



PGM EXPOSURE SCENARIOS UPDATE

1. Introduction

This document aims at providing Members of the PGM WG and PGM ES WG with a brief status update on the items that were on the agenda for discussion at the 13 March PGM ES meeting that was postponed to 19 June.

2. Substance identification, sameness and tonnage of Pd substances

2.1. ID cards

In order to clarify several issues on physical state/properties and to support the substance sameness discussions and other mandatory communication obligations with the SIEF, ID cards have been circulated to PMC Members for several prioritised PMC substances (including those undergoing testing to refine the 'skin corrosive 1A' classification). Members were asked to provide input on the ID cards by 15 March, in order to launch the SIEF communication end of March.

2.2. Sameness

An expert meeting was held 11 December 2012 on the sameness of the PGM nitrates. Some issues are still to be further clarified. Companies that have received a request for further info are asked to provide the requested clarifications as soon as possible.

2.3. Tonnage

The PMC secretariat recently became aware of an issue in determining the exact tonnage used for DDP. In order to reach the required purity, the DDP is sometimes re-dissolved in aqueous ammonia and re-precipitated by the addition of acid. This re-dissolution results in a chemical transition of DDP (it is no longer DDP) and it could be argued that this doubles the effective tonnage of DDP. Some Members may have thus counted the tonnage of DDP twice.

Example: manufacturing of DDP

- Raw product: 10 t
- Purification step:
 - o Dissolve 10 t raw product (e.g., in ammonia) = chemical transition
 - o Precipitate DDP = 10 t
- Total: 10 t or 20 t?

Two Possibilities to count tonnage:

- 1) Double-counting
 - o Production of raw product
 - o Production of non-isolated intermediate
 - o New production of pure product = need to count again
- 2) Single-counting
 - o Production of raw product
 - o Purification step
 - o Pure product = no need to count again

The PMC secretariat recommends considering the re-dissolution as a purification step and thus counting the DDP tonnage only once. This recommendation has been confirmed with the UK Reach Ready helpdesk and the implications are summarised in below table.

	Tonnage band old	Tonnage band new	REACH deadline
Diamine dichloropalladium	100-1000 t/a	10-100 t/a	5/2013 => 2018
Diammonium hexachloropalladate	100-1000 t/a	10-100 t/a	5/2013 => 2018
Diammonium hexachloroplatinate	100-1000 t/a	10-100 t/a	5/2013 => 2018

3. Final identified uses of Pd and Pd compounds

Following presentation of the identified uses at the last meeting, some clarification points were raised with respondents. All uses and use titles are unchanged since last meeting except for:

- Changes to use titles:



- o Dichlorobistriphenyl phosphine, Palladium (II) diacetate and Palladium (II) di(4-oxopent-2-en-2-oate): 'Processing aid - Industrial' changed to 'Catalyst - industrial'.
- o Tetrakis(triphenylphosphine)palladium: 'Processing aid - Industrial' moved under the title 'Catalyst - Industrial'.
- o Palladium dichloride:
 - 'Manufacture of inks and paints - Industrial' and 'Use of inks and paints - Consumer' added;
 - 'Use of Inks and paints - Professional', 'Service life of metal surface treated objects - Industrial/Professional/Consumer' and 'Service life of non-metal surface treated objects - Industrial/Professional/Consumer' removed.
- o Palladium Sulphate and Tetraammine Palladium dichloride: 'Service life of galvanised or metal surface treated objects - Industrial/Professional/Consumer' removed.
- o Palladium Oxide:
 - 'Industrial use resulting inclusion to the matrix' changed to 'Manufacture of Pd oxide containing catalyst'
 - 'Service life after inclusion onto matrix - Industrial/Professional/Consumer' changed to 'Use of Pd oxide containing catalyst - Industrial/Professional/Consumer'
- Additionally, WCA has removed some PROC and ERC codes from intermediate uses that are deemed by ECHA to be incompatible for intermediate uses and has noted those that ECHA considers inappropriate for SCC intermediate use.

