list-style-type: none"> Respiratory protection: No [Effectiveness Inhalation: 0%] 	

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	dihydrogen hexahydroxyplatinate	2.96 µg/m ³ (Measured data: Analogous data) RCR = 9.55E-3	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	0.01 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 0.023	Final RCR = 0.023
Combined routes, systemic, long-term			Final RCR = 0.033

**Remarks on measured exposure:**

Analogous data for dihydrogen hexahydroxyplatinate:

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.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

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

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

9.1.25.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid <i>Solution, suspension</i>	
• 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 <i>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.</i>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	



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	dihydrogen hexahydroxyplatinate	0.03 µg/m ³ (Measured data: Analogous data) RCR = 9.68E-5	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	0.29 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 0.674	Final RCR = 0.674
Combined routes, systemic, long-term			Final RCR = 0.675

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

Identity of the substance used: sol Pt

Inhalation exposure, long term concentration: Number of measured data points: 2 ; GSD: 2.2

Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #25 (GSD=2.2) taken from the Pt monitoring database from the “Methodology applied in the Occupational Exposure Scenarios for Platinum Substances” document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.



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 2.1	ERC 6a
CS 2	Use as an intermediate ES 2.2	ERC 6a
Worker contributing scenario(s):		
CS 3	Handling of solutions or low dusty material and reaction	PROC 3, PROC 15; PROC 26; PROC 4; PROC 5; PROC 8b; PROC 9
CS 4	Fully contained process	PROC 1
CS 5	Reaction process (furnace operation)	PROC 22
CS 6	Wet cleaning	PROC 8a
CS 7	Vacuum cleaning	PROC 26

9.2.1. Env CS 1: Use as an intermediate ES 2.1 (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)
<ul style="list-style-type: none"> Annual use amount at site: ≤ 30 tonnes/year <i>46.0 tonnes dihydrogen hexahydroxyplatinate (30 tonnes Pt metal equivalent); 90P from sector data</i> Daily use amount at site: ≤ 0.091 tonnes/day <i>Based on 330 days per year (50P from sector data)</i>
Conditions and measures related to biological sewage treatment plant
<ul style="list-style-type: none"> Biological STP: Site specific [Effectiveness Water: 57.1%] Discharge rate of STP: $\geq 3E3$ m³/day Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
<ul style="list-style-type: none"> Particular considerations on the waste treatment operations: No (low amount) <i>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.</i> <i>Fraction of daily/annual use expected in waste: 0%</i> <i>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</i> <i>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%</i> <i>A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2016)</i>
Other conditions affecting environmental exposure
<ul style="list-style-type: none"> Receiving surface water flow rate: $\geq 9.3E4$ 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 dissolved
Release to water	42.9%
Release to air	0%
Release to sludge	57.1%
Release degraded	0%

Explanation for Pt 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 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 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 dissolved	Estimated release factor	Release factor after on site RMM: 0% Explanation: No direct emissions to soil.

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 dissolved	Local PEC: 4.74E-6 mg/L RCR = 0.034	Final RCR = 0.034
Sediment (freshwater)	Pt dissolved	Local PEC: 8.84E-3 mg/kg dw RCR = 0.034	Final RCR = 0.034
Sewage Treatment Plant	Pt dissolved	Local PEC: 1.55E-4 mg/L RCR = 6.59E-4	Final RCR < 0.01



Protection target	Assessment entity	Exposure concentration	Risk quantification
Agricultural soil	Pt 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 2.2 (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)
<ul style="list-style-type: none"> Annual use amount at site: ≤ 30 tonnes/year <i>46.0 tonnes dihydrogen hexahydroxyplatinate (30 tonnes Pt metal equivalent); 90P from sector data</i> Daily use amount at site: ≤ 0.091 tonnes/day <i>Based on 330 days per year (50P from sector data)</i>
Conditions and measures related to biological sewage treatment plant
<ul style="list-style-type: none"> Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)
<ul style="list-style-type: none"> Particular considerations on the waste treatment operations: No (low amount) <i>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%</i> <i>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</i> <i>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%</i> <i>A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2016)</i>
Other conditions affecting environmental exposure
<ul style="list-style-type: none"> Receiving surface water flow rate: $\geq 3E6$ m³/day Discharge to: Freshwater only Discharge rate of effluent: $\geq 3E3$ 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 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 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



Release	Assessment entity	Release estimation method	Explanations
			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 dissolved	Estimated release factor	Release factor after on site RMM: 0% Explanation: No direct emissions to soil.

