Precious Metals Consortium

Precious Metals & Rhenium Consortium

PGM Tox Experts & Work Group Meeting

4 October 2016 | MCC, Brussels

Precious Metals Consortium

1. Welcome and introduction

1.1 Confidentiality and Competition law

1.2 Tour-de-table and apologies

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	
Restrict cooperation within the scope of the preliminary phase to the initially defined goals and purposes of the cooperation.	Pursuant to Art. 101 and 102 TFEU, activities which have the object of the effect of preventing, restricting and/or distorting competition are prohibited within the scope of this Agreement, including: - Coming to agreement, including arrangements or collusions, about prices, markets and customers (see Art. 101 paragraph 1 a)-e) TFEU); - Joint boycotting of other companies; - The unjustified unequal treatment of trade partners; - The abusive exploitation of a dominating market position.
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.	

1.3 Approval of the agenda

1 Welcome and Introduction (11:30 - 11:35)
- 1.1 Reminder on Confidentiality and Competition Law
- 1.2 Tour de table and apologies
- 1.3 Approval of the agenda
- 1.4 Approval of the minutes of the last meeting (21 Apr. 2016) and status of action points

2 Iridium and Iridium compounds (11:35-11:40)

3 Palladium and compounds (11:40-12:10)
- 3.1 Dossier status
- 3.2 Pending dossiers
- 3.3 RAAF (read-across justifications): discussion on proposed format

4 Platinum and compounds (12:10-14:55)
- 4.1 Dossier status
- 4.2 Hazard (Ongoing HH & ENV testing, phys-chem testing, Pt genetox review): update & technical discussion

Lunch break *(13:00-14:00)*

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

5 Ruthenium and compounds (14:55 -15:30)
- 5.1 Dossiers status
- 5.2 Hazard (Ongoing HH & ENV testing RuCl3): update & technical discussion
- 5.3 Exposure (Occupational Monitoring project): update

Coffee break *(15:30-15:45)*

6 Rhodium and compounds (15-45-16:20)
- 6.1 Dossiers – status
- 6.2 Hazard (Ongoing AMES testing, Rh(III) genetox review): update and technical discussion
- 6.3 Exposure (PNEC): update

7 Budget overview (16:20-16:30)

8 AOB, next meetings/calls and closing remarks (16:30-17:00)

1.4 Approval of minutes & status action points

Actions	Who?	When?	Status
Circulate final SID cards to the respective sub-assemblies.	JM / ME	ASAP after finalisation	√ OK for Pd and Pt
Organise additional phys-chem testing	JM / ME	<Q3 2016	√
Conduct an assessment of the technical feasibility of the hydrolysis test with Karstedt before deciding on a full test	ME	Test data available <Dec 2016	√ waiver included
Check the available literature on RuCl3 dissolution kinetics	JM	<29 April 2016	√ checked – additional pre-test included & algal test finalised
Check the stability of KC in corn oil (determined by IR spectra)	ME	<16 May 2016	√ checked and considered stable
Perform AMES tests on 3 poorly water soluble Rh(III) compounds	JM	<December 2016	√ running for 2, waiting 3rd sample
Review the existing Rh(III) genotox dataset internally, check SID/CoA of test substances and decide on intelligent in vivo testing program for Rh(III) genotox	JM / tox experts	<December 2016	**Ongoing**
Update ITS and IUCLID as appropriate, w.r.t. the Rh(III) genotox classification decisions.	Bibra	15 September	√
Circulate draft PNECs for Rh to the members.	JM	31 May 2016	**√ pending – internal decision to focus on Pd and Pt first**
Include additional wording in the Pd tetraammines AMES study record	Bibra	30 June 2016	√
Revise qualitative hazard bandings for Pd dossiers	Bibra	<June 2016	√

1.4 Approval of minutes & status action points

Actions	Who?	When?	Status
Check and summarise the complete Pt genotox database	Bibra	<June 2016	√
Check for external experts to revise Pt genotox dataset	JM	<May 2016	√
Selection of the external genotox expert to revise Pt genotox dataset	PMC WG	15 May 2016	√
Discussion on ClPt occupational risk assessment	ClPt Sub-group	<June 2016	√
Share the relevant CSR sections as an example for a qualitative apporach for occup. exposure/risk assessment with PMC Tox Experts	BASF	Week of 25 April 2016	√
Revise the draft Read-Across justification report for K2PdCl6 and discuss with Bibra and the relevant experts	JM/Dave Boyd	<June 2016	√ - new reports drafted for Pd dossiers
Revise and comment Pd ENV Generic Exposure Scenarios – special attention to Msafe for Downstream users	Pd registrant companies	13 May	√
Revise and comment Pd Occupational Exposure Scenarios – special attention to scenarios without nominated PROCs	Pd registrant companies	13 May	√
Contact Pt registrant companies by early May via email to complete online survey on selected workplaces & exposure categories	EBRC	Early May	√
Provide company specific inhalation and dermal monitoring data to PMC Secretariat	PGM member companies	<June 2016	√

1.4 Approval of minutes & status action points

Actions	Who?	When?	Status
Circulate Sameness meeting minutes to Mark Raffray and Dave Boyd	KR		√
Check if the reported EC50 value for HHPA is correct referring to solubility of that compound	WCA	<June 2016	√
Check timeslot for 2nd LLNA test KC	JM	<June 2016	√
Inform TE on vehicle & dosing for RDT test with TetradoRu	JM	When draft protocol is available	√
Provide to EBRC a brief explanation what hazard is driving the Pt DNELs	JM/Bibra	<June 2016	√
Check availability of Steven V and inform with sub-group members for most suitable date	JM	Week of 25 April 2016	√

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2. Iridium and Ir compounds

2 Status

- All three Ir substances registered by Lead-Registrant:

Substance	CAS	EC	LR	Status	
Iridium	7439-88-5	231-095-9	Johnson Matthey	**Registered**	May 2016
Hexachloroiridic acid, Hydrogen hexachloroiridate (IV)	16941-92-7	241-012-8	Heraeus Deutschland GmbH and Co. KG	**Registered**	June 2016
Diammonium hexachloroiridate	16940-92-4	241-007-0	Johnson Matthey	**Registered**	May 2016

- No immediate actions scheduled

- Questions/remarks?

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3. Palladium and Pd compounds

3.1 Dossier Status

Substance	CAS	EC	LR	Status	
Palladium	7440-05-3	231-115-6	Umicore NV/SA	Approval by SA	
Palladium dichloride	7647-10-1	231-596-2	BASF	Approval by SA	
Dihydrogen tetrachloropalladate(2-) (in solution)	16970-55-1	241-047-9	Heraeus	Approval by SA	
Diamminedichloropalladium	14323-43-4	238-269-3	Heraeus	Approval by SA	
Dichlorobis(triphenylphosphine)palladium	13965-03-2	237-744-2	Heraeus	Approval by SA	
Palladium (II) di(4-oxopent-2-en-2-oate)	14024-61-4	237-859-8	Heraeus	Approval by SA	
Palladium(II) acetate	**3375-31-3**	**222-164-4**	**Heraeus**	**REGISTERED**	**AnnexIII exempted**
Palladium monoxide	1314-08-5	215-218-3	Heraeus	Approval by SA	
Tetraamminepalladium (II) nitrate	**13601-08-6**	**237-078-2**	**Johnson Matthey**	**Registration ongoing**	**AnnexIII exempted**
Tetraamminepalladium(2+) dichloride	13815-17-3	237-489-7	Umicore AG&Co.KG	Approval by SA	
Tetraamminepalladium(2+) dihydroxide	68413-68-3	270-241-6	Heraeus	Approval by SA	
Tetrakis(triphenylphosphine)palladium	**14221-01-3**	**238-086-9**	**Umicore AG&Co.KG**	**Registration ongoing**	**AnnexIII exempted**
Palladium sulphate	*13566-03-5*	*236-957-8*	*Heraeus*	*Phys-chem testing running*	*See next slides*
Tetraamminepalladium(2+) diacetate	*61495-96-3*	*262-819-1*	*Umicore AG&Co.KG*	*Phys-chem testing running*	*See next slides*
Disodium tetrachloropalladate	13820-53-6	237-502-6	BASF	Approval by SA	
Palladium dinitrate	*10102-05-3*	*233-265-8*	*Heraeus*	*Phys-chem testing running*	*See next slides*
Palladium dihydroxide	*12135-22-7*	*235-219-2*	*Umicore AG&Co.KG*	*Removed as agreed with LR*	*See next slides*
Diammonium hexachloropalladate	19168-23-1	242-854-9	Johnson Matthey	Approval by SA	
Dipotassium hexachloropalladate	16919-73-6	240-974-6	C. Hafner	Approval by SA	

3.1 Dossier Status

- Phys-Chem testing running at BAM and Siemens:
  - Palladium sulphate
  - Palladium dinitrate
  - Tetraamminepalladium(2+) diacetate

cfr next slides

- Palladium dihydroxide
  - Dossier was in approval process Mgt Cttee, but LR noticed information was missing
  - Dossier taken out, timing under discussion

REQUEST to REVIEW INFORMATION and CHECK COMPLIANCE as much as possible DURING DOSSIER PREPARATION PHASE, NOT DURING APPROVAL PROCESS

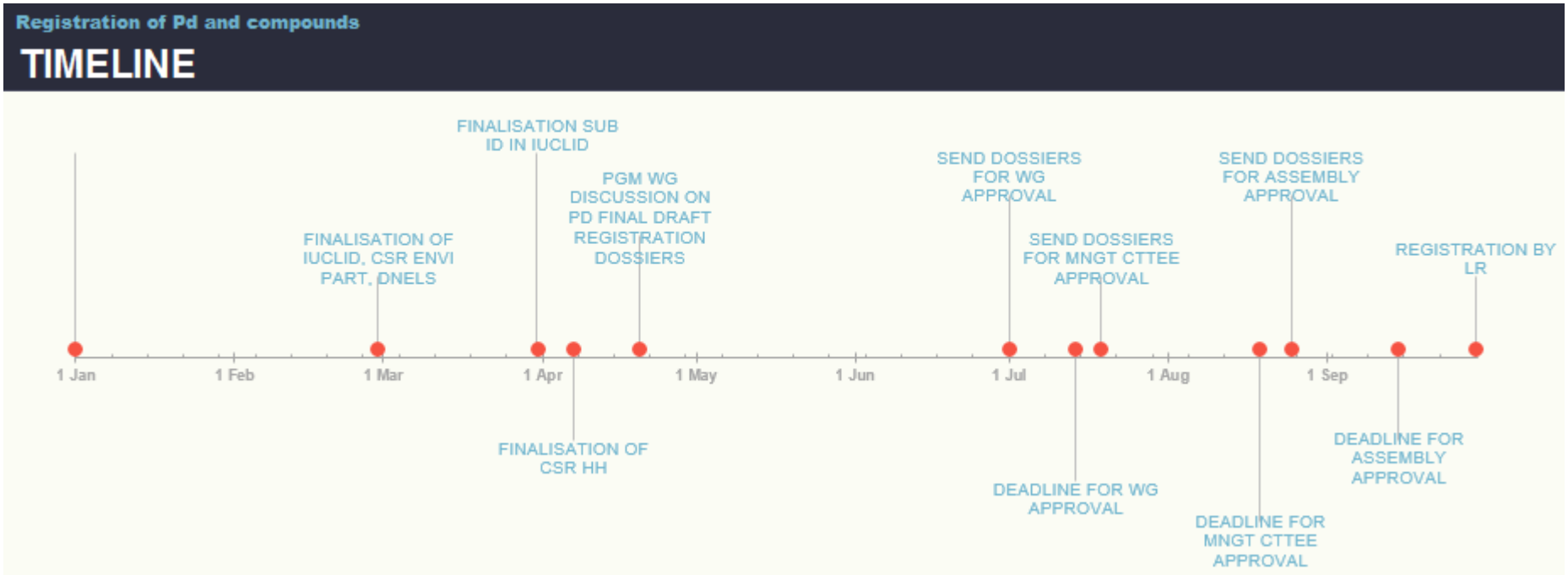
3.1 Dossier Status

- Dossiers with pending Phys-Chem testing:

  draft results available mid Oct, dossiers be circulated for review soon after.
  Deadline for final approval: end Nov 2016

