PGM Project
Exposure Scenario Meeting

Brussels, 12 December 2012

1. Welcome & Introduction

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Dave Boyd

- Reminder on Confidentiality and Competition Law
- Tour de table and apologies
- Approval of the Agenda
- Approval of the minutes of the last meeting and status of action items (9 October 2012)

Agenda

1. Welcome and introduction
2. Substance identification and sameness of Pd substances
3. Identified uses of Pd and Pd compounds
4. Environmental emissions of Pd and Pd compounds
5. Occupational exposure of Pd and Pd compounds
6. PNEC and DNEL refinement for diamminedichloropalladium (DDP)
7. Next steps and timeline
8. AOB, next meetings/calls and closing remarks

Actions 9 October (1)

Action	Who?	Status
Substance identification and sameness Pd substances		
Send input / comments to KA on the ID cards of prioritised PGMs	PMC Members	Done
PNECs / DNEL for diamminedichloropalladium (DDP)		
Derive tentative DNEL for DDP, based on RDT study tetraamminepalladium hydrogencarbonate, to enable conducting the ES calculations	PMC Sec / WCA	Done
Repeat RDT study (OECD TG422 combined toxicity/reproductive screen study) for DDP for final DNEL derivation	PMC Sec / CiToxLAB	Ongoing
Identified uses of Pd and Pd compounds		
Send input / comments on the compiled list of uses to WCA	PMC Members	Done
Assess which use descriptors can be combined and clarify remaining issues on uses with PMC Members (with focus on DDP first)	WCA	Ongoing
Once finalised, send list of DDP uses to downstream users clearly stating that uses not on the list may not be authorised	PMC Sec through PMC Members	Dec 2012
Depending on the outcome of the PROCs discussion at the Jan 2013 Eurométaux/ECHA workshop, review and/or justify PROCs of intermediate Dossiers	WCA	Jan 2013
Prepare and circulate one-pager on proposed intermediate workshop to check interest from PMC Members	KA	Done

Actions 9 October (2)

Action	Who?	Status
Environmental emissions of Pd and Pd compounds		
Send personalised reminder to PMC Members not having sent an env. emissions questionnaire yet, highlighting min info required for the GES	KA	Done
If not done yet, complete env. emissions questionnaire for each site producing Pd / Pd substances and return to project coordinator	PMC Members	Done
Clarify remaining issues on env. emissions of Pd compounds with PMC Members	WCA	Ongoing
Refine GES for Pd and Pd substances based on extra data provided	WCA	Ongoing
Based on results of the GES, decide whether or not there is a need to refine the PNECs and perform further effect studies	All	Dec 2012
Occupational exposure of Pd and Pd compounds		
Send personalised reminder to PMC Members not having sent an occ. exp. questionnaire yet	KA	Done
If not done yet, complete occ. exp. questionnaire and data collection form for each site producing Pd / Pd substances and return to project coordinator	PMC Members	Done
Clarify remaining issues on occ. exp. and on monitoring data with PMC Members	EBRC	Ongoing
Refine GES for DDP based on extra data provided	EBRC	Ongoing
List possible next steps for occ. exp. assessment EBRC will be looking at	EBRC	Ongoing
Select 3 damp DDP solids with different known water content for dustiness testing	PMC Sec	Ongoing

2. Substance identification & sameness of Pd substances

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Klaus ROTHENBACHER
Katrien ARIJS

Background

- ID cards circulated for the following Pd substances
- Aim
  - Clarify issues physical state/properties
  - Support the substance sameness discussions & other mandatory communication obligations with the SIEF (e.g. $PdCl_2$ in aq. HCl vs. H_2PdCl_4)
- Currently evaluating feedback
- PGM nitrates
  - Expert meeting 11th December 2012

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3. Identified uses of Palladium and Palladium compounds