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 dissolved	Local PEC: 3.83E-7 mg/L RCR = 2.73E-3	Final RCR < 0.01
Sediment (freshwater)	Pt dissolved	Local PEC: 7.14E-4 mg/kg dw RCR = 2.73E-3	Final RCR < 0.01
Agricultural soil	Pt dissolved	Local PEC: 1.22E-3 mg/kg dw RCR = 0.234	Final RCR = 0.234

9.2.3. Worker CS 3: Handling of solutions or low dusty material and reaction (PROC 3, PROC 15; PROC 26; PROC 4; PROC 5; PROC 8b; PROC 9)

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

9.2.3.1. Conditions of use

	Method
Product (article) characteristics	
<ul style="list-style-type: none"> Physical form of substance: Various <i>liquid (solution, suspension) or low dusty solids (e.g. wetted)</i> 	
<ul style="list-style-type: none"> Maximum emission potential of the substance: Low <i>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.</i> 	
<ul style="list-style-type: none"> Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%] 	
Amount used (or contained in articles), frequency and duration of use/exposure	
<ul style="list-style-type: none"> Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%] 	
Technical and organisational conditions and measures	
<ul style="list-style-type: none"> The following type of exhaust ventilation are appropriate for handling of platinum substances: <ul style="list-style-type: none"> - <i>Generic local exhaust ventilation</i> - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 80 % has to be assured.</i> 	
<ul style="list-style-type: none"> Level of containment: Partly contained systems <i>Platinum substances are always handled in at least partly-contained systems with only</i> 	



	Method
<i>limited manual interventions. The level of containment should be as high as possible, easy maintenance should be allowed by system design.</i>	
• 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 <i>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.</i>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	56.13 µg/m ³ (Measured data: Analogous data) RCR = 0.181	Final RCR = 0.181
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 2.33E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.183

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

Identity of the substance used: sol Pt manufacturers wet processing

Inhalation exposure, long term concentration: Number of measured data points: 4 ; GSD: 16.7

Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #10 (GSD=16.7) taken from the Pt monitoring database from the “Methodology applied in the Occupational Exposure Scenarios for Platinum Substances” document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

9.2.4. Worker CS 4: Fully contained process (PROC 1)

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

9.2.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown <i>Not relevant (fully contained systems)</i>	
• Maximum emission potential of the substance: Unknown <i>Not relevant (fully contained systems)</i>	
• 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 <i>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.</i>	
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%] <i>Precautionary measure as gloves are not needed to demonstrate safe use.</i>	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	0.01 µg/m ³ (Measured data: Analogous data) RCR = 3.23E-5	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 2.33E-3	Final RCR < 0.01



Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

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 dihydrogen hexahydroxyplatinate:

Identity of the substance used: Ni

Dermal exposure, long term systemic dose: Number of measured data points: 12

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

Risk characterisation

Qualitative risk characterisation (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

9.2.5. Worker CS 5: Reaction process (furnace operation) (PROC 22)

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

9.2.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Various <i>liquid, solution, suspension</i>	
• 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 <i>Below melting point</i>	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: - <i>Integrated exhaust ventilation</i> <i>A minimum efficiency of 84 % has to be assured.</i>	
• Level of containment: Partly contained systems	
• Removal of residuals: Dusty residuals <i>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.</i>	
• 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	



	Method
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	160 µg/m ³ (MEASE 1) RCR = 0.516	Final RCR = 0.516
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	1 µg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 2.33E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.518

Remarks on measured exposure:

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

9.2.6. Worker CS 6: Wet cleaning (PROC 8a)

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

9.2.6.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid <i>Solution, suspension</i>	
• 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	



	Method
<p><i>Removal of residuals is considered to be part of regular work.</i></p> <p><i>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.</i></p> <p><i>Workplaces are to be cleaned before any maintenance work starts.</i></p>	
• 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 <i>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.</i>	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

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	dihydrogen hexahydroxyplatinate	0.03 µg/m ³ (Measured data: Analogous data) RCR = 9.68E-5	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	0.29 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 0.674	Final RCR = 0.674
Combined routes, systemic, long-term			Final RCR = 0.675

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

Identity of the substance used: sol Pt manufacturers Packaging/Filling

Inhalation exposure, long term concentration: Number of measured data points: 2 ; GSD: 2.2

Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #25 (GSD=2.2) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.