The updated list of uses was circulated to the PMC Members on 1 Feb 2013 for final review and comment by 15 Feb 2013. One additional use was identified for Dihydrogen tetrachloropalladate ('Metal surface treatment - Industrial'). Furthermore, some additional SU, PROC and ERC codes were identified and some SU and ERC codes were removed from intermediate use based on ECHA guidance. The final list of declared uses and descriptors is available in Annex 1.

4. Current status of PNEC and DNEL refinement

4.1. PNEC derivation

The read across approach for Pd compounds was discussed and agreed at the 17 Jan 2013 PGM WG meeting. DDP (worst-case PNEC) will be used as a basis for read across to other Pd(II) substances. A decision on Pd(IV) substances is currently under discussion (Pd(IV) is not stable and will hydrolyse rapidly to Pd(II)).

To refine the PNEC for DDP, it was agreed at the last PGM ES meeting to conduct aquatic and sediment testing. The tests started in Jan 2013 at Fraunhofer Institute Schmallenberg (Germany) and results are expected in May 2013.

4.2. DNEL DDP

For the DNEL derivation for DDP, the repeated dose toxicity (RDT) study is currently ongoing at CiToxLAB. Results are expected by end 2013.

The current (tentative) DNELs used in the draft exposure scenarios are based on Tetraamminepalladium hydrogencarbonate (out of scope substance).

5. Environmental emissions Pd and Pd compounds

5.1. Generic Exposure Scenario (GES) for total Pd

Following the last PGM ES meeting, WCA received process flow diagrams from PMC Members indicating annual tonnage values for Pd processing starting materials, intermediates and final products. Consideration of 'net Pd tonnage' and calculation of emission factors from this were the final stage in the development of the GES.

The draft environmental GES for DDP manufacture, use as an intermediate and use in electroplating is available in Annex 2. The 'Msafe' approach was used, meaning that sector-specific emission factors and other GES exposure parameter values were used in conjunction with PNECs to calculate the maximum tonnage of DDP that can be safely processed (manufactured or used) without posing a risk to the environment:

- Msafe tonnage for DDP manufacture = 11 t/a (5,5 t Pd equivalent)



- Msafe tonnage for DDP use as intermediate = 11 t/a (5,5 t Pd equivalent)
- Msafe tonnage for DDP use in electroplating = 1 t/a (500 kg Pd equivalent)

The GES will be updated with revised PNECs.

5.2. Status of site-specific risk assessments (SSA)

WCA sent provisional SSAs for environmental emissions of Pd to all companies. This assessment is based on data provided in the environmental exposure questionnaire and subsequent follow-up questions. Where site-specific parameter values were missing, values taken from the GES were used.

Revised SSAs will be sent out when the revised PNECs have been agreed and it is anticipated that these will generate lower RCRs but the extent of this reduction cannot be guaranteed and further steps (e.g. monitoring of local environment) may be necessary in order to demonstrate an absence of risk to the environment. Therefore, WCA included recommendations on further steps that could be undertaken to refine the assessment and generate lower RCRs in each SSA. Discussions on possible monitoring programmes / guidelines on monitoring are currently on-going.

Provisional results of the SSAs are summarised in below table.

Site Ref	Receiving water body	Release factor to water	RCR STP	RCR Receiving water body	RCR Receiving water body sediment	Release factor to air	RCR Local Air	RCR Local soil (no sludge)
		g/T				g/T		
Site A	Freshwater via STP	5.8	3.00×10^{-7}	0.0528	1.50	1.1	1.1×10^{-5}	0.161
Site B	Freshwater via STP	109.5	4.41×10^{-4}	45.0	451	300	1.5×10^{-2}	0.163
Site C	Freshwater via STP	0.9	2.03×10^{-7}	0.0513	1.48	300	4.6×10^{-3}	0.162
Site D	Freshwater via STP	62.5	2.71×10^{-5}	0.327	4.23	300	7.3×10^{-3}	0.162
Site E	Freshwater	25.3	NR	0.084	1.81	61.0	1.7×10^{-3}	0.161
Site F	Freshwater via STP	0.2	5.17×10^{-9}	0.0493	1.46	158	1.4×10^{-4}	0.161
Site G	Marine water	68.2	NR	21.2	208	300	4.1×10^{-3}	0.162
Site H	Freshwater via STP	68.2	3.39×10^{-7}	0.0527	1.50	300	5.6×10^{-3}	0.162
Site I	No emissions							
Site J	Freshwater via STP	357.1	1.13×10^{-4}	1.20	13.0	300	9.7×10^{-3}	0.162
Site K	Freshwater via STP	833.3	9.04×10^{-4}	9.29	93.9	300	3.3×10^{-3}	0.162
Site L	Freshwater via STP	78.0	1.63×10^{-6}	0.0659	1.63	300	5.6×10^{-4}	0.161
Site M	Freshwater via STP	68.2	9.25×10^{-5}	0.995	10.9	300	5.6×10^{-4}	0.161
Site N	Marine water via STP	180.0	5.55×10^{-4}	5.05	50	300	5.6×10^{-3}	0.162