- Palladium dihydroxide:

  timing to be confirmed, **aim is simultaneous review/approval** with other 3 Pd dossiers



PNECs and exposure

- Minor update to terrestrial PNEC value to take into account soil Kd value found in literature
  - » Previous Kd back-calculated from suspended solids
  - » Soil Kd values more appropriate for use in terrestrial PNEC derivation, where available
  - » Consistent with approach used for Pt
- Safe use still demonstrated with updated PNEC
- Exposure scenario documents updated and included in CSRs for review
- GES scenarios and site-specific risk assessments complete

Palladium dinitrate

- Palladium dinitrate CAS: 10102-05-3
  - » Oxidising solid, Packing Group I
  - » Based on draft result, test report not yet received or reviewed

3.2 Pending dossiers

Cfr next slides

Phys-chem testing: Status

Substance	Test	Testing status	
		Siemens	BAM
Palladium dinitrate	Melting point (A1)	Study plan signed, testing in progress	
	Boiling point (A2)	Study plan signed, testing in progress	
	Readily combustible solid (N1)		Draft result: Negative
	Self-heating substances (N4)		Testing not conducted (melting point 123°C)
	Oxidising solid (N1)		Draft result: Positive, packing group I
	Granulometry		Testing finalised
Tetraammine palladium(2+) diacetate	Melting point (A1)	Study plan signed, testing in progress	
	Boiling point (A2)	Study plan signed, testing in progress	
	Density (A3)	Study plan signed, testing in progress	
	Water solubility	Waiting for test plan	
	Readily combustible solid (N1)		Sample received, testing ongoing
	Self-heating substances (N4)		Testing not conducted (melting point ~93°C)
	Granulometry		Testing finalised
Palladium sulphate	Density (A3)	Study plan signed, testing in progress	

3.3 RAAF justification reports

- Read-across part of many Pd dossiers (as well as other PGMs)

- RAAF (Read-Across Assessment Framework):
  - Published by ECHA in 2015
  - Focus on human health endpoints (RAAF for ENV has been drafted – will go to public consultation soon)
  - Sets framework and principles for the scientific examination of read-across
  - Sets out the critical scientific elements of a read-across case to be assessed.

- Pd dossiers:
  - 1st draft report prepared by Bibra before BtB meetings spring 2016
  - Considered too comprehensive
  - Revised format:
    - Discussed at EM level
    - Discussed with ECHA during WS in August
    - Compared with BASF example

3.3 RAAF justification reports

- Proposal:
  - Avoid repetition of information included in REACH Dossier
  - Make maximum use of previous efforts (eg ITS matrix)
  - Keep as short as possible, but ensure all requested information is included

- Proposed content:
  - Justification for approach taken (analogue vs category)
  - Substance ID and characterisation (target & source substances)
  - Analogue approach justification
  - Consideration of bias (common 'breakdown products', contribution counter ions etc)
  - Data matrix (copied from ITS matrix)
    - Key phys-chem properties (melting point, boiling point, state, relative density, water solubility, pH)
    - HH endpoints – ALL
    - Include per 'cell': tested form, study ref, study results, classification

3.3 RAAF justification reports

- Reports will be drafted in grouped way:
  1. Pd metal and non-chlorinated Pd salts (PdO, Pd(NO3)2, Pd(OH)2, Pd di(4-oxopent-2-en-2-oate))
  2. Chlorinated Pd salts (Pd dichloride, tetraClPd, DDP)
  3. Tetraammine Pd salts
  4. Pd(IV) hexachloropalladates

- Inclusion in dossier:
  - Justification report: added in IUCLID section 13
  - In each applicable Endpoint Study Record: Cross-reference to IUCLID section 13

- Available draft report(s) forwarded to PMC members (all drafts available w/c 3 Oct) .
- **Approval (fast-track procedure) mid October - dossiers ready for submission end October**
- For other PGM dossier (Pt, Ru, Rh):
  - Similar way forward than for Pd

    PLUS inclusion of source and target substance information & read-Across justification in IUCLID & CSR

AGREE WITH PROPOSAL?

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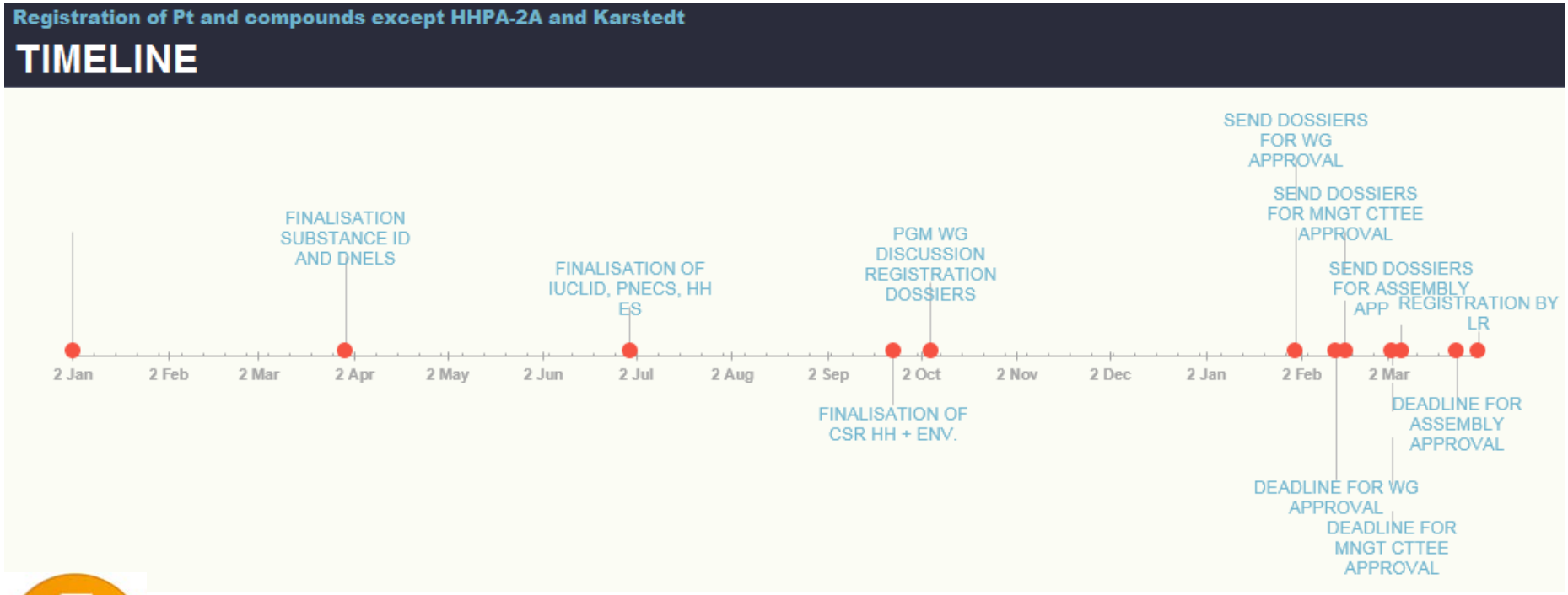
4. Platinum and Pt compounds

4.1 Dossier status

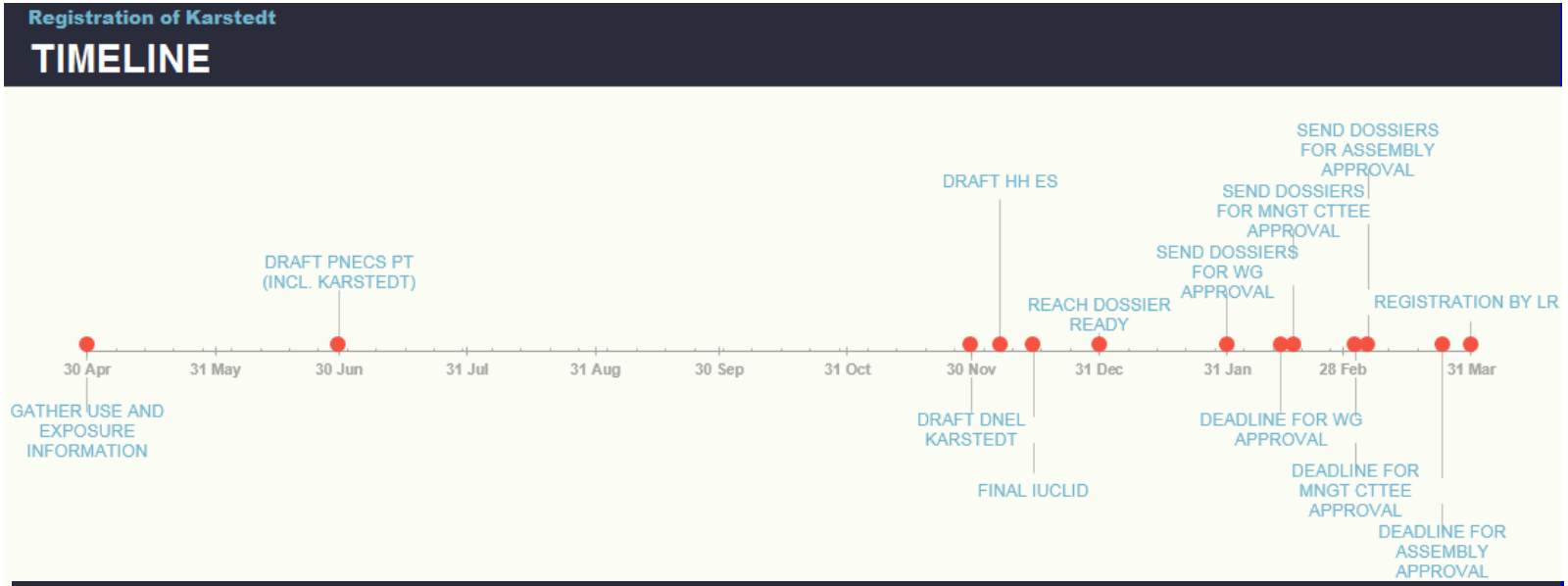
Substance	CAS	EC	LR	Status	
Platinum	7440-06-4	231-116-1	Vale	Dossiers being finalised	
Hexachloroplatinic acid	16941-12-1	241-010-7	Johnson Matthey	Dossiers being finalised	
Tetraammineplatinum dinitrate (in solution)	20634-12-2	243-929-9	Umicore AG&Co.KG	Dossiers being finalised	
Dipotassium tetrachloroplatinate	10025-99-7	233-050-9	Heraeus	Dossiers being finalised	
Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) (in solution)	*68133-90-4*	*268-717-3*	*BASF*	*HH and ENV testing running*	*See next slides*
Dipotassium hexachloroplatinate	16921-30-5	240-979-3	Heraeus	Dossiers being finalised	
Platinum dinitrate	*18496-40-7*	*242-383-9*	*Heraeus*	*Phys-chem testing running*	*See next slides*
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate (in solution)	*68478-92-2*	*270-844-4*	*Heraeus*	*HH and ENV testing running*	*See next slides*
Diammonium hexachloroplatinate	16919-58-7	240-973-0	Johnson Matthey	Dossiers being finalised	
Dihydrogen hexahydroxyplatinate	51850-20-5	257-471-2	Johnson Matthey	Dossiers being finalised	
Tetraammineplatinum dichloride	**13933-32-9**	**237-706-5**	**Johnson Matthey**	**REGISTERED**	**AnnexIII exempted**
Platinum dioxide	**1314-15-4**	**215-223-0**	**Umicore AG&Co.KG**	**Registration ongoing**	**AnnexIII exempted**