9.2.7. Worker CS 7: Vacuum cleaning (PROC 26)



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

9.2.7.1. Conditions of use

	Method
Product (article) characteristics	
<ul style="list-style-type: none"> Physical form of substance: Solid <i>Dusty residuals</i> 	
<ul style="list-style-type: none"> Maximum emission potential of the substance: High <i>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.</i> 	
<ul style="list-style-type: none"> Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%] 	
Amount used (or contained in articles), frequency and duration of use/exposure	
<ul style="list-style-type: none"> Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%] 	
Technical and organisational conditions and measures	
<ul style="list-style-type: none"> Removal of residuals: Dusty residuals <i>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.</i> 	
<ul style="list-style-type: none"> Dermal pattern of use: Non-dispersive use 	
<ul style="list-style-type: none"> Dermal pattern of exposure control: Non-direct handling 	
<ul style="list-style-type: none"> Dermal contact level: Extensive 	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> 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%] 	
<ul style="list-style-type: none"> Eye protection: Eye protection to be worn to protect from adverse effects to the eyes <i>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.</i> 	
<ul style="list-style-type: none"> Respiratory protection: No [Effectiveness Inhalation: 0%] 	

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	dihydrogen hexahydroxyplatinate	2.96 µg/m ³ (Measured data: Analogous data) RCR = 9.55E-3	Final RCR < 0.01
Dermal, systemic, long term	dihydrogen hexahydroxyplatinate	0.01 mg/kg bw/day (Measured data: Analogous data (Ni)) RCR = 0.023	Final RCR = 0.023
Combined routes, systemic, long-term			Final RCR = 0.033



Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate:

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 (Ni) for dihydrogen hexahydroxyplatinate:

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 (Eye, local):

Suitable eye protection equipment (e.g. goggles or visors) must be worn.



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 dissolved	0.714 kg/year
Air	Pt dissolved	1.8 kg/year
Soil	Pt 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 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): 4.19E-8 mg/L	Final RCR < 0.01
Sediment (freshwater)	Pt dissolved	Regional PEC: 1.56E-4 mg/kg dw RCR = 5.98E-4	Final RCR < 0.01
Marine water	Pt dissolved	Regional PEC: 4.18E-9 mg/L RCR = 2.99E-4	Final RCR < 0.01
Sediment (marine water)	Pt dissolved	Regional PEC: 1.56E-5 mg/kg dw RCR = 5.97E-4	Final RCR < 0.01
Agricultural soil	Pt dissolved	Regional PEC: 9.46E-4 mg/kg dw (Measured data: GEMAS) RCR = 0.181 Supportive exposure (not used for RC): 4.57E-6 mg/kg dw	Final RCR = 0.181

Remarks on exposure data from external estimation tools:**External EUSES calculation 2.1.2** for Pt dissolved:

Explanation: For the derivation of the regional background concentrations in the aquatic environment, the total tonnage of all platinum (Pt) compounds produced in the EU was sub-divided by region. The value input to modelling was the maximum proportion of Pt compounds produced in a single region. This regional assumption was combined with emission characteristics from the Pt manufacturing and processing sector data, STP removal efficiency and phys-chem properties to perform calculations of the regional PEC concentrations for freshwater. The estimated regional background PEC_{freshwater} was then incorporated into CHESAR.

Remarks on measured exposure:**GEMAS** for Pt dissolved:

Identity of the substance used: Platinum

Explanation: For the derivation of regional background concentrations in the terrestrial environment, data from the geochemical mapping of agricultural and grazing land soil of Europe (GEMAS) project were utilised. GEMAS is a project conducted by the EuroGeoSurveys Geochemistry Expert Group and Eurometaux for the production of exposure data on metals in agricultural and grazing land soil and soil properties, at the European scale. Sampling was performed at a density of 1 site per 2500 sq. km and was completed in 2009. 2108 samples of agricultural soil (Ap-horizon, 0-20 cm, regularly ploughed fields), and 2023 samples from land under permanent grass cover (grazing land soil, 0-10 cm) were collected based on an agreed protocol. For Pt, the mean concentrations for agricultural soil and grassland samples were 9.46×10^{-4} mg/kg d.w. and 9.26×10^{-4} mg/kg d.w., respectively. For these assessments, the mean for agricultural soil (9.46×10^{-4} mg/kg d.w.) was utilised in environmental exposure assessment.

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

Cobelo-Garcia A, Turner A, Millward G. 2008: Fractionation and reactivity of platinum group elements during estuarine mixing (publication), *Environmental Science and Technology*, 42:1096-1101.

Turner A, Crussell M, Millward G, Cobelo-Garcia A, Fisher A 2006: Adsorption kinetics of platinum group elements in river water (publication), *Environmental Science and Technology*, 40:1524-1531.

