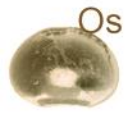
Precious Metals and Rhenium Consortium PGM Experts meeting

Conference Call

6th October 2011



1. Introduction and welcome

- Competition Law reminder
- Approval of the Agenda
- Approval of minutes last meeting
- Objectives

Objective of the Meeting

- Update enabling tests/ scope
- Finalise ITS reports
- Agree on way forward
  - Ecotox testing
  - Tier 1 mammalian tox testing
    - Sensitisation
    - Acute toxicity
    - Genotoxicity
- Time planning
    - 2013 deadline substances
    - Tier 2 mammalian tox testing (acute 2nd route, RDT)

2. PGM Project Scope

Scope – Feedback from members

Substance	Feedback	Conclusion
RhCl3 and RuCl3	• Anhydrous form not produced, • Not available for testing	• No testing of anh. forms • Dossiers will be prepared for hydrated forms only
Diamminedichloro palladium	• Mixture of several isomers (cis, trans, beta-trans) • Equilibirum mixture primarily trans isomer	• Test representative commercial product

Scope – Karstedt Concentrate

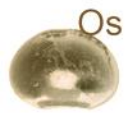
- Background
  - Significant data gaps
  - Important product for silicones industry; will also register
- Meeting Reconsile consortium 23 Sept. 2011, Bxl
  - Constructive discussion, both parties interested in sharing efforts/data/costs
  - Need for pre-studies: evaluate environmental fate/ biologically active form
  - Probable scenario: hydrolysis to siloxane ligand and Pt(0)
    - Reconsile hold data on siloxane ligand
    - PMC currently developing data on Pt (0)

Scope – Karstedt Concentrate

- Conclusions/ Next Steps
  - Agree on substance identity
  - Work out details of collaboration
    - Letter of intent, etc)
    - Need to decide on lead registrant
  - WCA and PFA (Peter Fisk Associates; siloxane consultants) to meet and recommend way forward
- Other
  - Siloxane ligand might be persistent and bioaccumulative; properties currently under evaluation

Scope - Other

- Palladium dioxide
  - On scope, but substance not available for testing = tests waived b/c non-availability of test material
- For discussion
  - New data available on Platinum tetraammine acetate for read across
  - Timing for updating ITS



3. Enabling Tests

Oxidising Properties – tests at BAM

Substance	CAS	State	Status
Iridium dioxide	12030-49-8	solid	done
Platinum dioxide	1314-15-4	solid	done
Platinum dinitrate	18496-40-7	solution	done
Dipotassium tetraoxoruthenate	31111-21-4	Solution in aqueous KOH	Not available in pure form test K_2OsO_4 instead, testing ongoing
Ruthenium IV oxide	12036-10-1	solid	Ongoing, substance provided late
Rhodium trinitrate	10139-58-9	Solid (hydrate)	done

Water Solubility –Standard tests

- Testing at JMTC
- Results by end of year

10025-65-7 Platinum dichloride
Dicarbonyl(pentane-2,4-dionato-O,O')rhodium 14874-82-9
Triammonium hexachlororhodate 15336-18-2
Diammonium sodium hexakis(nitrito-N)rhodate 64164-17-6
Diammonium hexachlororuthenate 18746-63-9
Tetraammonium decachloro-mu-oxodiruthenate(4-) 85392-65-0
Rhodium trichloride (anhydrous) 10049-07-7
Ruthenium trichloride 10049-08-8 (anhydrous)

Water Solubility – Non standard tests

Rhodium trihydroxide 21656-02-0	cannot be isolated as dry solid
Rhodium tris(2-ethylhexanoate) 20845-92-5	solution in 2-EH
Ruthenium trihydroxide 12135-42-1	damp unisolated solid
Iridium dioxide 12030-49-8	cannot be isolated as dry solid
16970-55-1 Dihydrogen tetrachloropalladate	only available as solution
68478-92-2 Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate (10-100 tonne substance)	decomposes in water
14221-01-3 Tetrakis(triphenylphosphine)palladium	decomposes in water
10102-05-3 Palladium dinitrate (and solution)	likely to precipitate in water
18496-40-7 Platinum dinitrate	likely to precipitate in water
12036-04-3 Palladium dioxide (and hydrate)	substance not isolated
16919-73-6 Dipotassium hexachloropalladate	substance not isolated
19168-23-1 Diammonium hexachloropalladate	substance not isolated