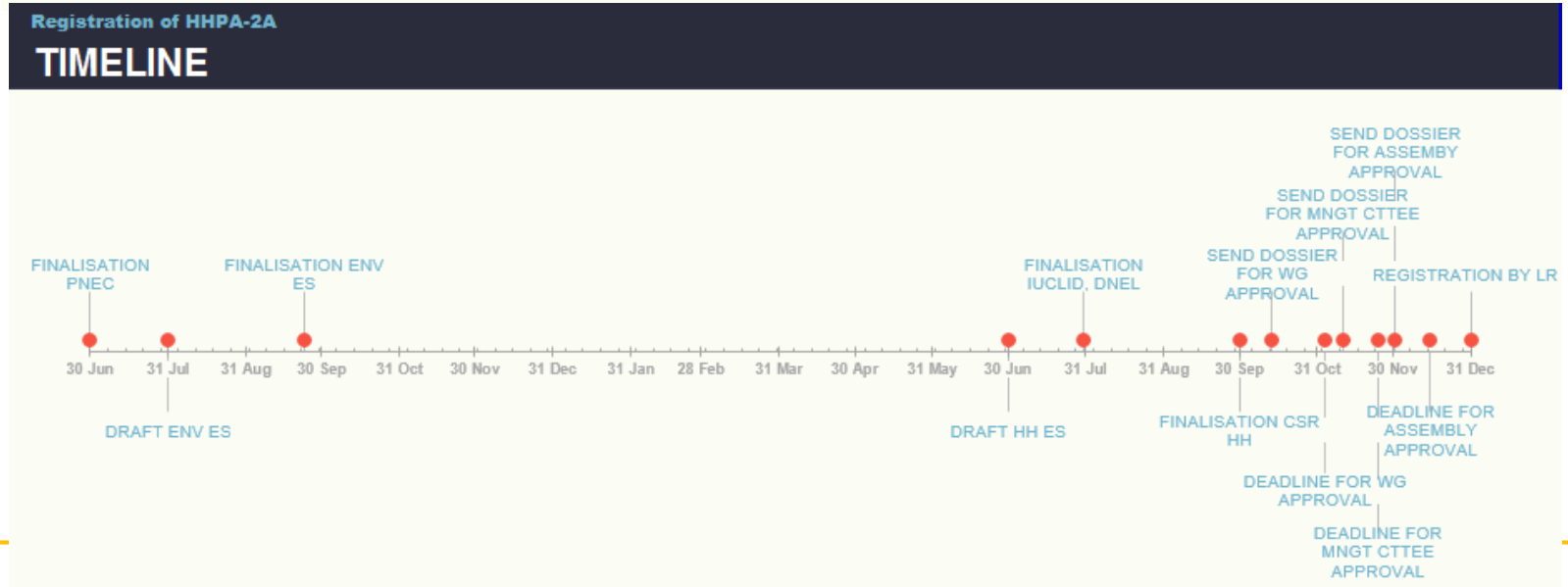
4.1 Dossier status



- Pt dinitrate (PC testing running) follows schedule of other Pt compounds

4.1 Dossier status





4.2 Hazard

- Ecotox testing: HHPA/2AE and Karstedt Concentrate
- Phys-Chem testing: Pt dinitrate
- Mammalian testing: HHPA/2AE and Karstedt Concentrate

Cfr. next slides

Ecotoxicity Testing Programme: Progress Oct 2016

Metal	Compound	Test	Progress	Result	Notes	
Platinum (cont.)	**Dihydrogen hexahydroxyplatinate with 2-aminoethanol (HHPA-2AE)**	*Daphnia* Immobility (48 hours)	Complete [Fraunhofer]	EC50 = >10.9 mg/L Pt / > 54.8 mg/L 2AE	Max. nominal test concentrations = 902 mg/L test item to ensure 100+ mg/L Pt. No effect up to highest test concentration. Measured 2AE concentrations 55-59% but stable over test duration. Measured (soluble) Pt concentrations 6-7% of nominal throughout test but stable so likely to be maximum achievable soluble concentrations.	The two compounds separate in water and therefore the same issues as testing HHPA alone arise, with good recoveries on preparation (if stirred for 1-2 hours only in stock) and then loss of Pt from solution over test duration. Definitive tests therefore conducted as semi-static tests (stocks stirred for 1 hour) with filtration to allow mean measured concentrations of soluble Pt to be used in results (alongside measured 2-AE concentrations).
		Fish Mortality (96 hours)	Complete [Fraunhofer]	LC50 = >11.1 mg/L Pt / > 55.1 mg/L 2AE		
		Algae Inhibition of growth (72 hours)	Complete [Fraunhofer]	EC50 (growth rate) = 117 ug/L Pt / 433 ug/L 2AE EC10 (growth rate) = 6.67 ug/L Pt / 21 ug/L 2AE NOEC (growth rate) = 15.8 ug/L Pt / 51 ug/L 2AE	Measured 2AE concentrations 65-80% but stable over test duration. Measured (soluble) Pt concentrations 11-16% of nominal throughout test but stable so likely to be maximum achievable soluble concentrations.	
		ASRIT (3 hours)	Complete [Laus]	3hr EC50: Without ATU = 1100 mg/L With ATU = 1400 mg/L.	-	

Ecotoxicity Testing Programme: Progress Oct 2016

Metal	Compound	Test	Progress	Result	Notes
Platinum (cont.)	**Hexachloroplatinic Acid (HCPA)**	ASRIT (3 hours)	Complete [Laus]	3 hr EC50: Without ATU = 104 mg/L With ATU = 83 mg/L	-
	Karstedt Concentrate	*Daphnia* Immobility (48 hours)	In Progress [Fraunhofer]	-	No effects in Range-finder tests, however soluble Pt was only detected at higher nominal concentrations (very low % of nominal), and soluble organic ligand not detected at all. Both Pt and organic ligand detected at appreciable levels in original preliminary testing, however, settlement rather than filtration employed to separate soluble and insoluble phases. Additional solubility trails ongoing to determine optimal method of separation of soluble and insoluble phases. **Cfr next slides**
		Fish Mortality (96 hours)	In Progress [Fraunhofer]	-	
		Algae Inhibition of growth (72 hours)	In Progress [Fraunhofer]	-	
		ASRIT (3 hours)	In Progress [Laus]	-	

Ecotoxicity Testing Programme: Karstedt Concentrate

- Substance is complex (Pt siloxane) and Pt
- Known to hydrolyse relatively quickly in water at neutral pH (a few hours) & extremely quickly as pH becomes (even slightly) acidic or alkaline (minutes).
  - » Initial hydrolysis to Pt and organic ligand (siloxane)
  - » Organic ligand then suspected to hydrolyse further
- Analysis of complex not possible, but Fraunhofer have now developed method for detection of organic ligand.
- Preliminary hydrolysis testing conducted (4.3mg/L test item, pH 7, 96 hours)
  - » Reducing concentrations of detectable Pt and organic ligand over time
  - » Both still detectable after 96 hours (approx. 270 ug/L Pt & 20 ug/L ligand)
  - » Settlement used to separate soluble and insoluble phases
- Primary ligand still detectable over period equivalent to acute ecotox tests
- May cause toxicity (in addition to Pt)
- Ecotox testing required

Ecotoxicity Testing Programme: Karstedt Concentrate

- Range-finder tests displayed no toxicity
- Filtration used to separate soluble and insoluble phases
- Much lower than expected concentrations of soluble Pt recovered
- No organic ligand recovered
- Investigations currently ongoing to investigate optimal method of preparing exposure solutions to maximise soluble Pt/ organic ligand in ecotox tests
- Filtration vs Centrifugation vs Settling
- Reduced pH will also be trialled for potential to improve solubility
- Additional solubility studies to be completed by end of Sept 2016
- Ecotox test to be completed by end 2016

4.2 Hazard

- Fish Embryo Acute Toxicity testing (OECD236)
  - ECHA published advice on its use under REACH (Sept 2016)
  - Results from OECD236 not sufficient to cover short-term fish toxicity test (Annex VIII, 9.1.3)
  - Useful for Weight of Evidence approach to decide on waiving vs testing
  - 2015 study commissioned by ECHA:

Comparison of FET/AFT for inorganic substances

- Given the very limited availability of quality data for inorganic compounds [n=6] no assessment of the predictive capacity of the FET was possible at present. Further assessment when more valid FET data are available would be needed.

Proposal to continue environmental testing as scheduled – AGREE?