Sako A, Lopes L, Roychoudhury A 2009: Adsorption and surface complexation modelling of palladium, rhodium and platinum in surficial semi-arid soils and sediment (publication), *Applied Geochemistry* 24:86-95.

Berthold K 1995: Hexahydroxoplatinum(IV) Acid. Acute toxicity. Testing the acute toxicity after single oral administration in rats. Report. No. 2 of 2 originals. (study report), Testing laboratory: ASTA Medica AG, Institute of Toxicology, Kantstraße 2, D-33790 Halle/Westfalen, Report no: 904961. Owner company; Initiative Umweltrelevante Altstoffe e.V., Kennedyallee 93, D-60596 Frankfurt am Main, Study number: 94-0151-DGT, Report date: May 11, 1995

Kiss I 2012: Dihydrogen hexahydroxyplatinate: skin corrosivity in vitro in the EPISKIN model (study report), Testing laboratory: CiToxLAB Hungary Ltd. (formerly known as LAB Research Ltd. before 1st September 2011), H-8200 Veszprém, Szabadságpuszta, Hungary, Report no: 11/261-039B. Owner company; The Precious Metal and Rhenium Consortium, Avenue de Broqueville 12, B – 1150 Brussels, Belgium, Report date: May 3, 2012

Kiss I 2012: Dihydrogen Hexahydroxyplatinate: In vitro skin irritation test in the EPISKIN model (study report), Testing laboratory: CiToxLAB Hungary Ltd. (formerly known as LAB Research Ltd. before 1st September 2011), H-8200 Veszprém, Szabadságpuszta, Hungary, Report no: 11/261-043B. Owner company; The Precious Metal and Rhenium Consortium, Avenue de Broqueville 12, B – 1150 Brussels, Belgium, Report date: May 3, 2012

Berthold K 1995: Hexahydroxoplatinum(IV)-acid. Acute toxicity. Testing the primary irritation after single application to the eye of the rabbit. (study report), Testing laboratory: ASTA Medica AG, Institute of Toxicology, Kantstraße 2, D-33790 Halle/Westfalen, Report no: 904937. Owner company; Initiative Umweltrelevante Altstoffe e.V., Kennedyallee 93, D-60596 Frankfurt am Main, Study number: 94-0152-DGT, Report date: Apr 11, 1995

Dearman RJ and Kimber I 2011: Assessment of the allergenic potential of platinum salts: hexahydroxyplatinate acid and carboplatin (study report), Testing laboratory: University of Manchester, Owner company; Johnson Matthey plc, Report date: Aug 31, 2011

Hansen B 2015: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening study of dihydrogen hexahydroxyplatinate in rats by oral administration. (study report), Testing laboratory: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Redderweg 8, 21447 Hamburg, Germany., Report no: 30083. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, 1150 Brussels, Belgium., Report date: Jun 29, 2015

Mc Garry S 2013: Dihydrogen hexahydroxyplatinate: Reverse mutation in five histidine-requiring strains of *Salmonella typhimurium* (study report), Testing laboratory: Covance Laboratories Ltd, Otley Road, Harrogate, North Yorkshire, HG3 1PY, England, Report no: 8284301. Owner company; Precious Metals and Rhenium Consortium, C/O European Precious Metals Federation aisbl, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Dec 3, 2013

Lloyd M 2014: Induction of micronuclei in cultured Chinese hamster ovary (CHO) cells (study report), Testing laboratory: Covance Laboratories Ltd., Otley Road, Harrogate, North Yorkshire, HG3 1PY, England, Report no: 8284302. Owner company; Precious Metals and Rhenium Consortium, C/O European Precious Metals Federation aisbl, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Jan 22, 2014

Eurlings IMJ 2020: A Combined Micronucleus and Alkaline Comet Test in the Rat with Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) (CAS 68133-90-4) (study report), Testing laboratory: Charles River Laboratories Den Bosch BV Hambakenwetering 7 5231 DD 's-Hertogenbosch The Netherlands Charles River Laboratories Den Bosch BV Nistelrooisebaan 3 5374 RE Schaijk The Netherlands,



Owner company; European Precious Metals Federation Avenue de Broqueville 12 1150 Brussels Belgium, Study number: 20232328, Report date: Jul 17, 2020

Walker JA, White DF 2011: Dihydrogen hexahydroxyplatinate (hydrated solid): Determination of Physico-Chemical Properties (study report), Testing laboratory: Harlan Laboratories Ltd Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, Report no: Project Number 41003633. Owner company; Precious Metals and Rhenium Consortium (PMC), c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Study number: Not reported, Report date: May 8, 2011