Claire Massey, Iain Wilson, Ed Stutt

Palladium Uses; Background

- Uses identified from PMRC member companies and downstream users
- Uses and their descriptors grouped where possible
- If intermediate or processing aid use identified; no subsequent service life included
- However, for other uses subsequent service life confirmed or assumed (if limited information provided)

Industrial and Professional Use

- Often both industrial and professional use identified under same set of descriptors
- Clarification sought with companies where this was case asking for a separate response for each use
- However, updated questionnaires not always received
- Therefore, descriptors applied to both industrial and professional use, though not always relevant to both

Consumer Use

- Some Consumer uses identified
- However, the use descriptors provided related to the upstream use rather than a consumer use
  - » E.g. jewellery production
- Moved use descriptors to Industrial or Professional, but kept consumer use without descriptors

Declared Uses; Ammonium hexachloropalladate

Use	SU	PROCs	ERCs
Intermediate - Industrial	8, 9, 0 (Catalysts)	3, 9, 22, 27a	6a

Declared Uses; Dichlorobistriphenylphosphine Palladium

Use	SU	PROCs	ERCs
Processing aid- Industrial	3, 8, 9, 24	1, 9, 15	1, 4, 5
Intermediate - Industrial	3	9	1, 6a

Declared Uses; Dihydrogen tetrachloropalladate

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 8, 9, 14, 15, 24	1, 3, 4, 8a, 8b, 9, 15, 27b	1, 2, 6a, 7, 9a
Intermediate - Professional	3, 9, 14, 15, 24	1, 3, 8b, 15, 27b	1, 2, 6a, 7, 9a

Use descriptors supplied for professional same as industrial

Declared Uses; Dipotassium hexachloropalladate

Use	SU	PROCs	ERCs
Intermediate - Industrial	3	4, 8a, 8b, 26	1, 6a

Declared Uses; Disodium tetrachloropalladate

Use	SU	PROCs	ERCs
Intermediate - Industrial	3	1, 4, 8b, 9	1, 6a

Declared Uses; Palladium (II) diacetate

Use	SU	PROCs	ERCs
Intermediate or reactive processing aid - Industrial	3, 9, 24	1, 3, 5, 8b, 9	1, 6a, 6b
Processing aid - Industrial	3, 8, 9, 24	1, 4, 8b, 9, 15	1, 4, 5

Declared Uses; Palladium

Use descriptors supplied for professional same as industrial

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 4, 8, 9, 10, 14, 0	1, 3, 4, 5, 8b, 9, 14, 15, 21, 23, 24, 26	1, 5, 6a
Production and use of Pd metal containing catalyst - Industrial	3, 9, 10, 0	1, 2, 3, 4, 8a, 8b, 13, 15, 27a	1, 3, 4, 6a
Reforming of Pd - Industrial	3, 14, 15, 16, 17, 20, 21, 24, 0	1, 3, 4, 5, 6, 8a, 8b, 9, 10, 13, 14, 19, 21, 22, 23, 24, 25, 26, 27a, 27b, 0	1, 2, 3, 4, 5, 7, 8c, 11a, 12a, 0
Reforming of Pd - Professional	3, 14, 15, 16, 17, 21, 22, 24, 0	1, 4, 5, 6, 8a, 8b, 9, 10, 13, 19, 22, 24, 25, 26, 0	1, 2, 3, 4, 5, 7, 8a, 8c, 8d, 10b, 11a, 12a
Manufacture of Pd containing Alloys - Industrial	2a, 3, 14, 15, 16, 17, 20, 21, 22, 0	1, 3, 4, 5, 6, 8a, 8b, 9, 13, 14, 22, 23, 24, 25, 26, 0	1, 2, 3, 6a, 8a, 8d, 10b, 11a, 12a, 0
Manufacture of Pd containing Alloys - Professional	3, 15, 22	1, 5, 22, 24, 26	1, 2
Metal Surface treatment - Industrial	3, 15, 24	2, 8b, 13, 20, 26, 0	2, 5
Handling and use of Pd containing materials – Industrial/Professional/Consumer	*No relevant use descriptors supplied, however, uses in Trading, Surface treated materials, Technical Products, Precious metal products, Coins, Medals, Electronics, Dental alloys and Jewellery were indicated*		

