



PGM Work Group Meeting – Minutes

Brussels, 4 October 2016 (11.30-16.40)

Actions	Who?	When?	Status
Review RAAF justification reports by chemistry expert	Dave Boyd	w/c 24 Oct	
Include impurity profiles from substance ID card in RAAF justification reports and elucidate on similarity between source/target substance	BIBRA	w/c 10 Oct	
circulate result of preliminary water solubility test with Karstedt concentrate to Tox Expert group, and decide on way-forward for ecotox testing	PMC	Expected w/c 10 Oct	
check read-across strategy for ENV classification Pt nitrate with WCA & circulate to Tox Experts	PMC	w/c 3 Oct	Done
Perform in vitro Mouse Lymphoma tk assay	PMC	Initiate ASAP	
Include testing proposals for in vivo genotox testing as agreed, and a waiver for in vivo genotox for Pt dinitrate	Bibra	< end 2016	
Verify if PNECs are (not) required for 1-10 tpa substances	PMC	w/c 3 Oct	Done
circulate the 5 revised occupational assessment reports	PMC	w/c 3 Oct	Done
Review Pt ES within 2 weeks deadline	PMC Companies	<21 Oct	
inform PMC secretariat what uses are believed not relevant in the PGM industry	PMC Companies	<21 Oct	
inform Mgt Cttee about need for a dermal monitoring campaign	France Capon	Meeting 6 Oct	Done
Discuss PGM reserves with Mgt Cttee	France Capon	Meeting 6 Oct	Done



Review site visit reports urgently (if not yet done)	PMC Companies	<end Oct	
Inform PMC secretariat (& EBRC) on Rh/Ru monitoring intentions (and newly gathered data)	PMC Companies	<end Oct	



1 Welcome and Introduction

1.1 Reminder on Confidentiality and Competition Law

Participants were reminded on their obligation to comply with Confidentiality and Competition Law.

1.2 Tour de table and apologies

The list of participants is available in Annex 1.

1.3 Approval of the agenda

No remark were made. The agenda was approved.

1.4 Approval of the minutes of the last meeting (21 Apr. 2016) and status of action points

No remarks were made. The minutes of the previous meeting of 21 April 2016 were approved

2 Iridium and Iridium compounds

All Ir dossiers have been registered by the Lead Registrants. No immediate actions on the Ir dossiers is foreseen.

No additional comments/questions were raised.

3 Palladium and compounds

3.1 Dossier status

An update was given on the registration / preparation status and timing of the Pd dossiers. Aim is to have all Pd dossiers ready for submission end November 2016 (but this depends largely on timely finalization of phys-chem testing and input from PMC members where needed).

The Chairman reminded the participants of a timely review of documents/REACH dossiers during the dossier preparation phase (including approval process with working group), and (preferably) not during the approval process at the Management Committee or Sub-Assembly.

The participants approve the classification of Pd dinitrate as Oxidising solid, PG1.

3.2 Pending dossiers

An overview is given of the ongoing phys-chem testing.

3.3 RAAF (read-across justifications): discussion on proposed format

The proposed format of the RAAF justification reports is approved by the participants. Bibra will finalise the draft RAAF justification reports w/c 10 Oct, and the participants agreed to review and approve using the fast-track procedure (2 weeks for review, 1 week for approval). The participants asked if Bibra was



happy with the read across justifications. Bibra was confident but some points could be strengthened with information on biotransformation and the impurity profiles.

ACTIONS:

- **The grouping justification needs to be reviewed by a PGM chemistry expert.**
- **Include impurity profiles as included substance ID cards (boundary composition), add that impurity profiles are similar between target-source substance and not driving classification**

4 Platinum and compounds

4.1 Dossier status

An update was given on the registration / preparation status and timing of the Pt dossiers.

4.2 Hazard (Ongoing HH & ENV testing Karstedt Conc and HHPA/2AE, phys-chem testing, Pt genotox review): update & technical discussion

The results of the preliminary water solubility test with Karstedt concentrate are expected w/c 10 Oct.