Michael-Schultz H 2012: Report on testing of the substance "Hexahydroxy Platinic Acid" according to the UN-Tests O.1, N.1 and N.4 (study report), Testing laboratory: BAM Federal Institute for Material Research and Testing, Unter den Eichen 87, 12205 Berlin, Report no: BAM reference: 2.2-69/12. Owner company; Precious Metals and Rhenium Consortium European Precious Metals Federation Avenue de Broqueville 12 1150 Brussels Belgium, Study number: Not reported, Report date: Apr 26, 2012

Michael-Schultz H 2012: Report on testing of the substance "Hexahydroxy Platinic Acid" according to the UN-Tests O.1, N.1 and N.4 (study report), Testing laboratory: BAM Federal Institute for Material Research and Testing, Unter den Eichen 87, 12205 Berlin, Report no: BAM reference: 2.2-69/12. Owner company; Precious Metals and Rhenium Consortium European Precious Metals Federation Avenue de Broqueville 12 1150 Brussels Belgium, Study number: Not reported, Report date: Apr 26, 2012

Pawlowski S and Wydra V 2005: Final report. Acute toxicity of dihydrogen hexachloroplatinate IV-solution to rainbow trout (*Oncorhynchus mykiss*) in a 96-hour static test (study report), Testing laboratory: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany, Report no: 19041230. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Feb 28, 2005

Muth-Kohne E 2016: Fish acute toxicity test over 96 h under semi-static conditions (OECD TG 203, 1992) with zebrafish (*Danio rerio*) (study report), Testing laboratory: Fraunhofer Institute for molecular biology and applied ecology IME, Auf dem Aberg 1, 57392 Schmallenberg, Germany, Report no: WCA-010/4-32/A. Owner company; Precious metals and rhenium consortium, c/o European precious metals federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Sep 6, 2016

Par R Jouhaud, S Biagianni-Risbourg, F Arsac and G Vernet 1999: Effets du platine chez *Brachydanio rerio* "Teleosteen\ Cyprinide#[I[Toxicite aigue] bioaccumulation et histopathologie intestinales (publication), *J Appl Ichthyol* 15, 41-48. Report date: Apr 17, 1999

Shacklady LG, Mullee DM 2001: Chloro Platinic Acid: Acute Toxicity to *Daphnia magna* (study report), Testing laboratory: SafePharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT, UK, Report no: 036/147. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: May 10, 2001

Moll M and Wydra V 2005: Final report: Acute toxicity of Dihydrogen hexachloroplatinate IV-solution to *Daphnia magna* in a 48-hour Immobilization Test. (study report), Testing laboratory: Institut für Biologische Analytik und Consulting IBACON GmbH, Report no: 19042220. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Jul 4, 2005

Simon M 2014: *Daphnia magna*, Acute Immobilization Test (OECD 202) Semi-static exposure - Effect of Hexahydroxyplatinic Acid on the immobilization of *Daphnia magna* (study report), Testing laboratory: Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), Auf dem Aberg 1, 57392 Schmallenberg, Germany Fraunhofer IME, Report no: WCA-004/4-20/G. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Dec 12, 2014

Simon M 2014: *Daphnia magna*, Acute Immobilization Test (OECD 202) Static exposure - Effect of diammonium hexachloroplatinate on the immobilization of *Daphnia magna* (study report), Testing laboratory: Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) Auf dem Aberg 1 57392 Schmallenberg, Germany Fraunhofer IME, Report no: WCA-005/4-20/G. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels,



Belgium, Report date: Dec 11, 2014

Simon M 2016: Effect of Dihydrogen hexahydroxyplatinate, compound with 2-amino-ethanol on the immobilisation of *Daphnia magna* (study report), Testing laboratory: Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), Auf dem Aberg 1, 57392 Schmallenberg, Germany, Report no: WCA-010/4-20/G. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Aug 1, 2016

Okamoto A et al 2015: Acute toxicity of 50 metals to *Daphnia magna* (publication), *J. Appl. Toxicol.* 35: 824–830.

Zimmermann S et al 2017: Toxicity of platinum, palladium and rhodium to *Daphnia magna* in single and binary metal exposure experiments (publication), *Environmental Pollution* 224, 368-376.

Biesinger KE, Christensen GM 1972: Effects of Various Metals on Survival, Growth, Reproduction, and Metabolism of *Daphnia magna* (publication), *J. Fish. Res. Bd. Canada* 29: 1691-1700.

