Chloroplatinates sub-group – Discussion&brainstorming on qualitative approach in ClPt REACH dossiers

Chairman: Steven Verberckmoes (Umicore)

Participant list : Steven Verberckmoes (Umicore), Mark Raffray (consultant), Daniel Vetter (EBRC), Jutta Schade (EBRC, *via conference call*), Olga Duerr (BASF), Michael Thiel (BASF, *via conference call*), Arno Buthe and Rudolf Eller (Heraeus), Mike Shepherd (Vale), France Capon, Maxime Eliat and Jelle Mertens (PMC)

ACTION LIST

Action	Who?	When?	Status
Inform PGM WG on revised DNELs for ClPt	PMC	w/c 30 May	Done
Inform Bibra on revised DNELs for ClPt	PMC	<27 May	Done
Revise ClPt DNEL reports	Bibra	Conclusions&IUCLID: w/c 30 May Reports: <21 June	Done Ongoing
Provide reference of US EPA study to PMC	Mark Raffray	<27 May	Done
Provide US EPA study to Bibra	PMC	<27 May	Done
Provide relevant chapter from guidance document	IPA	w/c 30 May	Done
Provide IPA information to EBRC	PMC	w/c 30 May	Done
Draft and circulate Occupational Monitoring Templates to companies	EBRC	<1 June	Done
Fill Occ. Monit. templates and revert to EBRC (PMC in cc of email)	Companies	<15 June	Ongoing
Provide 1st draft occup ES to PMC	EBRC	<21 June	
Inform with Nickel Institute if use of Ni monitoring data is OK	PMC	w/c 30 May	Ongoing

Discuss dermal monitoring campaign with IPA	France Capon	During meeting in June	
Provide contact details PROC7 nominator to EBRC	PMC or WCA	<21 June	done
Check PROC7 with registrant	EBRC	<21 June	
Check if erroneous sentence is still in draft DNEL reports and correct ('*OEL is protective against PSS*')	PMC	w/c 30 May	done
Document due diligence of PGM industry well/sufficiently in REACH dossiers	EBRC	<21 June	
Communicate CSA with DU	PMC/companies	After registration	
Revise dermal DNEL non-ClPt salts (incl. DNEL report)	Bibra	Conclusions&IUCLID: w/c 30 May Reports: <21 June	Done Ongoing
Provide IPA Guidance chapter on solubility of Pt salts to EBRC	Mark Raffray	<27 May	Done

1. Welcome + Tour-de-Table

The chairman welcomed the participants, followed by a tour-de-table.

The aim of the meeting was to agree on a clear approach for the qualitative assessment by the end of the meeting.

2. Approval draft agenda

The agenda was approved.

3. ClPt respiratory sensitisation under REACH – brief summary of previous discussions

Cfr. Slides 5-10

4. Preparing the ClPt qualitative assessment

1. Examples: BASF CSRs + practical examples in ECHA PG15

BASF presented two REACH dossiers containing a qualitative assessment as illustrative examples. For one of the dossier, ECHA asked clarification why, since the substance was classified as respiratory sensitizer ('RS'), the registrants did not submitted a request for harmonized classification (CLH dossier). BASF commented that the classification is based on a read across to the structurally similar substance Ethylenediamine (CAS 107-15-3) which is a known to be a human respiratory sensitizer.

A key difference between the BASF and ClPt dossiers might be the absence of strictly controlled conditions for some PGM processes. Processes with 'potential for exposure' need careful consideration with regard to RMM/OC, and potential exposure&risk.

All available monitoring data should be made available by companies and considered for CSA under REACH.

The ACGIH OEL is not considered protective against respiratory sensitization.

2. Steps in qualitative assessment (based on ECHA PG 15):

ClPt hazard assessment/banding

Agreed hazard bandings for ClPt are:

-for inhalation exposure: 'high'

° ACGIH OEL is not protective against respiratory sensitization

°derive DNEL for inhalation/systemic/long-term based on repeated dose toxicity as critical endpoint, but don't use this value as DNEL because not protective against PSS

°remove ACGIH OEL value as hazard conclusion in DNEL report and replace by 'high hazard'

-for dermal exposure: 'moderate' or 'high'

°cfr. US EPA study 2015 – key reference on potential induction of PSS (Platinum Salt Sensitisation) by dermal exposure).

°derive DNEL for dermal/systemic/long-term based on repeated dose toxicity as critical endpoint, but don't use this value as DNEL because not protective against PSS

°remove current value (route-to-route extrapolation from ACGIH OEL) as hazard conclusion in DNEL report and replace by 'moderate' or 'high hazard'.

Consequently, only qualitative hazard conclusions/DNELs are included.

ACTIONS:

-PMC to inform PGM WG on revised DNELs for ClPt

-PMC to inform Bibra of this decision

-Bibra to revise ClPt DNEL reports accordingly

-Mark Raffray to provide reference of US EPA study to PMC and PMC to forward to Bibra

Generate exposure scenario

Workplace approach will be used in all Pt dossiers for the manufacture step.

Combined exposure to ClPt and non-ClPt will be considered in each workplace by implementing a 'categorisation' (exposure solely to ClPt <-> combined exposure to ClPt and non-ClPt <-> exposure solely to non-ClPt). This information is gathered by EBRC via WebEx Questionnaires with registrant companies.