6. Occupational exposure scenarios for DDP

6.1. Reflection of comments received - open issues

At the last PGM ES meeting, EBRC presented a first draft of the occupational exposure scenario (ES) for DDP. Comments received on this version and EBRC's responses to them are summarised in Annex 3.2. Furthermore, since the last meeting:

- EBRC received clarification on some monitoring data and occupational exposure questionnaires;
- All relevant use descriptors have been included;
- EBRC received clarification on potential additional uses and physical forms

The final draft ES for DDP is available in Annex 3.1. Open issues include:

- Discussions are on-going with regard to interim DNEL levels and it is proposed to wait for further study results to have refined DNELs and relevant dustiness covered.
- Standard phrases could be used in the ES for eSDS. It is proposed to postpone the decision on



potential translation into standard phrases to the next meeting in June.

- Changes that were done in the latest version of the identified uses overview due to the definition of intermediates will be reflected in the occupational exposure scenarios.
- It is additionally proposed to delete PCs 20 (pH regulators,...) and 21 (laboratory chemicals) for ES 9.2 and only keep PC 19 (intermediate) to better reflect the intermediate use of DDP in this exposure scenario.
- It is proposed to change the title of ES 9.3 to “Industrial use of DDP for surface treatment”.

6.2. Results dustiness tests and impact on occupational exposure scenarios

The result from the performed dustiness test confirms low dustiness (result for substance humidity of 20.1 %). Additional questions to manufacture of DDP:

- Indication received that DDP is dried during manufacture:
 - o Dried to which moisture content?
 - o Resulting dustiness of DDP?
- If further results show other dustiness classes, specific moisture contents to be known for all process steps for inhalation exposure modelling with MEASE
 - o additional inhalation monitoring measurements could be conducted to reflect actual conditions in the occupational ES;
 - o results could also be used for other Pd substances.

Discussions on possible further dustiness testing are currently on-going.

7. Next steps and timeline for dossier submission

As discussed under 2.3, the timing has been revised and registration should be done by the 2018 deadline for all Pd compounds now. The PMC secretariat suggests keeping up the momentum and continuing with the testing and ES work as much as possible. But there will be no need to derive interim RMM or to submit incomplete dossiers in May 2013.

Proposed next steps are:

- 1) Complete the ongoing studies asap:
 - RDT study by end Dec 2013;
 - Ecotox tests by end May 2013;
- 2) Update PNEC and DNEL:
 - DNEL refinement by end Feb 2014;
 - PNEC refinement by end Jul 2013;
- 3) Reconsider exposure scenarios:
 - Update environmental ES by end Feb 2014;
 - Update occupational ES by end Mar 2014.

This will allow for sufficient time to refine the exposure scenarios (e.g., conduct specific monitoring studies, etc., if required). Registration is currently foreseen by end Jun 2014.

Annexes

1. List of declared uses (WCA, 13 Mar 2013)
2. Draft environmental exposure scenarios DDP (WCA, 6 Mar 2013)
3. Occupational exposure scenarios DDP:
 - 3.1. Final draft (EBRC, 26 Feb 2013)
 - 3.2. Comments received on first draft and responses (EBRC, 26 Feb 2013)