Wenzel A 2014: Freshwater Alga, Growth Inhibition Test. Effect of Hexahydroxyplatonic Acid on the Growth of *Pseudokirchneriella subcapitata* (study report), Testing laboratory: Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), 57392 Schmallenberg, Germany, Report no: WCA-004/4-10/A. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Dec 11, 2014

Pawlowski S and Wydra V 2005: Final report - Toxicity of Dihydrogen hexachloroplatinate IV-solution to *Desmodesmus subspicatus* in an Algal Growth Inhibition Test (study report), Testing laboratory: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany, Report no: 19043210. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Jul 3, 2005

Mead C, Mullee DM 2001: Chloro Platonic Acid: Algal Inhibition Test (study report), Testing laboratory: SafePharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT, UK, Report no: 036/146. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: May 14, 2001

Wenzel A 2016: Freshwater Alga, Growth Inhibition Test (OECD 201) (study report), Testing laboratory: Fraunhofer Institute for molecular biology and applied ecology IME, Auf dem Aberg 1, 57392 Schmallenberg, Germany, Report no: WCA-010/4-10/A. Owner company; Precious metals and rhenium consortium c/o European precious metals federation, Avenue de Broqueville 12, B 1150, Brussels, Belgium, Report date: Aug 10, 2016

Sorensen S et al 2016: A Multimethod Approach for Investigating Algal Toxicity of Platinum Nanoparticles *Environ. Sci. Technol.* 50 (19), pp 10635–10643.

Havelkova. B et al. 2014: Impact of platinum group elements on the soil invertebrate *Enchytraeus crypticus* (publication), *Neuroendocrinology Letters* 35 (2) 101–108.

Nemcova B et al 2012: Impact of platinum on the soil invertebrate *Folsomia candida* (publication), *Neuroendocrinology Letters* Volume 33 Suppl. 3.

Muckle M 2014: Determination of the Inhibition of the Respiration of Activated Sludge when exposed to Hexahydroxyplatonic Acid according to OECD 209 resp. EU C.11 (study report), Testing laboratory: LAUS GmbH, Auf der Schafweide 20, D-67489 Kirrweiler, Germany, Report no: 14090104G701. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Dec 22, 2014

Muckle M 2015: Determination of the Inhibition of the Respiration of Activated Sludge when exposed to Hexachloroplatonic acid according to OECD 209 resp. EU C.11 (study report), Testing laboratory: LAUS GmbH, Auf der Schafweide 20, D-67489 Kirrweiler, Germany, Report no: 15061602G701. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Nov 5, 2015



Muckle M 2016: Determination of the Inhibition of the Respiration of Activated Sludge when exposed to Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol according to OECD 209 resp. EU C.11 (study report), Testing laboratory: LAUS GmbH, Auf der Schafweide 20, D-67489 Kirrweiler, Germany, Report no: 15100102G701. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Feb 24, 2016



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: H₂PtCl₃ in 7 % HCl, 1000 ppm ICP-OES standards (CertiPur, Merck)Test material: **52438-26-3 / 52438-26-3 / 257-921-8; Hexahydroxoplatinum(IV) acid**

Form:

Composition type: Constituent	Reference substance: 52438-26-3 EC no.: 257-921-8 CAS no.: 52438-26-3 IUPAC name: 52438-26-3	Concentration range:
Composition type: Constituent	Reference substance: Hexahydroxoplatinum(IV) acid EC no.: CAS no.: IUPAC name: Hexahydroxoplatinum(IV) acid	Concentration range:

Details on test material: - Name of test material (as cited in study report): hexahydroxoplatinum(IV) acid - Note: According to ChemIDPlus, the CAS in this study report corresponds to "diaquatetrahydroxyplatinum". The name dihydrogen hexahydroxyplatinate (synonym hexahydroxoplatinum(IV) acid) corresponds to CAS 51850-20-5. This apparent discrepancy within the study report between CAS and name is inconsequential as these are equivalent from a toxicological perspective. - Molecular formula (if other than submission substance): No data - Molecular weight (if other than submission substance): No data - Smiles notation (if other than submission substance): No data - InChI (if other than submission substance): No data - Structural formula attached as image file (if other than submission substance): No data - Substance type: Product - Physical state: Powder - Analytical purity: >99.9% - Impurities (identity and concentrations): No data - Composition of test material, percentage of components: No data - Isomers composition: No data - Purity test date: No data - Lot/batch No.: 8188 - Expiration date of the lot/batch: 1999 - Stability under test conditions: Stable throughout the experimental period - Storage condition of test material: In a closed container in a refrigerator

