Precious Metals Consortium

Precious Metals & Rhenium Consortium

Discussion on occupational risk assessment in Pt REACH dossiers

7 July 2016 | MCC, Brussels

Precious Metals Consortium

1. Welcome and tour-de-table

Confidentiality and Competition Law

DO	DON'T
Application of competition law	
Art. 101 and 102 TFEU may be applicable to the conclusion of any preliminary agreement and activities of any preliminary phase.	Don't assume that conflicts with competition law are excluded simply by the fact that the Agreement complies with the provisions of the REACH Regulation.
Consultation in Matters of Competition Law	
Consult an in-house legal expert or the compliance officer of your company or an external lawyer whenever there are uncertainties respecting compliance with competition law. Stop all meetings/discussions which are not in compliance with these Compliance Guidelines until a legal expert has been involved.	Don't assume that these Compliance Guidelines deal with all competition law issues exhaustively. Basically, compliance with Art. 101 and 102 TFEU can be determined only on the basis of market impact in each individual case. These Compliance Guidelines may therefore be regarded only as a means of providing general conduct recommendations.
Activities in any preliminary phase and at any other stage of operation of the Consortium	
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Exchange of Confidential Information	
Involve a Trustee for the exchange of Confidential Information.	The exchange of information concerning market behaviour and having the object or the effect of preventing, restricting and/or distorting competition is inadmissible; in particular, this relates to : - Production capacities; - Productions or sales volumes; - Import volumes; - Market shares; - Price policy; - Distribution and marketing terms; - Marketing strategies; - Information regarding the relationship with suppliers.
Documentation on Cooperation	
Keep minutes of all meetings which detail the subject of the meeting. In case of uncertainty, have the contents of the minutes reviewed by an external legal expert prior to sending them to all parties of the Agreement. Stop all meetings which are not in compliance with these Guidelines until a legal expert has been involved.	

Approval of the agenda

- Welcome, tour de table & anti-trust (11.00-11.05)
- Introduction to the ClPt Occupational ES & overview of next steps (11.05-11.15)
- Discussion draft ES (11.15-12.30)
- Lunch (12.30-13.00)
- Further discussions draft ES (13.00-14.30)
- Coffee break (14.45-15.00)
- Conclusions and wrap-up of meeting (15.00-16.00)

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Introduction to the ClPt Occupational ES & overview of next steps

Introduction

- Occupational exposure scenarios developed for
  - Hexachloroplatinic acid (CAS 16941-12-1) (10-100 tpa)
  - Dipotassium hexachloroplatinate (CAS 16921-30-5) (10-100 tpa)
  - Diammonium hexachloroplatinate (CAS 16919-58-7) (10-100 tpa)

  } chloroplatinates

  - Dihydriogen hexahydroxyplatinate
  - Platinum dinitrate

  } Soluble Pt compounds

- Overview hazard conclusions workers

Substance	Inhalation				Dermal				Eyes
	systemic		local		systemic		local		
	longterm	acute	longterm	acute	longterm	acute	longterm	acute	
Diammonium hexachloroplatinate	high	medium	high	high	high	medium	medium	medium	medium
Dipotassium hexachloroplatinate	high	medium	high	high	high	medium	medium	medium	medium
Hexachloroplatinic acid	high	high	high	high	high	high	medium	medium	medium
Dihydrogen hexahydroxyplatinate	OT: 2 µg soluble Pt/m³	NHI	NHI	NHI	0.667 mg/kg bw/d	NHI	NHI	NHI	low
Platinum dinitrate	OT: 2 µg soluble Pt/m³	HU	high	high	0.356 mg/kg bw/d	HU	high	high	medium

OT: other threshold
NHI: No hazard identified
HU: hazard unknown, no further information necessary

Introduction

- From occup exposure questionnaire – grouping of workplaces, tasks and activities

  -> development 11 **activity classes** (ACs)
- At later stage: change of ‘standard’ **substance-specific** to **workplace-specific** approach
- Via WebEx, assign substances and process steps (with ACs) to **workplaces** (WPs)

  -> 10 WPs identified
- Combined exposure to Pt substances possible: ClPt - traces ClPt - solPt - insolub Pt
- Occupational exposure data gathered via questionnaire from companies:
  - 385 values from 6 companies
  - 163 personal and 65 static data points considered

Introduction

Table 9: Analysis of personal air monitoring data [µg solPt/m³]