Phys-chem testing: Status

Substance	Test	Testing status	
		Siemens	BAM
Platinum dinitrate	Melting point (A1)	Study plan signed, testing in progress	
	Boiling point (A2)	Study plan signed, testing in progress	
	Density (A3)	Study plan signed, testing in progress	
	Readily combustible solid (N1)		Draft result: Negative
	Self-heating substances (N4)		Draft result: Negative
	Granulometry		Sample received, testing in progress
	Oxidising solid (N1)		Draft result: Positive, Packing group I

TE suggestion to include some wording on pos testing from Reconsile

Karstedt Concentrate (1)

Test	Status	Report date
Skin irritation in vitro Epiderm - OECD 439	Non-irritant	30-Jun-16
Eye irritation in vitro - OECD 437	Not a severe irritant	13-Jun-16
Local Lymph Node Assay - OECD 442B	Negative	Reporting
In vitro mammalian cell micronucleus test (human lymphocytes) – OECD 487	Positive	Reporting
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD 476	Cancelled	
Acute oral toxicity Up-and-down procedure - OECD 425	> 5000 mg/kg	Reporting
Acute dermal toxicity - OECD 402	Cancelled	
Preliminary repeat dose toxicity	Complete	Reporting
Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test	In life	

PMC decision to include in vivo MN testing in OECD422 cfr next slides

Karstedt Concentrate (2)

14-day range finding study:

- 1000 mg/kg/day: terminated on day 12 due to 1 mortality, adverse clinical signs and effects on body weight. Males showed no body weight gain to day 7 and body weight loss to day 12. Lower food consumption in both sexes (more pronounced in week 1). Evidence of GI tract irritation at necropsy in both sexes (more severe in males).
- 750 mg/kg/day: adverse clinical signs in both sexes, lower body weight in males (-13% day 15), lower food consumption in both sexes (more pronounced in week 1)
- 500 mg/kg/day: minor adverse clinical signs (2M, 1F), lower body weight in males (-9.8% day 15, ns), lower food consumption in both sexes (more pronounced in week 1)

Karstedt Concentrate (3)

Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD 422 2015 version):

- Dose levels of 30, 125 and 500 mg/kg/day
- Includes satellite animals dosed at 0 or 500 mg/kg/day for 28 days for blood sampling (TK and micronucleus testing). *In vivo* micronucleus assessment by Micro Flow method at Litron Laboratories, USA. Positive controls included (2 dose levels of mitomycin C or vincristine) for micronucleus.
- Includes pre-treatment smears for animal selection, and thyroid hormone analysis
- Currently in-life
- Draft report due end Jan 17

Karstedt Concentrate (4)

422 study

- **At 500 mg/kg/day:** males had lower bw on day 15 (-11.5%), lower food consumption both sexes week 1 only, salivation was noted in all males and several females
- Summary of litter data day 1

	Dose level (mg/kg bw/day)			
	0 control	30	125	500
Females paired	10	10	10	10
No of litters	9	10	8	8*
Mean pups/litter day 1	14.2	14.0	13.0	13.0
Total dead pups day 1 (litters affected)	0	5 (2)	0	7 (3)
Mean pup body weight day 1	6.97	6.84	6.68	5.89

* one female not yet littered (reached gestation day 16)

Dihydrogen hexahydroxyplatinate – 2AE

- Formulation analysis demonstrates that HHPA-2AE is stable in corn oil at nominal concentrations of 1, 30 and 100 mg/mL for 7 days.
- **Preliminary repeat dose toxicity study (complete):**
  - 14 day gavage at 500, 750 and 1000 mg/kg/day
  - Slightly lower (not significant) body weight both sexes:

Dose	Males	% difference	Females	% difference
Control	351.74		270.60	
500 mg/kg	364.70		259.72	-4.0%
750 mg/kg	361.54		256.12	-5.4%
1000 mg/kg	335.38	-4.7%	254.18	-6.1%

  - Significantly reduced food consumption in week 1 only
- **Combined repeated dose toxicity study with the reproduction/developmental screening test (OECD 422):**
  - Starts w/b 28 Nov 16 (earlier date requested)

Dose level selection – cfr next slide

4.2 Hazard

- HHPA/2AE
    - Dose levels for OECD422 to be selected

PROPOSAL Study Director & RSA: 0, 100, 300, 1000 mg/kg/d

-dosing levels ~ thresholds for STOT-RE

-similar doses than HHPA testing

AGREE WITH PROPOSED DOSE LEVELS?

Classification changes

- Platinum dinitrate CAS: 18496-40-7
  - » Oxidising solid, Packing Group I
  - » Based on draft result, test report not yet received or reviewed
  - » Aquatic acute 1, Aquatic chronic 1 (Acute M factor 1, Chronic M factor 1)
  - » Based on read across from Dihydrogen hexahydroxyplatinate and Dihydrogen hexahydroxyplatinate compound with 2-AE
- 16919-58-7 Diammonium hexachloroplatinate
  - » Aquatic acute 1, Aquatic chronic 1 (Acute M factor 1, Chronic M factor 1)
  - » Based on data for the substance itself and read across from hexachloroplatinic acid

Classification changes

- 68133-90-4 Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2)
  - » Aquatic acute 1, Aquatic chronic 1 (Acute M factor 1, Chronic M factor 1)
  - » Based on data for the substance itself
  - » Both Pt and 2-AE measured in the ecotox studies
  - » Classification is based on test item concentrations calculated from measured Pt concentrations
- 51850-20-5 Dihydrogen hexahydroxyplatinate
  - » Aquatic acute 1, Aquatic chronic 1 (Acute M factor 1, Chronic M factor 1)
  - » Based on read across from Dihydrogen hexahydroxyplatinate and Dihydrogen hexahydroxyplatinate compound with 2-AE

4.2 Hazard

- Pt genetox review
  - Prof Kirkland contracted for review
  - Scope:
    1. Definition of genetox profiles for a logical grouping of Pt substances
    2. Identification data gaps and recommendations for gap filling (via tests not requiring test proposals).
    3. Recommendations for optimal in vivo assays (via test proposals ('TP')).
    4. For benchmark purposes, a comparison of genetox profiles of platins vs nonplatin Pt substances.
  - Work (review & discussions) performed July-Sept 2016
  - Deliverables (end Sept 2016)
    - Pt genetox review incl. recommendations for in vivo testing
    - Review of genetox potential nanoPt (in separate document!)
    - Table comparing genetox profile (per endpoint!) of cis-platin vs identified non-platin Pt groups

4.2 Hazard

- Pt genetox review (continued)
  - Key conclusions:
    - Pt(0) metal:
      - Data lacking on Pt genotoxicity/mutagenicity – datagap in strict terms
      - No further testing proposed (in vitro/in vivo): Exposure based waiving based on inertness, toxicokinetics assessment etc.

    - Karstedt concentrate:
      - HLM assay (*In Vitro Human Lymphocyte Micronucleus Assay*): clear evidence for genotoxic/mutagenic activity
      - Decided by members to include *in vivo* micronucleus assay in OECD422
      - Assay is running…

4.2 Hazard

- Pt genetox review (continued)
  - Key conclusions:
    - Pt(0) nano:
      - Not in PMC scope, but 'nano' in ECHA scope + existing external publications
      - Additional review by prof Kirkland (separate from 'main' document):
        - Clear induction of genotoxic effects in eukaryotic cells (mainly DNA strand breakage and formation of micronuclei)
        - Evidence for induction Reactive Oxygen Species (ROS) is confusing
        - Penetration nucleus: not nanoPt as such, maybe released Pt-ions?
        - Effects similar to these of other nanos
        - Unclear if threshold effect (e.g. if via ROS) vs non threshold (e.g. via direct DNA modification)
        - Anti-oxidant at low conc (scavenger) vs pro-oxidant at high conc

    → data on genotoxicity of nanoPt quite limited

    → much more work needed to evaluate full profile of effects and whether thresholds exist

    → "*if Pt-NPs can release Pt ions, then perhaps this is also possible for larger sized Pt particles.*" ?

4.2 Hazard

- Pt genetox review (continued)
  - Key conclusions:
    - Tetraammine Pt:
      - Pattern of activity different from other Pt substances
      - Negative *in vivo* evidence exists, but considered not robust
      - Clear positive *tk* mutation study with Tetraammine Pt hydrogen carbonate, but DMSO as solvent

        → Proposal: perform *in vitro* Mouse Lymphoma *tk* assay with Tetraammine Pt dichloride using water as vehicle
      - If study outcome clearly negative, then (via WoE):
        - Positive AMES highly likely not translating into genotoxic effects *in vitro / in vivo*
        - Negative *in vitro* test with Cl- salt overruling test with HCO3-salt
        - further *in vivo* testing not required for this group

4.2 Hazard

- Pt genetox review (continued)
  - Key conclusions:
    - Tetraammine Pt:
      - 2 options offered by Covance:
        - 3 treatment condition in 1 main exp. (3h –S9, 3h +S9, 24h –S9)
        - 2 treatment conditions in 2 main exp. (3h –S9, 3h +S9; as main exp. plus confirmatory exp.)
      - Kirkland: '*…trying to build a WoE from in vitro data that the tetraammines are not genotoxic in mammalian cells, that the positive MLA with the hydrogen carbonate is not predictive of mutagenic risk, and that further in vivo testing is not needed, the more extensive and robust the in vitro data the better. Therefore I would* ***argue that the 3-treatment condition option is the best***.'
      - Covance offer:
        - 3 treatments in 1 main exp = £13,390
        - Exp1 = (3h –/+S9), Exp2 = (24h –S9, 3h +S9) or (3h –/+S9) = £17,185

AGREE TO PERFORM ADDITIONAL IN VITRO TEST?

AGREE TO GO FOR 1st OPTION IN COVANCE PROPOSAL

4.2 Hazard

- Pt genetox review (continued)
  - Key conclusions:
    - Pt nitrate
      - Recognised as being UVCB
      - Changing speciation with increasing pH
      - Representative sample of Pt(IV) cationic group
        - No alternative substances (not in PMC scope or lack of data)
        - Exposure based waiving not defensible
        - No potential to waive further testing (eg low pH)

OPTION 1: submit TP for in vivo test with Pt nitrate (intragastric administration, logistic requirements limiting CRO options?)

OPTION 2: submit TP for in vivo test with Pt nitrate but with a recommendation that testing is deferred until in vivo testing other Pt groups is conducted to provide a more definitive foundation dataset

OPTION 3: defer TP until in vivo testing other Pt groups is conducted, and decide afterwards on need for in vivo testing

PROPOSAL to go for OPTION 2 – AGREE?

4.2 Hazard

- Pt genetox review (continued)
  - Key conclusions:
    - Testing proposals:
      - Proposed test: Micronucleus/Comet assay with TK (approx. 60 k£/test)
      - Proposed TP to be included in dossiers:
        - Pt(II)-cationic with Tetraammine Pt dichloride) **- wait outcome in vitro testing**
        - Pt(II)-anionic with Potassium tetrachloroPt
        - Pt(IV)-cationic with Pt dinitrate **- cfr discussion previous slide**
        - Pt(IV)-anionic with ammonium hexachloroPt
        - Pt(IV)-anionic with **dihydrogen hexahydroxoPt (compound with 2AE) or Na or K salt**

AGREE WITH TEST SUBSTANCES?

AGREE WITH TESTING PROPOSALS TO BE INCLUDED?