Declared Uses; Palladium (II) di(4-oxopent-2-en-2oate)

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 9	3, 4, 8b, 9	1
Processing aid - Industrial	3, 8, 9, 24	1, 9, 15	1, 4, 5

Declared Uses; Palladium chloride

Use descriptors supplied for professional same as industrial

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 8, 10	1, 2, 3, 4, 8b, 9, 15, 26	1, 2, 6a
Metal Surface Treatment - Industrial	3, 4, 10, 11, 14, 16, 17	2, 4, 5, 8a, 8b, 9, 13, 15, 26, 0	2, 4, 5, 7
Metal Surface Treatment - Professional	3, 10, 16	2, 4, 5, 8b, 9, 13, 15, 26	2, 5, 7
Service life of metal surface treated objects – Industrial/Professional/Consumer	*Implied use*		
Non-metal surface treatment - Industrial	3, 10, 16	1, 2, 4, 5, 7, 8b, 9, 13, 15, 19, 26	2, 5, 6a, 6b, 7
Service life of non-metal surface treated objects – Industrial/Professional/Consumer	*Implied use*		
Catalyst - Industrial	10, 0	1, 3, 15	1, 6a, 7
Inks and paints - Industrial	3, 9, 16, 24	4, 9, 15, 26, 27b	1, 2, 5, 6a
Inks and paints - Professional	3, 9, 16, 24	4, 9, 15, 26, 27b	1, 2, 5, 6a

Declared Uses; Palladium dinitrate

Use descriptors supplied for professional same as industrial

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 8, 9, 14, 15, 17, 24	1, 3, 4, 5, 8a, 8b, 9, 13, 15, 21, 27b	1, 2, 5, 6a, 7, 9a
Intermediate - Professional	3, 9, 14, 15, 24	1, 3, 8b, 15, 27b	1, 2, 6a, 7, 9a
Manufacture of Pd dinitrate containing catalysts - Industrial	3, 8, 9, 16, 17, 0	2, 3, 4, 5, 8a, 8b, 9, 13, 19, 22, 0	2, 5, 8a
Use of Pd dinitrate as a catalyst - Industrial/Professional/Consumer	*Implied use*		

Declared Uses; Palladium sulphate

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 10	2, 3, 4, 8b, 9, 15, 26	1, 2, 6a
Used in galvanation or metal surface treatment- Industrial	3, 10, 15	2, 4, 8b, 9, 13, 26	1, 2, 5, 6a
Service life of galvanised or metal surface treated objects - Industrial/Professional/Consumer?	*Implied use*		

Declared Uses; Palladium Hydroxide

Use	SU	PROCs	ERCs
Intermediate - Industrial	3	3, 4, 5, 8b, 9, 13, 21	2, 5, 6a

Declared Uses; Palladium oxide

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 0 (Catalyst)	4, 5, 8b, 9	1, 2, 6a
Industrial use resulting inclusion to the matrix	3	1, 2, 4, 5, 8b, 9, 13, 21,	2, 5, 11a
Service life after inclusion onto matrix - industrial/professional/consumer?	*Implied use*		

Declared Uses; Sodium tetrachloropalladate

Use	SU	PROCs	ERCs
Intermediate - Industrial	8, 9	3	6a

Declared Uses; Tetraammine Palladium diacetate

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 8, 9, 24	1, 3, 4, 8b, 9, 15, 0 (Decomposing of compound by calcinating process)	1, 2, 6a