#	Workplace	Exposure Category	Physical form*	Counts	Min	Median	GM	GSD	P75	P90	P95	Max
01	WP01	ClPt	DDS	17	0.10	0.67	0.74	3.7	2.91	3.63	4.19	4.72
02	WP01	ClPt	LSSD	3	0.11	0.22	0.21	1.9	0.31	0.36	0.38	0.40
03	WP01	tracesClPt	all	3	0.02	0.05	0.05	2.2	0.08	0.10	0.11	0.12
04	WP01**	insolPt	all	2	0.01	0.11	0.05	6.9	0.15	0.18	0.19	0.20
05	WP02	ClPt	DDS	14	0.09	0.33	0.42	4.3	1.20	3.25	4.68	5.92
06	WP02**	ClPt	LSS	2	0.01	0.03	0.02	5.1	0.04	0.05	0.05	0.05
07	WP02**	tracesClPt	DDS	5	<0.01	0.10	0.05	5.8	0.10	0.10	0.10	0.10
08	WP02	insolPt	all	5	0.10	0.10	0.13	1.6	0.13	0.23	0.27	0.30
09	WP03	ClPt	all	21	0.05	0.22	0.24	2.5	0.51	0.68	1.59	1.71
10	WP03**	solPt	all	5	0.39	29.92	15.38	9.4	37.42	107.79	131.24	154.70
11	WP04**	ClPt	LSS	5	0.01	0.02	0.03	8.1	0.20	0.36	0.41	0.46
12	WP04	ClPt	LSSD	3	0.10	0.59	0.39	3.4	0.81	0.95	1.00	1.04
13	WP04	ClPt	LDS	13	0.03	1.00	0.66	5.6	1.90	4.08	5.86	8.08
14	WP04	tracesClPt	all	2	0.38	0.39	0.39	1.0	0.39	0.40	0.40	0.40
15	WP04**	solPt	all	2	4.81	24.35	14.54	4.8	34.12	39.98	41.94	43.89
16	WP04	insolPt	all	2	0.01	0.02	0.02	1.9	0.03	0.03	0.03	0.03
17	WP06	ClPt	all	4	0.19	1.27	0.80	2.6	1.31	1.33	1.34	1.35
18	WP06***	insolPt	all	1	0.10	0.10	0.10	n.a.	n.a.	n.a.	n.a.	0.10
19	WP07	ClPt	all	6	0.71	1.38	1.94	2.5	3.36	6.38	7.58	8.77
20	WP07**	solPt	all	5	0.04	2.73	2.14	15.6	2.98	55.78	73.39	90.99
21	WP07**	insolPt	all	3	0.10	0.10	0.22	3.8	0.57	0.84	0.94	1.03
22	WP09	ClPt	DDS	6	0.08	2.07	1.02	7.3	3.38	6.53	7.88	9.24
23	WP09	ClPt	LSS	7	<0.01	0.30	0.15	15.9	0.72	1.46	1.93	2.40
24	WP09**	solPt	DDS	3	3.26	30.44	20.39	5.3	57.93	74.43	79.93	85.43
25	WP09	solPt	LSS	2	0.01	0.02	0.02	2.2	0.03	0.03	0.03	0.03
26	WP09	insolPt	all	5	0.01	0.01	0.02	2.9	0.02	0.08	0.10	0.12
27	WP10	ClPt	all	17	0.02	1.37	0.85	5.1	2.39	2.96	6.52	19.00

= value x 1,5
= value x 2

Shaded cells indicate the selected percentile.
*LSSD=liquid, solution, suspension, damp material; LSS=liquid, solution, suspension, DDS=dry (dusty) solids, LDS=low dusty solids
**Maximum value to be multiplied with a factor of 1.5.
***Maximum value to be multiplied with a factor of 2.

Introduction

- Analogous data: read-across to similar exposure conditions
- Modelled data: in cases where no monitoring or analogous data were available
- Dermal exposure: analogous data from Nickel

- Quantitative (*ClPt without DNEL/threshold*) vs semi-quantitative (*inhal with 'other toxicol. threshold' available*) vs quantitative assessment (*dermal*)

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Discussion draft ES

Issues raised by EBRC

- *Undue risks identified*

  Undue risks have been identified for some CES and exposure categories. These are highlighted in red background colour. These CES need to be refined (see below).

- Occasional high exposure levels for solPt

  As per provided hazard conclusion, inhalation exposure to solPt were to be compared with the ACGIH value of 2 µg/m³. Monitoring data for solPt (not ClPt) suggest in some cases rather high exposure levels at up to 150 µg/m³. An APF of > 40 is required to demonstrate safe use here. Please compare estimates 10, 15, 20, 24 reported in Table 9 of the methodology document. These high exposure levels lead to undue risks for some CES for solPt. **In-depth clarification is required with the respective data submitters to resolve this.**

  °Data point 10: most likely contamination – suggestion from company to remove!

  °Previous highest value = 37,42 µg/m³

  °remove 'outliers' where reasonable

  °3 other 'critical' points not identified by PMC – request to provide your monitoring data!

  °avoid use of MEASE (very conservative estimate) and aim for read-across/analogous data

Issues raised by EBRC

- Combined effects for solPt

  It can be seen that the contribution of the dermal route is leading to undue risk in some solPt CES. We strongly suggest generating dermal exposure data in the platinum industry.

- Assessment of background exposure

  We believe that an assessment of background exposure should be conducted in order to strengthen the exposure category approach.

- *Apparent incomplete catalyst lifecycle*

  For some substances "Formulation of catalysts" uses were nominated. We note that apparently (i) the corresponding use of the catalyst formulation is missing (could be the case if exclusively exported), (ii) the formulation is effectively a chemical transformation or (iii) the formulation represents an artefact that should be deleted for lack of relevance. Feedback on this would be appreciated.

Additional issues…

- Split ESs:
  - 3 ClPt dossiers: only ClPt / traces ClPt vs 2 sol Pt dossiers: no mentioning of ClPt exposure
  - What with insol Pt (no risk determined)?

	ClPt	tracesClPt	solPt		insolPt
			DHHP	DNOP	
Relevance of EG for sub-CES	yes	yes if not ClPt	yes if not ClPt/tracesClPt		yes if not ClPt/tracesClPt/solPt
RC required for EG, inhalation route	qualitative	qualitative	semi-quantitative		not needed
EC inhalation,	0.01 µg solPt/m³ (Monitoring	0.01 µg solPt/m³ (Monitoring	0.01 µg solPt/m³ (Monitoring		0.01 µg solPt/m³ (Monitoring

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5. AOB

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6. Conclusions

THANK YOU

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