NO classification of any Pt substance for mutagenicity before in vivo evidence becomes available

4.3 Exposure

- PNEC derivation
- DNEL derivation
- Environmental and Occupational assessment

Cfr. next slides

PNECs

- PNEC values have been derived for Pt(IV) substances based on data for the most toxic Pt(IV) substance, hexachloroplatinic acid (HCPA)
- Key value for aquatic PNECs is a chronic *Daphnia* literature study (Biesinger and Christensen 1972)
  - » NOEC (reproduction) 0.007 mg Pt L^{-1} (LOEC / 2)
- Terrestrial and sediment PNECs derived using equilibrium partitioning
- PNEC for microorganisms based on ASRIT result for HCPA
- No read across between oxidation states therefore data for Pt(II) substances is not included in PNEC derivation
- All Pt(II) substances in project scope are <10 tpa and do not require PNECs

Pt(IV) PNEC values

PNEC	Units	PNEC	PNEC derivation method
Freshwater	µg Pt L^{-1}	0.14	Lowest NOEC of 0.007 mg Pt L^{-1} for Daphnia and an assessment factor of 50
Intermittent releases	µg Pt L^{-1}	0.205	Lowest EC50 of 0.0205 mg Pt L^{-1} for Daphnia and an assessment factor of 100
Freshwater sediment	mg Pt kg^{-1} wwt	0.0568	Equilibrium partitioning
	mg Pt kg^{-1} dwt	0.261	Equilibrium partitioning
Marine water	µg Pt L^{-1}	0.014	Lowest NOEC of 0.007 mg Pt L^{-1} for Daphnia and an assessment factor of 500
Marine sediment	mg Pt kg^{-1} wwt	0.00568	Equilibrium partitioning
	mg Pt kg^{-1} dwt	0.0261	Equilibrium partitioning
Soil	mg Pt kg^{-1} wwt	0.00461	Equilibrium partitioning
	mg Pt kg^{-1} dwt	0.00523	Equilibrium partitioning
Microorganisms	mg Pt L^{-1}	0.125	Lowest NOEC of 1.25 mg Pt L^{-1} from a respiration inhibition test and an assessment factor of 10
Secondary poisoning	Secondary poisoning assessment not required		

4.3 Exposure

- For Pt(0):
  - PNECs Pt(IV) too conservative.
  - Strategy agreed: PNEC waiving based on the TD results using ERVs from hexachloroplatinic acid for the discussion on classification

- For Pt(II): no PNECs derived, as no risk assessment required (<10 tpa)

- Environmental exposure/risk assessment currently being performed - safe use for all compartiments

Reminder: PNEC and ENV assessment Karstedt concentrate and HHPA/2AE will be performed later

4.3 Exposure – hazard conclusions

Route		Hexachloroplatinic acid		Ammonium HexaClPt		Potassium HexaClPt		HHPA		Pt nitrate	
Inhalation	Syst,LT	Qual	HH	Qual	HH	Qual	HH	**Quant**	**DNEL:0.47 mg/m³**	**Quant**	**DNEL:0.50 mg/m³**
	Syst,acute	Qual	HH	Qual	MH	Qual	MH	Qual	No hazard identified	Qual	No hazard identified
	Local,LT	Qual	HH	Qual	HH	Qual	HH	Qual	No hazard identified	Qual	HH
	Local,acute	Qual	HH	Qual	HH	Qual	HH	Qual	No hazard identified	Qual	HH
Dermal	Syst,LT	Qual	HH	Qual	HH	Qual	HH	**Quant**	**DNEL:0.67 mg/kg/d**	Qual	HH (skin corr 1A)
	Syst,acute	Qual	HH	Qual	MH	Qual	MH	Qual	No hazard identified	Qual	No hazard identified
	Local,LT	Qual	MH	Qual	MH	Qual	MH	Qual	No hazard identified	Qual	HH
	Local,acute	Qual	MH	Qual	MH	Qual	MH	Qual	No hazard identified	Qual	HH
Oral	Syst,LT	N/A	Not relevant	N/A	Not relevant	N/A	Not relevant	N/A	Not relevant	N/A	Not relevant
Eyes	Local	Qual	MH	Qual	MH	Qual	MH	Qual	LH	Qual	MH

4.3 Exposure assessment by EBRC

- Occupational exposure assessment (all except HHPA/2AE and Karstedt concentrate)
  - Workplace approach used for all Pt substances
  - Inhalation exposure estimate via monitoring data (derived or read-across), or modelled (using MEASE)
  - Dermal exposure: use of Ni-database

reminder: need to collect PGM dermal exposure data

- Occupational exposure assessment prepared by EBRC:
  - commented by PMC members & discussed with EBRC
  - EBRC offer to update ES: estimated at 30 d, not able to finalise within deadline
  - Proposal to do revisions in house

    → approved by PGM Chairman

4.3 Exposure assessment updated by PMC

- Occupational exposure assessment (all except HHPA/2AE and Karstedt concentrate)
  - **General changes:**
    - Removed data from ClPt in solPt and vice versa
    - Removed data from insolublePt as not applicable to our substances needing a CSA/ES
    - Clarified where analogous data came from (analogous substance/workplace)
    - Alignment of tables in M and DU scenario's
    - Minor clarification in introduction text
    - Consolidation of industrial use scenario resulting in **change in use descriptors!** Only one relevant use was kept: « Use as intermediate ». PROCs were all merged except for PROC14 which was deemed not relevant anymore.
    - Use of correct abbreviations for HHPA and PtN

4.3 Exposure assessment updated by PMC

- Occupational exposure assessment (all except HHPA/2AE and Karstedt concentrate)
  - **Chloroplatinates:**
    - Created 1 master file for the 3 ClPts to facilitate review as exposure data is identical
    - Qualitative assessment (cfr highly potent respiratory sensitizers)
    - Benchmark Value included as reference level (0.1 µgPt/m^3)

      → allows decision on adequate control of risks (or not)

      → NO RCR DERIVED!
    - « *risk adequately controlled* » for all uses, except 1:

      'handling of dry/dusty platinum substances during packaging/filling - PROC26'

      Exposure estimate (monitoring data) = 9.24 µg solPt/m^3

      with APF=40 → 0.23 µg solPt/m^3 >> Benchmark value of 0.1 µgPt/m^3

      → **agreed by WG to not support this use in REACH dossier**

      → **needs to be performed under full containment**

4.3 Exposure updated by PMC

- Occupational exposure assessment (all except HHPA/2AE and Karstedt concentrate)
  - **HHPA**:
    - Quantitative assessment for inhalation,syst,LT and dermal,syst,LT
    - Step away from OEL of 2µgPt/m^3 and use DNELs
    - All uses safe (RCR<<1) even without the use of RPE

  - **Pt nitrate**:
    - Quantitative assessment for inhalation,syst,LT
    - Step away from OEL of 2µgPt/m^3 and use DNEL
    - Qualitative assessment for dermal,syst,LT (cfr classification as skin corr 1A)
    - All uses safe (RCR<<1 or « risk adequately controlled ») even without the use of RPE

Revised ES circulated to members – agree with format & content?

4.3 Exposure updated by PMC

- HHPA / 2AE and dipotassium hexaClPt:
  - Reported ‘use as catalyst’
  - Request from consultant for more details, and email sent by PMC Secretariat to members
  - From responses:
    - Use as intermediates during ‘manufacture of catalysts’
    - Not used as catalysts

No company (or Downstream User) uses ‘as catalyst’, use will be deleted from REACH dossier!

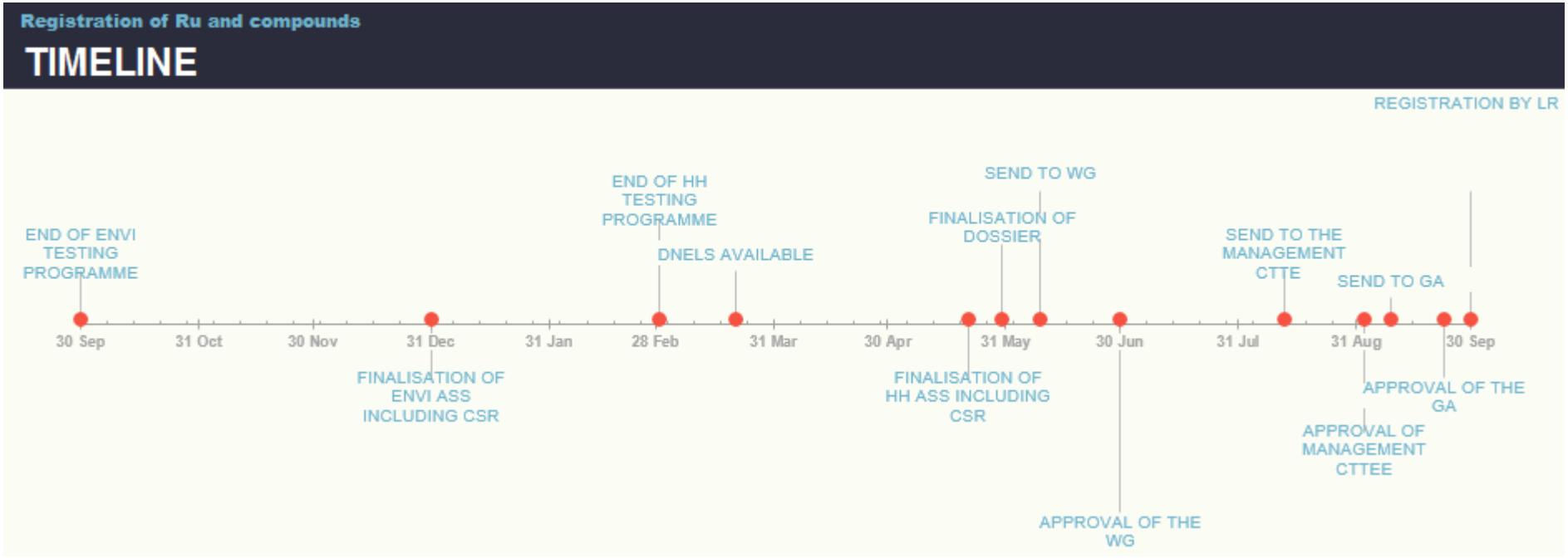
Precious Metals Consortium

5. Ruthenium and Ru compounds

5.1 Dossier status

Substance	CAS	EC	LR	Status	
Ruthenium	7440-18-8	231-127-1	Heraeus		
Ruthenium trichloride (hydrate)	*10049-08-8*	*233-167-5*	*Heraeus*	*HH and ENV testing running*	*See next slides*
Ruthenium (IV) oxide	12036-10-1	234-840-6	Heraeus		
Tris(nitrato-O)nitrosylruthenium	**34513-98-9**	**252-068-8**	**Umicore AG&Co.KG**	**Registration ongoing**	**AnnexIII exempted**
Hexakis[mu-(acetato-O:O')]-μ3-oxo-triangulo-triruthenium acetate / Ruthenium acetate	55466-76-7	259-653-7	Johnson Matthey		
Tetraammonium decachloro-mu-oxodiruthenate(4-)	*85392-65-0*	*286-924-7*	*Heraeus*	*HH testing running*	*See next slides*
Ruthenium trihydroxide	12135-42-1	235-221-3	Umicore NV/SA		

5.1 Dossier status



5.2 Hazard

- Ecotox testing: RuCl3
- Mammalian testing: RuCl3 and TetradoRu

Cfr. next slides

Ecotoxicity Testing Programme: Progress Oct 2016

Metal	Compound	Test	Progress	Result	Notes
Ruthenium	**Tetraammonium decachloro-mu-oxodiruthenate (TERTADO Ru)**	Algae Inhibition of Growth (72 hours)	Complete	EC50 (Growth rate) = 0.38 mg/L EC10 (Growth rate) = 0.019 mg/L NOEC (Growth rate) = 0.023 mg/L	Recovery 80-90% at test start, dropping to 40-80% at test end.
		Daphnia Immobility (48 hours)	Complete	EC50 = >55.7 mg/L	No effects in definitive test. Measured Ru concentrations 49-57% of nominal.
		Fish Mortality (96 hours)	Complete	No effects up to maximum exposure concentration (nominally 100 mg/L). EC50/ NOEC = > 73.6 mg/L	50-60% losses over 48 hour renewal period (semi-static test). Toxicity values based on time weighted measured concentrations.
		ASRIT (3 hours)	Complete	EC50 = 740 mg/L (with ATU) & 500 mg/L (without ATU)	-