Declared Uses; Tetraammine Palladium dichloride

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 8, 9, 10, 17, 24	2, 3, 4, 5, 8a, 8b, 9, 13, 15, 19, 26, 27b	1, 2, 4, 5, 6a
Metal Surface treatment - Industrial	3, 10, 15	2, 4, 8b, 9, 13, 26, 27b, 0 (rinsing)	1, 2, 5, 6a
Metal Surface Treatment - Professional	3, 15	8b, 13, 26, 27b, 0 (rinsing)	5
Service life of metal surface treated products - Industrial/Professional/Consumer?	*Implied use*		

Declared Uses;
Tetrammine palladium dihydroxide

Use	SU	PROCs	ERCs
Intermediate – Industrial	3, 9	4, 8b, 9	1, 6a

Declared Uses;
Tetraammine palladium dinitrate

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 8, 9, 24	1, 3, 4, 8b, 9, 15, 0 (Decomposing of compound by calcinating process)	1, 2, 5, 6a

Declared Uses;
Terakis(triphenylphosphine) palladium

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 9	1, 3, 8b, 9	1, 2, 5, 6a
Use as a catalyst - Industrial	3, 9	1, 3, 8a, 15	1, 4
Processing aid - Industrial	3, 8, 9, 24	1, 9, 15	1, 4, 5

Declared Uses;
Palladium diammine dichloride (DDP)

Use	SU	PROCs	ERCs
Intermediate - Industrial	3, 8, 9, 10, 15, 24	3, 4, 8a, 8b, 9, 15, 26	1, 6a
Electroplating - Industrial	3, 16	4, 8b, 13	5, 6a

Declared Uses;
Palladium diammine dichloride (DDP)

- Some clarification points:
  - » Are we confident that these are all the uses, or do we need to follow up with additional customers/downstream users?
  - » Exposure scenario required to cover service life of electroplated objects?
  - » For the environment, does the emissions data provided for DDP cover any of these uses in addition to production?

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4. Environmental Exposure Modelling

Ed Stutt, Dawn Maycock & Adam Peters

Content

- Updated summary on response level and use of data from exposure questionnaire
- Development of GES for total Pd
- Regional EUSES Modelling
- Risk characterisation
- Site-specific risk assessment
- Additional data requirements
- PNEC refinement and potential testing strategies
- Assessment of waste

Response to the questionnaire

- 14 questionnaires received from 12 companies
- Good rate of response now and improved level of detail, but.....
  - » very little data for emissions to air (3 sites)
  - » additional data on receiving water bodies would be helpful (otherwise we have to use conservative default values from ECHA)
- Further follow-up is necessary on tonnage
- As much refinement as possible due to low PNECs for aquatic environment

Use of data from exposure questionnaire

- Derivation of sector-wide Generic Exposure Scenario (GES)
  - » Representative ('reasonable worst case') GES for all Pd based on values calculated from compiled dataset
  - » Sector-wide approach to exposure assessment (consistent and harmonised across the industry)
- Site-specific risk assessment (SSA)
  - » If Tier 1 assessments indicate a pass (i.e. RCR <<1 then this will be all that is required)
  - » Beyond this options for substance-specific refinement, input of additional data (e.g. on dilution in receiving water body) or requirement for monitoring

Generic Exposure Scenario (GES)

- **GES for overall Pd (complete dataset and applicable to all Pd compounds)**

Parameter	**Value**	
Tonnage	47.5 T/a	90P
EF water	62.5 g/T	50P
Emission days to water	250 d	Mean
WWTP flow rate	120 m^3/d	50P
STP flow rate	2000 m^3/d	Default
Further dilution	10x	Default
EF air	300 g/T	SpERC
Emission days to air	300 d	Mean

Generic Exposure Scenario (GES)

- Multiple scenarios required for emissions to water
  - » Freshwater without STP
  - » Freshwater via STP
  - » Marine without STP
  - » Marine via STP
- Emission factors will stay the same but can adjust tonnage, dilution factors etc
- Possible to develop GES for specific substances either by assigning all emissions or maintaining EFs etc and tonnage for individual substance