The IPA Guidance document chapter on RMM/OC (draft version!) will be provided by IPA (high level description) to EBRC via PMC. EBRC will check for consistency of terminology in ES (that are based on questionnaires/WebEx) with IPA Guidance where possible.

According to Mark Raffray, the IPA Guidance will be promoted by industry as 'best practice' once finalised (Q3 2016?).

Intermediate use/catalysts potential Downstream Uses. Today no information is available on RMM/OC with DU. ES will be developed using RMM/OC used by registrants. DU have to show same diligence to ensure safe use. Input from DU is expected later via REACH process. If safe use cannot be demonstrated for a specific DU, this use can be identified later in the dossier as 'use advised against'.

ACTIONS:

-IPA to provide relevant chapter from guidance document

-PMC to provide IPA information to EBRC

Exposure estimation

Exposure data are key in the process.

Inhalation exposure:

-EBRC will provide each company, which has participated in the WebEx survey, with a template for the submission of occupational exposure data by 1st June 2016

-companies are requested to provide their monitoring data to EBRC by 15th June 2016. Only data that are provided to EBRC by this date at the latest will be included in the Occupational Exposure scenarios by EBRC.

Dermal exposure:

-modelling dermal exposure gives estimates above current DNEL (based on ACGIH OEL).

-monitoring data are not available for PGMs. Daniel V has identified this as a severe data gap, and a monitoring campaign needs to be considered for the future (in cooperation with IPA?).

-According to Daniel V, Nickel dermal exposure data can be considered as analogous data.

No DU exposure data are available. This is also a data gap which will need to be filled in the future and will be included in the maintenance phase of the dossier. A DUs program is under development by PMC and will be implemented after the registration in preparation of the maintenance.

PROC7 is reported by some registrants – this can be problematic considering high potential for exposure – contact details of PROC nominator will be provided to EBRC by PMC or WCA.

ACTIONS:

-EBRC to draft and circulate Occupational Monitoring Templates to companies (by 1 June)

-Companies to fill templates and revert to EBRC (PMC in cc of email) (by 15 June)

-EBRC to provide 1st draft occup ES to PMC (by 21 June)

-PMC to inform with Nickel Institute if use of Ni monitoring data is

-France C to discuss dermal monitoring campaign with IPA during meeting in June

-PMC or WCA to provide contact details PROC7 nominator to EBRC

-EBRC to check PROC7 with registrant

Risk characterisation

Mark Raffray mentioned a mistake in the draft ClPt DNEL reports saying 'the OEL is protective against PSS' – needs to be corrected.

ACTIONS:

-PMC to check erroneous sentence in draft DNEL reports and correct (if still in)

Validation of adequate control + implications for DU

There are still cases of PSS observed with workers today. However, there is a vast improvement compared to the past:

-today's occupational exposure is lower than reported data in Heederick et al (2016)

-workers identified as sensitized to ClPt are transferred to other workplaces with no ClPt exposure so that no workplace related PSS symptoms are observed

-IND target value of 100 ng/m³ to minimize risk of PSS (agreed not to mention this value in the dossier!)

Adequate control will be shown using:

-ALARA principle, in combination with

-Benchmark Value (compare the company exposure data per workplace with the OEL to show (much) lower exposures)

Margin of Exposure is considered not applicable, mainly due to absence/uncertainty of dose-response relationship of IPA data.

The development process of ES is an iterative process:

-during development to ensure all companies are covered

-after development to validate the ES with DU.

ACTIONS:

-EBRC to well document in REACH dossiers due diligence of PGM industry

-PMC/companies to communicate CSA with DU

Documentation in REACH dossier

cfr previous bullet points

It is agreed that a clear and transparent documentation in the REACH dossier is important!

5. AOB

The Dermal DNEL for non-ClPt dossiers has to be recalculated starting from Repeated-dose toxicity as critical endpoint.

All non-ClPt dossiers requiring CSA are considered 'soluble Pt salts' (cfr IPA Guidance)

ACTIONS:

- BIBRA to revise DNEL report accordingly

-Mark Raffray to provide IPA Guidance chapter on solubility of Pt salts to EBRC

6. Conclusions

The main conclusions have been summarized (cf. Slides 34-35)

A next meeting (face-to-face) of this group is scheduled on 7 July (Metals Conference Center, BXL) as face-to-face meeting.

Annex I: SLIDES OF THE MEETING

Cfr. attachment to email

Annex II: AGENDA

1. Welcome + Tour-de-Table (SV) (10.30-10.35)
2. Approval draft agenda (SV) (10.35-10.40)
3. ClPt respiratory sensitisation under REACH – brief summary of previous discussions (PMC) (10.40-10.50)
4. Preparing the ClPt qualitative assessment (ALL) (10.50-15.45)
    a. Examples: BASF CSRs + practical examples in ECHA PG15
    b. Steps in qualitative assessment (based on ECHA PG 15):
        i. ClPt hazard assessment/banding
        ii. Generate exposure scenario
        iii. Exposure estimation
        iv. Risk characterisation
        v. Validation of adequate control + implications for DU
        vi. Documentation in REACH dossier
5. AOB (SV) (15.45-15.50)
6. Conclusions (SV) (15.50-16.00)