Ecotoxicity Testing Programme: Progress Oct 2016

Metal	Compound	Test	Progress	Result	Notes
Ruthenium (cont)	**Ruthenium trichloride**	Algae Inhibition of Growth (72 hours)	Complete	EC50 (growth rate) = 0.602 mg/L EC10 (growth rate) = 0.233 mg/L NOEC (growth rate) = 0.184 mg/L	Measured (soluble) Ru concentrations 3-25% of nominal throughout test but stable so likely to be maximum achievable soluble concentrations.
		Fish Mortality (96 hours)	Complete	LC50 = > 0.94 mg/L	Limit test at nominal concentration of 10 mg/L. Measured (soluble) Ru concentrations 4-27% of nominal throughout test, decreasing over 48 hour renewal period.
		ASRIT (3 hours)	Complete	EC50 (without ATU) = 530 mg/L, EC50 (with ATU) = 330 mg/L	-

PNECs and exposure

- Ecotoxicity testing finalised for ruthenium trichloride, waiting testing reports
- PNECs will be derived following receipt of final test reports
- Emissions questionnaires received, exposure assessment to follow PNEC derivation
- Two substances currently requiring exposure work

Ruthenium Chloride (1)

14-day dose range finding toxicity/palatability study in rats:

- Dietary inclusions at 3750, 7500 and 15000 ppm (eq ~ 311, 639, 1194 mg/kg/day)
- No significant toxicity at any dose level
- 15000 ppm was associated with lower body weight (~ 6% on day 13), body weight gain (-31.4% days 0-13) and reduced food consumption in males. No effects in females
- Draft report under review

Ruthenium Chloride (2)

28-day dietary toxicity study with 14 day recovery period (OECD 407):

- Dietary inclusions at 500, 1500, 5000, 15000 ppm (eq. 38/47, 114/147, 365/449, 1149/1326 mg/kg/day in males/females)
- Recovery groups included at 0, 5000 and 15000 ppm
- Preliminary data (clinical signs, FOB data, body weight, food consumption, macroscopic findings, organ weights, haematology and clinical chemistry) indicate no notable signs of significant treatment-related toxicity.
- Body weight slightly lower at 15000 ppm (5.4%/3.1% on day 27)
- In-life complete
- Pathology due end October. Draft report due 25 Nov 16.

Ruthenium Chloride (3)

Reproduction/developmental toxicity screening test (dietary route) (OECD 421 2016 version):

- Dietary inclusions at 1500, 5000, 15000 ppm (nominally 100, 300, 1000 mg/kg/day)
- Includes pre-treatment smears for animal selection and thyroid hormone analysis (subcontracted to LPT in Germany)
- Currently in-life (started 20 Sept - mating starts wb 3 October)
- Draft report due 15 Jan 17

Tetraammonium decachloro-mu-oxodiruthenate

14 day preliminary repeat dose oral in rats:

- No treatment-related clinical signs or effects on organ weight or macropathology.
- Dose related effects on body weight

	Male		Female	
Dose (mg/kg)	Body weight (g)	Difference	Body weight (g)	Difference
0	311.90		223.66	
500	290.76	-7.6%	219.08	-2.0%
750	280.50*	-10.1%	214.36	-4.2%
1000	266.76**	-14.5%	209 6	-6.3%

- Report issued 20-Jun-16

Repeated dose oral toxicity with reproduction/developmental toxicity screen (OECD 422):

- In-life. Dosing starts 12 Oct 16 (0, 100, 300, 1000 mg/kg/day)

Classification changes

- Diammonium sodium hexakis(nitrito-N)rhodate
  CAS: 64164-17-6
  - » Aquatic chronic 2
  - » Based on algal test results for substance itself

5.3 Exposure

- Uses (as received by companies) will be revised by PMC Secretariat

- **REQUEST to check if:**

  - all uses are COVERED

  - all uses are CORRECTLY DESCRIBED (PROC,ERC,AC,PC…)

  ! Check description per PROC in ES (e.g. PROC 8a for transfer but also wet cleaning)

  - 'CONFIDENTIAL' uses are not covered in generic dossier

  → include use in company specific dossier

  + perform own risk assessment if CSA required

5.3 Exposure

- Occupational Monitoring Project (Rhodium & Ruthenium)
  - 3 site visits have been performed
  - SV reports drafted:
    - 1 finalised
    - 2 under review
  - Recommendations in SV report for follow-up monitoring

    → sufficient and high-quality data for occupational assessment

    → companies encouraged to monitor on short term and in house

    ! Project deadline end November 2016

    ! Internal registration deadlines Ru and Rh dossiers

Request to:

- **Urgently review / approve the SV report**
- **Indicate your intentions to monitor (and how)**
- **Timely provide the monitoring results**

5.3 Exposure

Action	By whom	Duration	Time
Agree on date for site visit	Companies / EBRC	1 month	Mid March 2016
Easter break	*All*		
Perform site visit	Companies / EBRC (/EPMF)	2 weeks	Mid April 2016
Draft site visit report	EBRC	2 weeks	End April 2016
Revise / approve site visit report	Companies	1 month	End May 2016
Develop data submission form	EBRC	1 month	End June 2016
Summer break	*All*		
Submit monitoring data	Companies	1 month	Mid Aug 2016
Generate database	EBRC	2 weeks	End Aug 2016
Conduct sampling	Sampling institute / Companies	2 weeks	Mid Sep 2016
Sample analysis & drafting report	Sampling institute / EBRC	1.5 month	End Oct 2016
Finalisation of database	EBRC	2 weeks	Mid Nov 2016

ONGOING

5.3 Exposure

Action	By whom	Duration	Time
Agree on date for site visit	Companies / EBRC	1 month	Mid March 2016
Easter break	*All*		
Perform site visit	Companies / EBRC (/EPMF)	2 weeks	Mid April 2016
Draft site visit report	EBRC	2 weeks	End April 2016
Revise / approve site visit report	Companies	1 month	End May 2016
Develop data submission form	EBRC	1 month	End June 2016
Summer break	*All*		
Submit monitoring data	Companies	1 month	Mid Aug 2016
Generate database	EBRC	2 weeks	End Aug 2016
Conduct sampling	Sampling institute / Companies	2 weeks	Mid Sep 2016
Sample analysis & drafting report	Sampling institute / EBRC	1.5 month	End Oct 2016
Finalisation of database	EBRC	2 weeks	Mid Nov 2016

ONGOING

NOT REQUIRED?