Test material: **hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**

Form:

Composition type: Constituent	Reference substance: dihydrogen hexahydroxyplatinate EC no.: 257-471-2 CAS no.: 51850-20-5	Concentration range:
---	--	-----------------------------



Dihydrogen hexahydroxyplatinate

	IUPAC name: hexahydroxyplatinate(2-)	
--	---	--

Details on test material: - Name of test material (as cited in study report): Dihydrogen hexahydroxyplatinate - Substance type: Technical product - Physical state: Solid (yellow) - Analytical purity: 99.9% (Pt content 64.80%) - Impurities (identity and concentrations): a copy of the analysis report constitutes Appendix 3 of the attached full study report; trace amounts of elements other than platinum are documented - Purity test date: No data - Lot/batch No.: CW0466 - Expiration date of the lot/batch: 30 September 2015 - Storage condition of test material: Controlled Room Temperature (15-25°C, below 70 RH%)

Test material: **Hexahydroxyplatonic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**

Form:

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: Hexahydroxyplatonic Acid EC no.: CAS no: IUPAC name: Hexahydroxyplatonic Acid	Concentration range:

Details on test material: - Name of test material (as cited in study report): Dihydrogen Hexahydroxyplatinate - Substance type: Technical product - Physical state: Solid (yellow) - Analytical purity: 99.9% (platinum content 64.80%) - Impurities (identity and concentrations): metallic impurity concentrations are detailed in Appendix 3 of the attached full study report - Purity test date: not reported - Lot/batch No.: CW0466 (manufactured 05 October 2010) - Expiration date of the lot/batch: 30 September 2015 - Storage condition of test material: Controlled Room Temperature (15-25°C, below 70 RH%)

Test material: **52438-26-3 / 52438-26-3 / 257-921-8; Hexahydroxoplatinum (IV) acid**

Form:

Composition type: Constituent	Reference substance: 52438-26-3 EC no.: 257-921-8 CAS no: 52438-26-3 IUPAC name: 52438-26-3	Concentration range:
Composition type: Constituent	Reference substance: Hexahydroxoplatinum (IV) acid EC no.: CAS no: IUPAC name: Hexahydroxoplatinum (IV) acid	Concentration range:

Details on test material: - Name of test material (as cited in study report): hexahydroxoplatinum(IV)-acid - Note: The CASRN in this study report corresponds to "diaquatetrahydroxyplatinum". The name dihydrogen hexahydroxyplatinate (synonym hexahydroxoplatinum(IV) acid) corresponds to CAS 51850-20-5. This discrepancy within the study report between CAS and name is inconsequential as these substances would be equivalent from a chemical/toxicological perspective. - Substance type: Product - Physical state: Powder - Analytical purity: >99.9% - Purity test date: No data - Lot/batch No.: 8188 - Expiration date of the lot/batch: 1999 - Stability under test conditions: Stable throughout the experimental period - Storage condition of test material: In a closed container in a refrigerator - pH: ~6.2

Test material: **52438-26-3 / 52438-26-3 / 257-921-8; Hexahydroxyplatonic acid**

Form: **solid - liquid: suspension**

Composition type: Constituent	Reference substance: Hexahydroxyplatonic acid EC no.: CAS no: IUPAC name: Hexahydroxyplatonic	Concentration range:
---	---	-----------------------------



Dihydrogen hexahydroxyplatinate

	acid	
Composition type: Constituent	Reference substance: 52438-26-3 EC no.: 257-921-8 CAS no: 52438-26-3 IUPAC name: 52438-26-3	Concentration range:

Details on test material: - Name of test material (as cited in study report): Hexahydroxyplatonic acid (HHPA) - Analytical purity: records of test compound characterisation, including purity, were held by the sponsor - Other: All test preparations were fine suspensions of HHPA in DMF after sonification for 15 mins

Test material: **hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**

Form: **solid: particulate/powder - migrated information: powder**

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: - Name of test material (as cited in study report): dihydrogen hexahydroxyplatinate. - Substance type: powder. - Physical state: solid. - Analytical purity: no data. - Impurities (identity and concentrations): no data. - Composition of test material, percentage of components: 64.83% platinum w/w. - Isomers composition: not applicable. - Purity test date: 28 May 2013. - Lot/batch No.: CZ0185. - Expiration date of the lot/batch: June 2018. - Stability under test conditions: 5 years. - Storage condition of test material: At +10 to +25 deg C, in a tightly closed container, protected from direct sunlight.