Regional EUSES Modelling

- EUSES is chemical risk assessment model used for regional and local level assessment
- For overall Pd (i.e. covering all substances)
- Phys-chem data: typical values for metals in EUSES & partition coefficients selected from literature
- Tonnage & EF from GES (tonnage may need to be revised)
- Regional % of EU tonnage taken from GES dataset

➢ Calculation of regional background concentrations for freshwater, sediment and soil

Regional EUSES Modelling

- Background concentrations to be added to local GES PECs and for site-specific RA

Compartment	PEC	RCR
Air	8.2 x10^{-15} mg/m3	8.2 x10^{-12}
Surface water (dissolved)	6.5 x10^{-7} mg/L	0.049
Freshwater sediment (total)	0.0014 mg/kg	0.97
Seawater (dissolved)	6.7 x10^{-8} mg/L	0.052
Marine sediment (total)	1.4 x10^{-4} mg/kg	0.996
Soil (agricultural)	1.9 x10^{-3} mg/kg	1.6*

GES Risk Characterisation (overall Pd)

	Freshwater with STP mg/L	Marine water with STP mg/L	FW sed with STP mg/kg wwt	Marine sediment with STP mg/kg wwt	STP mg/L	Soil mg/kg wwt
PEC$_{local}$	1.39 x10^{-4}	1.20 x10^{-5}	1.52 x10^{-1}	4.26 x10^{-2}	1.49 x10^{-3}	2.83 x10^{-1}
PNEC	1.33 x10^{-5}	1.33 x10^{-6}	1.45 x10^{-2}	4.70 x10^{-3}	1.46	1.17 x10^{-2}
RCR	10.45	9.23	105.5*	90.65*	0.001	241*
No. of individual sites with RCRs > 1	4	4	12	7	0	nd

*Additional factor of 10 in RCR calculation

Man via the Environment (stack emissions)

- PEC/DNEL for concentration in air 100m downwind of stack emissions
- Interim DNEL = 0.001 mg/m^3 extrapolated from TPHC (using most conservative NOAEL)
- RCR = 0.014 for overall Pd GES
- RCR<<1 for individual sites
- RCR = 6.7 x10^{-3} for DDP

Pd overall or DDP

- Assessments performed under REACH are intended for specific substances, and in principle the assessments should be performed individually for each substance
- For metals it may be more appropriate to consider those substances which result in the same forms of the metal in the environment collectively
- Option exists of substance specific refinement if RCR<1 cannot be achieved by other refinements

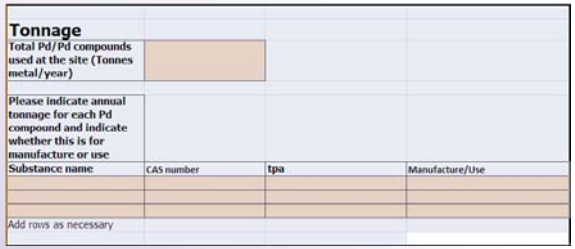
Site specific risk assessment

- Currently calculating exceedances (RCR>1) for several sites for fresh & sea-water & sediment
- Further refinement possible in some cases (i.e. dilution factor in receiving water body) but not in others. Options include
  - » Refinement of PEC based on exposure data (if possible)
  - » PNEC refinement
  - » Monitoring of local environment (specifically freshwater (dissolved and sediment)

Additional data

- Emissions to air – to refine EF in GES or further justify use of SpERC for production of metals & metal compounds
- Dilution factor in final receiving water body – for site-specific assessment
- RMMs and efficiency
- Tonnage and process stream description

Additional data - tonnage



Tonnage			
Total Pd/Pd compounds used at the site (Tonnes metal/year)			
Please indicate annual tonnage for each Pd compound and indicate whether this is for manufacture or use			
Substance name	CAS number	tpa	Manufacture/Use
Add rows as necessary			