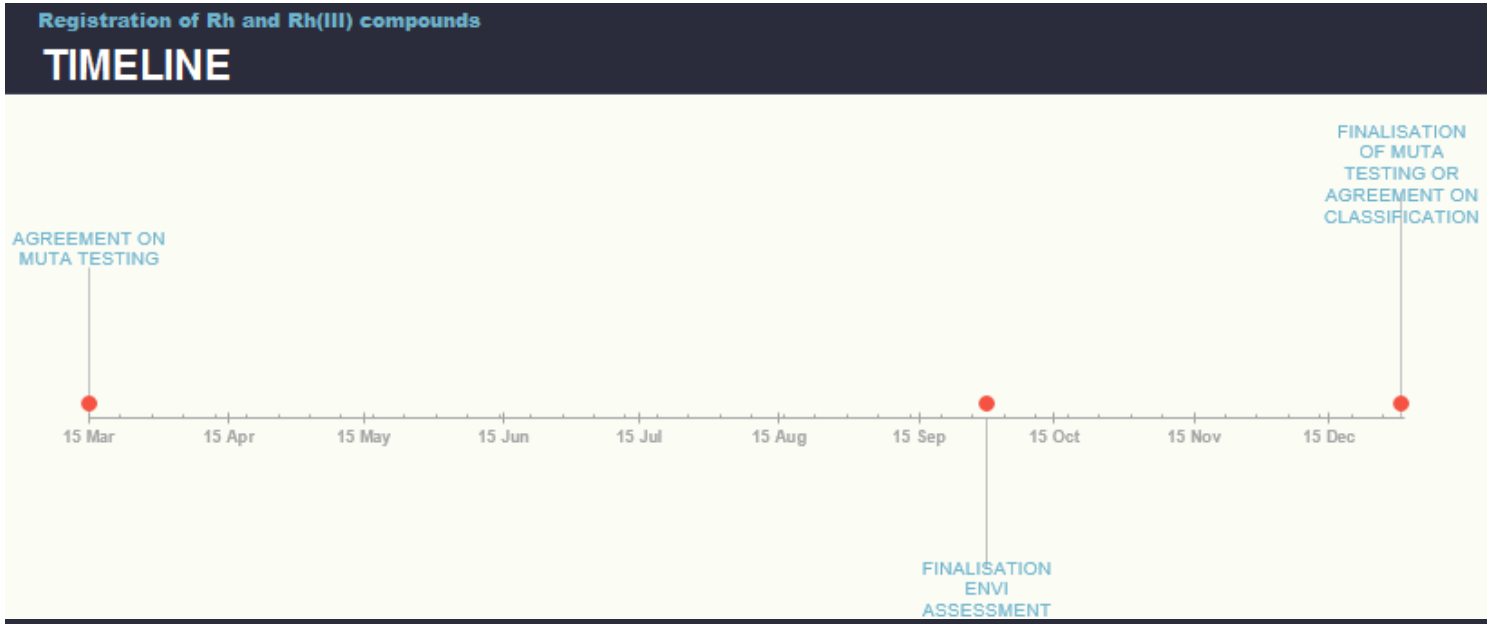
Precious Metals Consortium

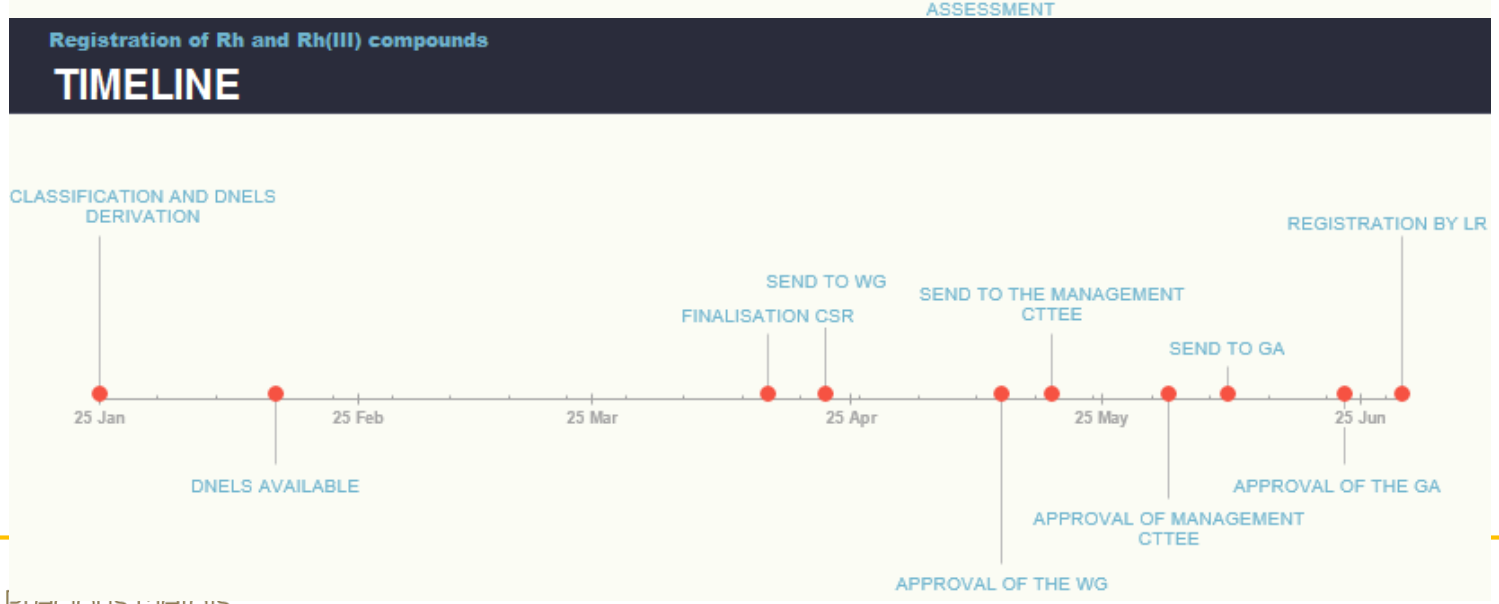
6. Rhodium and Rh compounds

5.1 Dossier status

Substance	CAS	EC	LR	Status	
Rhodium	7440-16-6	231-125-0	Johnson Matthey		
Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium	**25470-96-6**	**247-015-0**	**Johnson Matthey**	**REGISTERED**	**AnnexIII exempted**
Carbonylhydrotris(triphenylphosphine)rhodium	**17185-29-4**	**241-230-3**	**Umicore AG&Co.KG**	**Registration ongoing**	**AnnexIII exempted**
Dicarbonyl(pentane-2,4-dionato-O,O')rhodium	14874-82-9	238-947-9	Umicore AG&Co.KG		
Rhodium tris(2-ethylhexanoate) (in solution)	*20845-92-5*	*244-079-1*	*Umicore AG&Co.KG*	*PC and HH testing running*	
Rhodium trichloride (hydrate)	10049-07-7	233-165-4	Heraeus		
Di-µ-chloro-bis(hapto-1,5-cyclooctadiene)dirhodium(I)	**12092-47-6**	**235-157-6**	**Heraeus**	**REGISTERED**	**AnnexIII exempted**
Tris(triphenylphosphine) rhodium (I) chloride	**14694-95-2**	**238-744-5**	**Umicore AG&Co.KG**	**Registration ongoing**	**AnnexIII exempted**
Rhodium triiodide	15492-38-3	239-521-5	Umicore AG&Co.KG		
Dirhodium trisulphate	*10489-46-0*	*234-014-5*	*Umicore AG&Co.KG*	*PC testing running*	
Dirhodium trioxide	*12036-35-0*	*234-846-9*	*Umicore AG&Co.KG*	*HH testing running*	
Rhodium (III) acetate	42204-14-8	255-707-9	Umicore AG&Co.KG		
Rhodium trinitrate	10139-58-9	233-397-6	Johnson Matthey		
Rhodium trihydroxide	*21656-02-0*	*244-508-2*	*Heraeus*	*HH testing running*	
Triammonium hexachlororhodate	15336-18-2	239-364-2	Vale		
Diammonium sodium hexakis(nitrito-N)rhodate	64164-17-6	264-713-0	Vale		

5.1 Dossier status





5.1 Dossier status

- 5 Rh(I) substances scheduled for early registration:
  - 4 dossiers are ready for registration.
  - 1 finalised after deadline – proposal to go together with other Rh substances

5.2 Hazard

- PhysChem testing:
  - Rhodium tris(2-ethylhexanoate)
  - Dirhodium trisulfate
- Mammalian testing:
  - Rh2O3
  - Rh(OH)3
  - Rhodium tris(2-ethylhexanoate)

Cfr. next slides

Phys-chem testing: Status

Substance	Test	Testing status	
		Siemens	BAM
Rhodium tris(2-ethylhexanoate)	Melting point (A1)	Sample not yet obtained (discussed with sample provider)	
	Boiling point (A2)		
	Density (A3)		
	Readily combustible solid (N1)		
	Self-heating substances (N4)		
Dirhodium trisulphate	Density (A3)	Sample not yet obtained (discussed with sample provider)	
	Granulometry		

Rhodium salts - Ames studies

Rhodium (III) oxide:

- Study initiated 26 Aug 16
- Currently unable to prepare appropriate dosing formulation
- Advice re vehicles sought from sponsor/supplier

Rhodium trihydroxide:

- Test substance delivered 28 Sep 16

Rhodium tris (2-ethylhexanoate):

- Awaiting test substance delivery

5.2 Hazard

- Rh_2O_3 solubilisation / suspensions for AMES test:
  - Insoluble in common vehicles: water, ethanol, acetone, dimethylformamide, tetrahydrofuran, DMSO
  - suspension: not stable in low and high viscosity 1% Methylcellulose
  - Sonication not helping
  - Dispersing agents (Pluronic or Serum Albumin) not considered appropriate for bacterial assay
  - Use of extraction method: not used (ISO method, high amount of test material)

2 OPTIONS:

OPTION1: waive testing ("*Insolubility should be assessed as precipitation in the final mixture under the actual test conditions and evident to the unaided eye. The precipitate should not interfere with the scoring")* – fill endpoint via read-across

OPTION2: Use Silverson mixer (create finer particles which may prevent dropping out of suspension) - more test substance needed - use of Methylcellulose or water/DMSO

Proposal for OPTION2 with MC – AGREE?

Classification changes

- Diammonium sodium hexakis(nitrito-N)rhodate
  CAS: 64164-17-6
  - » Aquatic chronic 2
  - » Based on algal test results for substance itself

5.2 Hazard

- Rh(III) genetox:
  - Decision during Spring BtB meeting:
    - No mutagenicity classification Rh metal
    - Classify soluble Rh compounds (Rh(III) trichloride, trinitrate, sulphate, acetate and triammonium hexachlororhodate) as **Muta2** (pos in vitro and in vivo testing)
    - Classify diammonium sodium hexakis(nitrito-N)rhodate as **Muta2** (precautionary principle)
    - Perform AMES on 3 poorly water soluble Rh compounds
    - Perform internal review on Rh genetox for intelligent design in vivo TP

STATUS:

-PMC summarising the available information – first draft anticipated 2nd half Oct

-AMES testing still running – include in review as far as possible

5.3 Exposure

- Rh PNEC
  - Derived by WCA in 2015
    - Ecotoxicity data available for:
      - tris(triphenylphosphine) rhodium (I) chloride
      - dicarbonyl(pentane-2,4-dionato-O,O')rhodium
      - rhodium trichloride hydrate
      - rhodium trinitrate and hydrate and
      - diammonium sodium hexakis(nitrito-n)rhodate.
    - Diammonium sodium hexakis(nitrito-n)rhodate: most toxic Rh substance (as [Rh])
    - Cfr other PGM dossiers:
      - generic PNECs for all Rh substances
      - based on ecotox data for most toxic Rh substance

    - New literature search performed – ***cfr next slides!***

PNECs and exposure

- Draft PNECs derived in 2015
- New literature search conducted to identify additional literature data that may affect the PNECs
- *Daphnia* result for rhodium trichloride identified (EC50: 0.290 mg/L)
  - » Slightly lower than current result driving the PNECs (EC50: 0.66 mg/L)
  - » If included, this would reduce the PNEC value slightly, but still expected to demonstrate safe use in risk assessment
- Only one rhodium substance (Diammonium sodium hexakis(nitrito-N)rhodate) requires risk assessment based on tonnage
- Propose to determine PNECs based on data for this substance alone and not to read across rhodium trichloride result
  - » PNECs would be unchanged from draft versions (***cfr next slide***)
- Emissions information has been collated and GES scenarios developed for 'Manufacture and Use as Industrial Intermediate' based on sector data
- Based on draft PNEC - safe use is demonstrated for 'Manufacture and Use as an Intermediate'

5.3 Exposure

PNEC	Units	PNEC	PNEC derivation method
Freshwater	µg Rh /L	0.66	Lowest EC50 of 0.66 mg Rh /L for algae of and an assessment factor of 1000
Intermittent releases	µg Rh/L	6.6	Lowest EC50 of 0.66 mg Rh /L for algae of and an assessment factor of 100
Freshwater sediment	mg/kg Rh wwt	2.16	Equilibrium partitioning
	mg/kg Rh dwt	9.8	Equilibrium partitioning
Marine water	µg Rh/L	0.066	Lowest EC50 of 0.66 mg Rh /L for algae of and an assessment factor of 10, 000
Marine sediment	mg/kg Rh wwt	0.216	Equilibrium partitioning
	mg/kg Rh dwt	0.98	Equilibrium partitioning
Soil	mg/kg Rh wwt	0.00229	Equilibrium partitioning
	mg/kg Rh dwt	0.0026	Equilibrium partitioning
Microorganisms	mg Rh/L	14.6	NOEC or EC10 from an activated sludge respiration inhibition test and an assessment factor of 10
Secondary poisoning	Requirement for a secondary poisoning assessment to be determined on completion of mammalian toxicity testing		

5.3 Exposure

AGREE WITH PROPOSAL TO DERIVE SUBSTANCE SPECIFIC PNECs FOR Diammonium sodium hexakis(nitrito-N)rhodate ?

REQUEST to REVIEW INFORMATION and CHECK COMPLIANCE as much as possible DURING DOSSIER PREPARATION PHASE, NOT DURING APPROVAL PROCESS

Classification changes

- Diammonium sodium hexakis(nitrito-N)rhodate CAS: 64164-17-6
  - » Aquatic chronic 2
  - » Based on algal test results for substance itself
- Rhodium trichloride
  - » Propose to include *Daphnia* result from literature in dossier (Okamoto et al. 2014)
  - » Would lead to Acute category 1, chronic category 1 classification (M factor 1)

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6. Budget overview

Budget Ir

		PMC 2017 Budget *to be spent*	PMC 2017 Budget *to be invoiced*	PMC 2017 HR	PMC 2018 Budget *to be invoiced*	PMC 2018 HR	PMC 2019 Budget *to be invoiced*	PMC 2019 HR
2.5.E	***Iridium-specific costs***	***13.850 €***	***13.850 €***	***0,1***	***18.050 €***	***0,1***	***18.250 €***	***0,1***
2.5.E.1	**Ir REACH registration**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.E.1.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €		0 €		0 €	
2.5.E.1.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €		0 €		0 €	
2.5.E.1.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	0 €	0 €		0 €		0 €	
2.5.E.1.4	*Phase 4: Generation of Chemical Safety Reports*	0 €	0 €		0 €		0 €	
2.5.E.1.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	0 €	0 €		0 €		0 €	
2.5.E.1.5b	*Phase 5b: IUCLID 5 Hosting System*	0 €	0 €		0 €		0 €	
2.5.E.2	**Ir REACH dossier maintenance**	**2.000 €**	**2.000 €**		***6.000 €***		**6.000 €**	
2.5.E.2.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €					
2.5.E.2.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €					
2.5.E.2.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	0 €	0 €					
2.5.E.2.4	*Phase 4: Generation of Chemical Safety Report*	0 €	0 €					
2.5.E.2.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	1.000 €	1.000 €					
2.5.E.2.5b	*Phase 5b: IUCLID 5 Hosting System*	1.000 €	1.000 €		1.000 €		1.000 €	
2.5.E.2.6	*Ir Rolling maintenance (as from 2018)*				5.000 €		5.000 €	
2.5.E.2.7	*Ir Further improvement (as from 2018)*				0 €		0 €	
2.5.E.2.8	*Ir Testing proposal (as from 2018)*				0 €		0 €	
2.5.E.3	**Ir REACH evaluation**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.A.3.1	*Dossier evaluation*	0 €	0 €		0 €		0 €	
2.5.A.3.2	*Substance evaluation*	0 €	0 €		0 €		0 €	
2.5.E.4	**Ir REACH classification & labelling**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.E.5	**Ir REACH authorisation**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.E.6	**Ir internal and external fixed Scientific Managers**	**11.850 €**	**11.850 €**		**12.050 €**		**12.250 €**	
2.5.E.7	**Ir Building reserves**	**0 €**	**0 €**					