Test material: **hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**

Form: **solid - liquid: suspension**

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: - Name of test material (as cited in study report): dihydrogen hexahydroxyplatinate - Substance type: no data - Physical state: yellow powder - Analytical purity: 99-100% - Impurities (identity and concentrations) (ppm): carbon (795); (ppm with respect to metal): silver (137), aluminium (20), calcium (48), chromium (15), copper (20), iron (128), iridium (26), potassium (15), magnesium (6), manganese (3), molybdenum (8), sodium (714), nickel (28), osmium (29), palladium (74), rhodium (32), ruthenium (11), silicon (54), tellurium (2), zirconium (3) - Composition of test material, percentage of components: 64.83% platinum - Isomers composition: no data - Purity test date: 28 May 2013 - Lot/batch No.: CZ0185 - Expiration date of the lot/batch: May 2018 - Stability under test conditions: no data - Storage condition of test material: 15-25°C, protected from light

Test material: **hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**

Form: **solid - liquid: suspension**

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: - Name of test material (as cited in study report): dihydrogen hexahydroxyplatinate - Substance type: no data - Physical state: yellow powder - Analytical purity: 99-100% - Impurities (identity and concentrations) (ppm): carbon (795); (ppm with respect to metal): silver (137), aluminium (20), calcium (48), chromium (15), copper (20), iron (128), iridium (26), potassium (15), magnesium (6), manganese (3), molybdenum (8), sodium (714), nickel (28), osmium (29), palladium (74), rhodium (32), ruthenium (11), silicon (54), tellurium (2), zirconium (3) - Composition of test material, percentage of components: platinum at 64.83% - Isomers composition: no data - Purity test date: 28 May 2013 - Lot/batch No.: CZ0185 - Expiration date of the lot/batch: 17 May 2018 - Stability under test conditions: no data - Storage condition of test material: stored at



15-25°C, protected from light

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: **hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	Reference substance: dihydrogen hexahydroxyplatinate EC no.: 257-471-2 CAS no: 51850-20-5 IUPAC name: hexahydroxyplatinate(2-)	Concentration range:
---	---	-----------------------------

Test material: **Hexahydroxyplatonic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**Form: **solid**

Composition type: Constituent	Reference substance: Hexahydroxyplatonic Acid EC no.: CAS no: IUPAC name: Hexahydroxyplatonic Acid	Concentration range:
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: **51820-20-5; Dihydrogen hexahydroxyplatinate (hydrated solid)**Form: **not specified**

Composition type: Constituent	Reference substance: 51820-20-5 EC no.: CAS no: IUPAC name: 51820-20-5	Concentration range:
Composition type: Constituent	Reference substance: Dihydrogen hexahydroxyplatinate (hydrated solid) EC no.: CAS no: IUPAC name: Dihydrogen hexahydroxyplatinate (hydrated solid)	Concentration range:

Details on test material: - Label: Dihydrogen hexahydroxyplatinate (Hydrated Solid) - Physical description: Yellow solid - Purity: 64.94% (as Platinum) - Batch number: CW0225 - CAS number: 51850-20-5 - EC number: 257-471-2 - Storage and Handling: stored at room temperature in the dark

Test material: **hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**

Form: **Solid**

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: The test sample is technically pure. BAM code: 2.23/090212/01 Test item name as stated in study report: Hexahydroxy platinic acid

Test material: **Hexahydroxy Platinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**Form: **Solid**

Composition type: Constituent	Reference substance: Hexahydroxy Platinic Acid EC no.: CAS no: IUPAC name: Hexahydroxy Platinic Acid	Concentration range:
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: The test sample is technically pure. BAM code: 2.23/090212/01 Test item name as stated in study report: Hexahydroxy platinic acid

Test material: **16941-12-1 / 241-010-7**Form: **liquid**

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: - Colour/form: orange liquid - Density: 2.069 g/mL

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; 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: - 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: Constituent	Reference substance: Hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	Concentration range:
---	--	-----------------------------

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	Concentration range:
---	--	-----------------------------



Dihydrogen hexahydroxyplatinate

	EC no.: 241-010-7 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: **Hexahydroxyplatonic 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: Hexahydroxyplatonic Acid EC no.: CAS no: IUPAC name: Hexahydroxyplatonic Acid	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: **Hexahydroxyplatonic 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: Hexahydroxyplatonic Acid EC no.: CAS no: IUPAC name: Hexahydroxyplatonic Acid	Concentration range:



3. Annex: Mode of action / Human relevance Framework

Section 5.6.3: Repeated dose toxicity.001

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.001

Detailed information on mode of action / Human relevance framework:

No data identified.