ACTION:

- **Circulate result of preliminary water solubility test with Karstedt concentrate to Tox Expert group, and decide on way-forward for ecotox testing**

The participants did not consider Fish Embryo Acute Toxicity test as relevant for the PGM dossiers, and agreed to continue the ecotox testing strategy as foreseen.

The participants agree with the proposed dosing levels for the OECD422 testing with HHPA/2AE (0-100-300-1000 mg/kg/d), and the proposed classification changes for

- Pt dinitrate as Oxidising solid (PG1) and Aq acute1 and Aq chronic1 (M factor 1) (with the remark that the strategy for Pt nitrate needs to be checked),
- diammonium hexachloroplatinate as Aq acute1 and Aq chronic1 (M factor 1),
- HHPA/2AE as Aq acute1 and Aq chronic1 (M factor 1) and
- HHPA as Aq acute1 and Aq chronic1 (M factor 1).

ACTION:

- **check read-across strategy with WCA**

[Post meeting note: answer WCA: *"The read across approach for the Pt substances is based on the standard approach for read across of environmental endpoints for metals, assuming that the toxicity is due to the metal, unless additional toxicity is anticipated due to the co-ordinating ligand. For Pt substances there is some indication that substances with a chloro ligand are more toxic, therefore we are only reading across between substances in the same oxidation state and for substances like Pt dinitrate that do not contain a chloro ligand we are reading across from other substances without a chloro ligand – in this case HHPA, and HHPA-2AE for fish (due to the difficulties testing HHPA in the ecotox studies).*



This is the approach that was used in the original ITS and has been reflected in all of the data matrices since then – the slide for the WG meeting did not represent a change in read across strategy, it was simply due to the test data for HHPA and HHPA-2AE now being available, so that we can now assess the classification.

If we do not follow this read across approach, the alternative would be to conduct additional testing with platinum dinitrate itself.”]

The participants agree to perform an *in vitro* Mouse Lymphoma tk assay with tetraammine Pt dichloride as proposed (3 treatments, 1 main experiment). It was highlighted that care needs to be taken for false positive outcome related to impurities of the test substance (such as chloroplatinates – cfr previous experience with Skin sensitization testing of this compound).

ACTION:

- **Initiate in vitro ML tk assay test at Covance**

The participants agree with the proposed *in vivo* genotox testing strategy for Pt compounds (use of Micronucleus/Comet assay with TK). Testing should be conducted at a knowledgeable institute to avoid false positives. Once testing is initiated, a good dose selection is warranted, as well as the assessment of target organ exposure. For the Pt(IV) anionic group, HHPA/2AE is agreed as test substance. For Pt dinitrate: the participants agreed to include a waiver for *in vivo* genotoxicity (strategical decision) rather than a testing proposal. In that waiver, it needs to be specified that we postpone the inclusion of a testing proposal (if deemed necessary) until the *in vivo* genotox testing for the other Pt groups is finalised. As the testing results become available, the need to include a testing proposal for Pt dinitrate will be reconsidered.

ACTIONS:

- **Prepare testing proposals and waiver as agreed**
- **Include a waiver for in vivo genotox test with Pt dinitrate**

The participants agreed to not classify any Pt substance for mutagenicity before *in vivo* evidence becomes available.

4.3 Exposure (PNEC, DNEL, ENV & Occupational assessment): update and discussion

It was clarified that a lower assessment factor for the Pt PNECs was possible if a chronic fish test was performed. This is not required at this point in time, as safe use is shown.

The PNEC strategy for Pt (split per oxidation state) is supported by the participants. This methodology is different from the Pd dossiers, where we have one generic PNEC for all dossiers. The participants prefer to avoid generic PNECs as much as possible, but the Pd strategy is protective/conservative and as such defensible.

It was explained that PNEC values are not required for the PMC 1-10 tpa substances, and are as such not included in these REACH dossiers

ACTION:

- **Verify if PNECs are (not) required for 1-10 tpa dossiers**



[Post meeting note: in ECHA Guidance R10, it is mentioned in section R.10.2.1 '*The derivation of PNECs is required for the chemical safety assessment (CSA) of substances manufactured/imported/used in quantities from 10 t/y onwards*']

The revised occupational assessment reports will be circulated to the PGM WG. The participants agree that a dermal exposure monitoring campaign needs to be initiated soon, and this message should be raised at the Mgt Cttee meeting. The participants are reminded to check the use descriptors in the revised documents (including the associated brief explanation in the exposure scenario) and verify compliance. The members agreed to keep the revised exposure scenarios generic as long as safe use is shown. PMC secretariat asked the members to specify those uses/section they feel not applicable in the PGM industry, so that a further refinement/simplification can be done. Members agree with a 2-week revision deadline.