- Have all sites provided data for 'total Pd tonnage' in the same way
- Net Pd tonnage (i.e. Initial Pd feedstock processed or amount sold/stockpiled + discharge)

Additional data – tonnage (mass balance as Pd metal equivalent)

Pd ore or refinable (x Tonne/annum)

↓

Pd compound 1 (x T/a; intermediate)

↓

Pd compound 2 (y T/a to market)

(z T/a; intermediate)

↓

Pd compound 3 (z T/a to market)

PNEC refinement and test strategies

- Substance grouping approach
  - » 3 main groups for ecotoxicity grouping
  - » 4 minor groups
  - » PNEC and exposure assessment for each substance using relevant group PNEC
- Single assessment of all Pd substances
  - » Covers all forms of palladium
  - » Only a single reasonable worst case PNEC required

PNEC refinement – Grouping approach

- Likely to require significant refinement of PNECs for each group
  - » Read across justifications required for each group
- Aquatic PNEC refinement
- Sediment issues due to use of EQP to derive sediment PNECs (extra factor of 10 on RCR)
- Direct sediment testing likely to be required

PNEC refinement – Single assessment

- Covers all forms of palladium
  - » Single read across justification required
- PNEC derived for single RWC substance (DDP)
- Performing all testing on a single substance will provide a greater increase in the PNEC than spreading the same testing across several different substances (i.e. lower AFs)
- Recommend assessments based on a single grouping of palladium substances
  - » Derive PNEC for DDP (expressed as Pd)

Assessment of Waste

- Basic information on waste needs to be included for all tonnage bands - A waste exposure assessment is now required in the CSR for substances >10tpa.
- Waste generally in the form of sludges or filter cakes, or press cakes
- Majority of respondents recycle their waste, primarily for re-use (on-site or off-site)
- Some sites send waste to landfill (1 on-site, other unknown)
- Assess potential for exemption (e.g. Recycling)

Assessment of waste

- Potential requirement for several exposure scenarios based on different waste options identified
- Assessment for recycling consists of three steps:
  1. Assessment of relevance of recycling and justification of no relevance.
  - » *Note:* Recycling processes should only be excluded after careful consideration
  2. Checking if recycling process is already covered by earlier assessments
  3. Estimation of released amounts from relevant recycling processes
- ECHA Guidance R18 details default release fractions for landfill

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EBRC

5. Occupational exposure scenarios for Pd & Pd compounds

Platinum Group Metals Meeting

Brussels

12 December 2012

Jutta Schade & Daniel Vetter
EBRC Consulting
Hannover, Germany

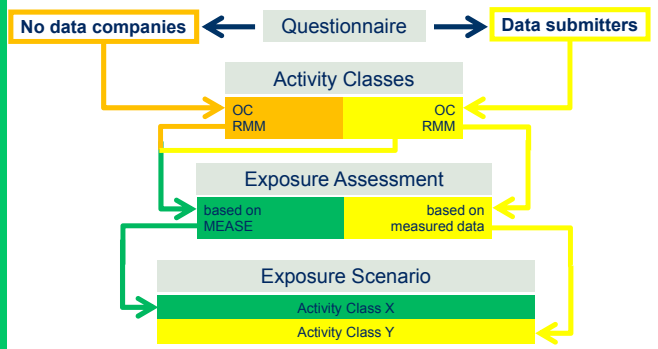
Progress since last meeting

- Additional occ. exp. questionnaires received
- Outstanding information on occ. exp. questionnaires received (still awaiting further information)
- Additional monitoring data received
- Outstanding information on measured data received (still awaiting further information)

→ Information used for development of draft ES for DDP

→ Outstanding information on occ. exp. questionnaires and measured data may be included in next version of ES (if relevant for DDP)

Occ. ES building approach



Scope of exposure assessment (2013)

- Exposure assessment for 2013 substances:
  - 1 relevant substance (diamminedichloropalladium)
  - exposure scenario for manufacture
  - exposure scenarios for downstream uses
    - Industrial use of DDP as intermediate in the manufacture of other substances
    - Industrial use of DDP for electroplating of massive objects
  - Service life of electroplated massive objects?