Budget Pd

		PMC 2017 Budget *to be spent*	PMC 2017 Budget *to be invoiced*	PMC 2017 HR	PMC 2018 Budget *to be invoiced*	PMC 2018 HR	PMC 2019 Budget *to be invoiced*	PMC 2019 HR
2.5.B	***Palladium-specific costs***	***25.200 €***	***25.200 €***	***0,1***	***574.095 €***	***0,4***	***362.309 €***	***0,3***
2.5.B.1	**Pd REACH registration**	**10.000 €**	**10.000 €**		**0 €**		**0 €**	
2.5.B.1.1	*Phase 1: Literature search, data gap analysis and recommendations*							
2.5.B.1.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €					
2.5.B.1.3	*Phase 3: Experimental studies (testing programme including cost of samples)*							
2.5.B.1.4	*Phase 4: Generation of Chemical Safety Reports*	5.000 €	5.000 €					
2.5.B.1.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	5.000 €	5.000 €					
2.5.B.1.5b	*Phase 5b: IUCLID 5 Hosting System*	0 €	0 €					
2.5.B.1.6	*Phase 6: Administration/others (secretariat work for project management, organisation & participation in meetings, communication)*							
2.5.B.2	**Pd REACH dossier maintenance**	**1.000 €**	**1.000 €**		**516.000 €**	**0**	**321.000 €**	
2.5.B.2.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €					
2.5.B.2.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €					
2.5.B.2.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	0 €	0 €					
2.5.B.2.4	*Phase 4: Generation of Chemical Safety Report*	0 €	0 €					
2.5.B.2.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	0 €	0 €					
2.5.B.2.5b	*Phase 5b: IUCLID 5 Hosting System*	1.000 €	1.000 €		1.000 €		1.000 €	
2.5.B.2.6	*Pd Rolling maintenance (as from 2018)*				130.000 €		130.000 €	
2.5.B.2.7	*Pd Further improvement (as from 2018)*				285.000 €		190.000 €	
2.5.B.2.8	*Pd Testing proposal (as from 2018)*				0 €		0 €	
2.5.B.2.9	*Pd Nano*				100.000 €			
2.5.B.3	**Pd REACH evaluation**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.B.3.1	*Dossier evaluation*	0 €	0 €		0 €		0 €	
2.5.B.3.2	*Substance evaluation*	0 €	0 €		0 €		0 €	
2.5.B.4	**Pd REACH classification & labelling**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.B.5	**Pd REACH authorisation**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.B.6	**Pd internal and external fixed Scientific Managers**	**14.200 €**	**14.200 €**		**58.095 €**		**41.309 €**	
2.5.B.7	**Pd Building reserves**	**0 €**	**0 €**					
2.5.B.8	**Chloropalladates**	**0 €**	**0 €**					

Budget Pt

		PMC 2017 Budget *to be spent*	PMC 2017 Budget *to be invoiced*	PMC 2017 HR	PMC 2018 Budget *to be invoiced*	PMC 2018 HR	PMC 2019 Budget *to be invoiced*	PMC 2019 HR
2.5.A	***Platinum-specific costs***	***753.900 €***	***738.400 €***	***0,3***	***281.621 €***	***0,4***	***1.263.618 €***	***0,6***
2.5.A.1	**Pt REACH registration**	**325.650 €**	**310.150 €**		**0 €**		**0 €**	
2.5.A.1.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €					
2.5.A.1.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	31.000 €	31.000 €					
2.5.A.1.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	160.500 €	145.000 €					
2.5.A.1.4	*Phase 4: Generation of Chemical Safety Reports*	133.150 €	133.150 €					
2.5.A.1.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	0 €	0 €					
2.5.A.1.5b	*Phase 5b: IUCLID 5 Hosting System*	1.000 €	1.000 €					
2.5.A.2	**Pt REACH dossier maintenance**	**0 €**	**0 €**		**226.000 €**		**1.181.000 €**	
2.5.A.2.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €					
2.5.A.2.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €					
2.5.A.2.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	0 €	0 €					
2.5.A.2.4	*Phase 4: Generation of Chemical Safety Report*	0 €	0 €					
2.5.A.2.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	0 €	0 €					
2.5.A.2.5b	*Phase 5b: IUCLID 5 Hosting System*	0 €	0 €		1.000 €		1.000 €	
2.5.A.2.6	*Pt Rolling maintenance (as from 2018)*				90.000 €		90.000 €	
2.5.A.2.7	*Pt Further improvement (as from 2018)*				135.000 €		90.000 €	
2.5.A.2.8	*Pt Testing proposal (as from 2018)*				0 €		1.000.000 €	
2.5.A.3	**Pt REACH evaluation**	**10.000 €**	**10.000 €**		**0 €**		**0 €**	
2.5.A.3.1	*Dossier evaluation*	10.000 €	10.000 €		0 €		0 €	
2.5.A.3.2	*Substance evaluation*	0 €	0 €		0 €		0 €	
2.5.A.4	**Pt REACH classification & labelling**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.A.5	**Pt REACH authorisation**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.A.5.1.	*Chloroplatinates*	0 €	0 €		0 €		0 €	
2.5.A.6	**Pt internal and external fixed Scientific Managers**	**40.250 €**	**40.250 €**		**55.621 €**		**82.618 €**	
2.5.A.7	**Pt Building reserves**	**378.000 €**	**378.000 €**					

Budget Ru

		PMC 2017	PMC 2017	PMC 2017	PMC 2018	PMC 2018	PMC 2019	PMC 2019
		Budget *to be spent*	Budget *to be invoiced*	HR	Budget *to be invoiced*	HR	Budget *to be invoiced*	HR
2.5.D	***Ruthenium-specific costs***	***501.700 €***	***435.200 €***	***0,6***	***236.674 €***	***0,4***	***112.279 €***	***0,4***
2.5.D.1	**Ru REACH registration**	**183.550 €**	**117.050 €**		**0 €**		**0 €**	
2.5.D.1.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €					
2.5.D.1.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	10.000 €	10.000 €					
2.5.D.1.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	87.500 €	21.000 €					
2.5.D.1.4	*Phase 4: Generation of Chemical Safety Reports*	63.000 €	63.000 €					
2.5.D.1.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	22.050 €	22.050 €					
2.5.D.1.5b	*Phase 5b: IUCLID 5 Hosting System*	1.000 €	1.000 €					
2.5.D.1.6	*Phase 6: Administration/others (secretariat work for project management, organisation & participation in meetings, communication)*							
2.5.D.2	**Ru REACH dossier maintenance**	**0 €**	**0 €**		**186.000 €**		**61.000 €**	
2.5.D.2.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €					
2.5.D.2.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €					
2.5.D.2.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	0 €	0 €					
2.5.D.2.4	*Phase 4: Generation of Chemical Safety Report*	0 €	0 €					
2.5.D.2.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	0 €	0 €					
2.5.D.2.5b	*Phase 5b: IUCLID 5 Hosting System*	0 €	0 €		1.000 €		1.000 €	
2.5.D.2.6	*Ru Rolling maintenance (as from 2018)*				30.000 €		30.000 €	
2.5.D.2.7	*Ru Further improvement (as from 2018)*				55.000 €		30.000 €	
2.5.D.2.8	*Ru Testing proposal (as from 2018)*				0 €		0 €	
2.5.D.2.9	*Ru Nano*				100.000 €		0 €	
2.5.D.3	**Ru REACH evaluation**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.D.3.1	*Dossier evaluation*	0 €	0 €		0 €		0 €	
2.5.D.3.2	*Substance evaluation*	0 €	0 €		0 €		0 €	
2.5.D.4	**Ru REACH classification & labelling**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.D.5	**Ru REACH authorisation**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.D.6	**Ru internal and external fixed Scientific Managers**	**78.150 €**	**78.150 €**		**50.674 €**		**51.279 €**	
2.5.D.7	**Ru Building reserves**	**240.000 €**	**240.000 €**					

Budget Rh

		PMC 2017 Budget *to be spent*	PMC 2017 Budget *to be invoiced*	PMC 2017 HR	PMC 2018 Budget *to be invoiced*	PMC 2018 HR	PMC 2019 Budget *to be invoiced*	PMC 2019 HR
2.5.C	***Rhodium-specific costs***	***171.050 €***	***153.550 €***	***0,6***	***334.624 €***	***0,3***	***267.750 €***	***0,3***
2.5.C.1	**Rh REACH registration**	**90.550 €**	**73.050 €**		**0 €**		**0 €**	
2.5.C.1.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €					
2.5.C.1.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	10.000 €	10.000 €					
2.5.C.1.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	17.500 €	0 €					
2.5.C.1.4	*Phase 4: Generation of Chemical Safety Reports*	40.000 €	40.000 €					
2.5.C.1.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	22.050 €	22.050 €					
2.5.C.1.5b	*Phase 5b: IUCLID 5 Hosting System*	1.000 €	1.000 €					
2.5.C.1.6	*Phase 6: Administration/others (secretariat work for project management, organisation & participation in meetings, communication)*							
2.5.C.2	**Rh REACH dossier maintenance**	**0 €**	**0 €**		**1.000 €**		**1.000 €**	
2.5.C.2.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €					
2.5.C.2.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €					
2.5.C.2.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	0 €	0 €					
2.5.C.2.4	*Phase 4: Generation of Chemical Safety Report*	0 €	0 €					
2.5.C.2.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	0 €	0 €					
2.5.C.2.5b	*Phase 5b: IUCLID 5 Hosting System*	0 €	0 €		1.000 €		1.000 €	
2.5.C.2.6	*Rh Rolling maintenance (as from 2018)*				100.000 €		100.000 €	
2.5.C.2.7	*Rh Further improvement (as from 2018)*				195.000 €		130.000 €	
2.5.C.2.8	*Rh Testing proposal (as from 2018)*				0 €		0 €	
2.5.C.3	**Rh REACH evaluation**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.C.3.1	*Dossier evaluation*	0 €	0 €		0 €		0 €	
2.5.C.3.2	*Substance evaluation*	0 €	0 €		0 €		0 €	
2.5.C.4	**Rh REACH classification & labelling**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.C.5	**Rh REACH authorisation**	**0 €**	**0 €**		**0 €**		**0 €**	
2.5.C.6	**Rh internal and external fixed Scientific Managers**	**80.500 €**	**80.500 €**		**38.624 €**		**36.750 €**	
2.5.C.7	**Rh Building reserves**	**0 €**	**0 €**					

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8. AOB, Next meeting(s) and closing remarks

AOB

- REACH flags

- Next BtB meetings:
  - Spring: 21, 22 and 23 March 2017
    - Wednesday 22 March: Full day PGM WG
  - Autumn: 17, 18 and 19 October 2017

Precious Metals Consortium

THANK YOU

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