ACTIONS:

- **Circulate the 5 revised occupational assessment reports**
- **Inform Mgt Cttee about need for a dermal monitoring campaign**
- **PMC members to inform what uses are believed not relevant in the PGM industry**
- **Review the revised occupational ES before 21 Oct**

5 Ruthenium and compounds

5.1 Dossiers status

An update was given on the registration / preparation status and timing of the Ru dossiers.

5.2 Hazard (Ongoing HH & ENV testing RuCl₃): update & technical discussion

An update was given on the testing status of the Ru dossiers. No remarks were made.

5.3 Exposure (Occupational Monitoring project): update

The use summary of Rh and Ru substances will be circulated soon. The participants were reminded to check if all uses are covered, and if all uses are correctly described (cfr check use descriptors and the tasks that are attributed to them). It was also explained that uses marked as 'confidential' in the use questionnaires, are not included in the generic REACH dossier (unless reported by another company as non-confidential), and need to be included in the company specific dossier (together with the risk assessment if required).

An update was given on the status of the occupational monitoring project. Participants / companies were reminded to review the site visit reports urgently (if not yet done), and inform PMC/EBRC on their monitoring intentions and data for Ru and Rh. The deadline for this project is set at 2nd half of November 2016.

ACTIONS:

- **PMC members to review the site visit reports urgently (if not yet done)**
- **PMC members to inform PMC secretariat (&EBRC) on Rh/Ru monitoring intentions and (newly) gathered data**



6 Rhodium and compounds

6.1 Dossiers – status

An update was given on the registration / preparation status and timing of the Rh dossiers.

6.2 Hazard (Ongoing AMES testing, Rh(III) genotox review): update and technical discussion

The participants agreed to postpone the decision on the Rh₂O₃ AMES testing (do silverson mixing vs waive testing) until the testing results with Rh(OH)₃ are available.

The participants agree with the proposed classification changes for

- Diammonium sodium hexakis(nitrito-N)rhodate as Aq chronic2
- Rhodium trichloride as Aq acute1 and Aq chronic1 (M factor 1).

6.3 Exposure (PNEC): update

The PNEC derivation for Rh & Rh compounds might not be needed anymore due to lowering of tonnage class of the Rh compound triggering this work. It was agreed that –if a PNEC report would be required– the PNEC should be derived for that compound only (and not as a generic Rh PNEC covering all Rh substances).

7 Budget overview

The members approved the proposed budget, with a remark that calculation of the reserves (%age based on historical cost) needs to be discussed during the Mgt Cttee meeting.

ACTION:

- **Discuss reserves during Mgt Cttee meeting**

[Post meeting note: this topic has been discussed at the Mgt Cttee meeting. It was decided that to keep the structure as agreed by the Assembly in 2014 and reconsider it in 2017 when registration will be close to finalisation. This is recommended due to the number of remaining uncertainties (overall costs, forecast, LoA incomes etc.). It is also important at this stage of the process to avoid that the organisation is facing cash deficiency. Also, for some metals (like Pt and Ru), the reserves are negative and part of the proposed budget is to fill this gap.]

8 AOB, next meetings/calls and closing remarks

The chairman thanked the participant of the meeting, and PMC secretariat for the preparatory work. The Participants were in favour of having a combined PGM Tox Experts and PGM WG meeting.

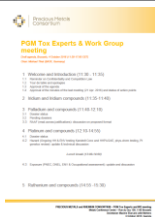
Next PGM TE&WG meeting is scheduled 22 March 2017 (full day).



1. Agenda & List of participants
2. Slides presented at the meeting



Annex I: Agenda & List of participants



Annex II: Slides presented at the meeting