Exposure assessment for DDP I/III

- DNEL, long-term, systemic, for inhalation & dermal
- RCR has to be below 1, in consideration of both systemic DNELs ($RCR_{inhalation} + RCR_{dermal} < 1$)
- Acute DNELs/DNELs for local effects not derived

  → acute exposure assessment not required
- Eye irritating effects → protection required
- Dustiness of DDP reported to be “very low” to “low”

  →already reflected in EA but not yet confirmed by testing

  →change to higher dustiness class may be required

Exposure assessment for DDP II/III

- Exposure assessment based on measured/analogous data:
  - measured data from all Pd substances (similar emission potential)
  - analogous data from similar workplaces
  - OCs and RMMs from data submitters used (in most cases also applicable to “no data companies”)

  → stricter RPE/gloves required in some cases (due to RCR(s))
- Exposure assessment based on MEASE:
  - OCs and RMMs from all companies used (worst-case conditions as basis)

  → stricter RMMs required in some cases (due to RCR(s))

Exposure assessment for DDP III/III

AC	Activity Class description	Availability of measured data / MEASE assessment required
2	Manual transfer of dusty materials at ambient temperature	21 values, p90 = 146 µg DDP/m³, supportive data from job rotation available
3	Handling of non-/very low dusty materials at ambient temperature	MEASE assessment required, 5 supportive data points available
4	Manipulation of solutions/suspension in open or semi-closed processes	MEASE assessment required, 2 supportive data points available
5	Wet chemistry in closed systems/vessels	9 values from job rotation, p95 = 3.9 µg DDP/m³, supportive data available
7	Closed processes at elevated temperatures	MEASE assessment required Measured data not available
9	Operations in closed processes at ambient temp.	MEASE assessment required Measured data not available
10	Non-routine work	6 values, p95 = 30 µg DDP/m³ (very low dusty), supportive data from AC2 and JR used

Open questions for downstream uses

- Industrial use of DDP for electroplating of massive objects
  - Used for treatment solution and chemically transformed before plating?
  - Or still available in the solution and directly used for surface treatment?

  → Additional workplaces to be included?

  → Professional use of electroplated objects required?

  → Service life scenario of electroplated objects required?

Action points

- Additional information on measured data to be included

  → May influence exposure assessment due to assignment of measured data to ACs/workplaces
- Result of additional dustiness testing to be reflected

  → May influence exposure assessment due to higher dusty forms
- Additional uses to be included?
- Comments on OCs & RMMs from members to be reflected
- Feedback on questions about downstream uses

→ All: to be reflected in next version of ESs

EBRC

Thank you for your attention!

6. PNEC and DNEL refinement for diamminedichloropalladium (DDP)

Klaus ROTHENBACHER

PNEC DDP

- Recalculated PNECs (reassessment of existing data)
  - Calculation error for PNEC water, affected other PNECs as well
  - Refined approach for using Kd values
- Potential risk for most compartments = need for refinement

Diamminedichloropalladium (DDP) (CAS 14323-43-4) PNEC cal

Endpoint	EC50	AF	PNEC 9/2012	PNEC 11/2012	Unit
$PNEC_{freshwater}$	69.91	1000	0.07	0.026	µg/L DDP
$PNEC_{marinewater}$	69.91	10000	0.007	0.0026	µg/L DDP
$PNEC_{water, intermittent}$	69.91	100	0.7	0.059	µg/L DDP
$PNEC_{microorganisms}$	EC10: 29000	10	2900	unchanged	µg/L DDP
$PNEC_{sediment, FW}$	equilibirum partitioning based on PNECwater		0.054	28.7	µg/kg DDP
$PNEC_{sediment, SW}$			0.991	9.35	µg/kg DDP
$PNEC_{soil}$			0.036	23.3	µg/kg DDP
$PNEC_{oral}$	not required				

PNEC DDP

Need to refine PNECs

- Potential risk for freshwater, marine water, sediment, marine sediment and soil
- Additional testing needed
- Once testing done, several approaches possible
  - Derive PNECs for each substance/group
  - Derive worst-case PNECs to cover all Pd emissions

Discussion

- Need to discuss/agree strategy with PGM WG
- Time line testing
- Need RMMs between registration and dossier update

DNEL DDP

No valid repeated dose tox. (RDT) study available on DDP yet

- One available and valid RDT study on Pd compounds:
  - Tetraamminepalladium hydrogencarbonate (out of scope substance, NOAEL = 15 mg $kg^{-1}day^{-1}$)
  - Used as basis to derive tentative DNELs, converted to DDP (based on Pd content)

Tentative DNELs

- Assumptions
  - Oral exposure not relevant, no DNEL oral derived
  - Only DNELs for workers derived (not for consumers)
  - Acute dermal: no acute effects seen for DDP = long-term dermal DNEL will be protective
  - DDP is an eye irritant – qualitative assessment
- $DNEL_{long\text{-}term\ for\ dermal\ route\text{-}systemic}$: 0.0119 mg kg^{-1} day^{-1} (0.83 mg day^{-1})
- $DNEL_{long\text{-}term\ for\ inhalation\ route\text{-}systemic}$: 0.0419 mg m^{-3}

Discussion

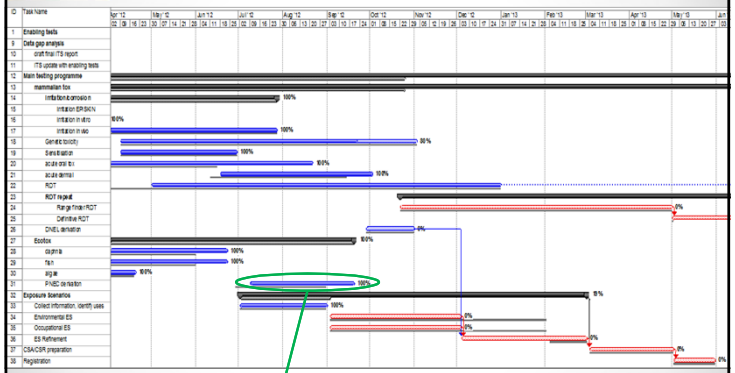
- Do we need a $DNEL_{acute\ inhalation}$?

7. Next steps and timeline for data refinement/generation and ES refinement

Klaus ROTHENBACHER
Katrien ARIJS

Timeline for 2013 deadline

(status: 07 Oct. 2012)



- Tight timing
- Need to revise PNEC derivation

Timeline for ES work

> May 2013 — Update registration (final DNEL + PNEC)
- Derive final DNEL from results RDT study DDP
- Derive final PNECs depending on testing
- Update dossier as soon as data are available

May 2013 — Registration
- IUCLID 5 file completion, review and submission
- CSA/CSR + ES finalisation and upload onto IUCLID 5 file

Early Mar

Jan-Feb 2013 — Final draft ES (tentative DNEL + PNEC)
- Tier 2 ES reports + tentative RMMs
- Presentation to PGM ES WG
- Agree on testing programme for final PNEC derivation
- Finalise ID cards

Early Dec

Oct-Dec 2012 — Draft ES (tentative DNEL + PNEC)
- Tier 1 ES reports
- Presentation to PGM ES WG

Early Oct

Sep-Oct 2012 — Assessment of available data
- One-to-one clarifications between members and consultants
- Report assessment of available data to PGM ES WG

8. AOB, Next Meetings/Calls & Closing Remarks

David BOYD

Thank you!