Water Solubility – TD - Other

Substance	Status
Palladium monoxide (hydrate) 1314-08-5	TD test CANMET
Palladium dihydroxide 12135-22-7	TD test CANMET
14024-61-4 Palladium di(4-oxopent-2-en-2-oate)	Existing data sufficient, no TD test required
Dirhodium trisulphate 10489-46-0	Check if limit value available - done
Potassium tetraoxoruthenate 31111-21-4	Check if limit value available - done
61495-96-3 Tetramminepalladium(2+) diacetate (1-10 tonne substance)	Check if limit value available - done

Dustiness tests

- Scope
  - Testing completed at DMT (9 substances), reports available
  - No testing of chloroplatinates (3 substances)
  - PSD data available
    - Substances tested at CANMET (Pt, Pd, Rh, Ru, PdO)
    - New substance: PtCl2
- Next steps
  - Lung deposition modelling based on dustiness data
  - Too many uncertainties with modelling based on PSD data =>
  - **Recommend dustiness tests for Pt, Pd, Rh, Ru, PdO, PtCl2**
- Timing
  - 9 substances: MPPD modelling by end October
  - 6 substances
    - dustiness tests by mid November
    - MPPD modelling by end November

Bio-elution tests

- Testing at CIMM

CASRN	Substance name	Chemical analysis required as:
7440-06-4	Platinum	Platinum
10025-65-7	Platinum dichloride	Platinum
16921-30-5	Dipotassium hexachloroplatinate	Platinum
7440-05-3	Palladium	Palladium
1314-08-5	Palladium monoxide	Palladium
12135-22-7	Palladium dihydroxide	Palladium
13815-17-3	Tetraamminepalladium (2+) dichloride	Palladium
14024-61-4	Palladium (II) di(4-oxopent-2-en-2-oate)	Palladium
16919-73-6	**Dipotassium hexachloropalladate***	Palladium
19168-23-1	**Diammonium hexachloropalladate***	Palladium
7440-16-6	Rhodium	Rhodium
64164-17-6	Diammonium sodium hexakis(nitrito-N)rhodate	Rhodium
7440-18-8	Ruthenium	Ruthenium

Bio-elution tests

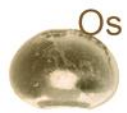
- Testing at CIMM
  - Standard media (no PBS, “artificial blood”)

- Dipotassium hexachloropalladate and Diammonium hexachloropalladate
  - No data on water solubility available yet
    - Indicative solubility: single-digit g/l range
    - (Solubility difficult to predict, strongly dependent on other ions present)
    - Indicative solubility: single-digit g/l range
  - Recommendation: no bio-elution testing needed

4. ITS

Timeline/ critical path

- Suggest to discuss under agenda point 7.1
- See MS Project file



5. Ecotoxicity Part

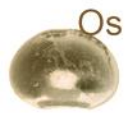
Environmental Section

Proposed testing (slides Adam)

Points for discussion

- Confirm read-across strategy hexachloropalladates
  - Test diammonium and read across to dipotassium CP or vice versa?
  - Same non-SCC tonnage/data requirements for both substances
- Proposal
  - Pre-test daphnia
  - Decide on read-across based on pre-test results

Time Line, CRO selection



6. Mammalian toxicity part

Genotoxicity

- Testing strategy/ testing recommendations
  - Slides Paul

- For discussions
  - Impact of extreme pH on genotox study results
    - Expert opinion needed?
  - (Conflicting) micronucleus studies on RhCl3 and RhNO3
    - BIBRA re-evaluation: different tested concentrations explain different results, soluble Rh(III) is genotoxic, no further testing needed
    - pH influence?
    - Additional expert opinion needed?
  - Hexchloroplatinic acid
    - In vivo micronucleus test currently recommended
    - Re-evaluate based on above expert feedback (pH confounding effects)?

Sensitisation

- Testing recommendations
  - Slides Paul

Irritation

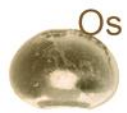
Substance	In vitro skin (EPISKIN) test	In vitro eye (e.g. BCOP or ICE) test	In vivo eye irritation test	
Diammonium hexachlororuthenate (CAS 18746-63-9)	X	X	X	Low water solubility / liable to sediment rapidly from suspension – ICE recommended
Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium (CAS 25470-96-6)		-	-	Due to reduction in tonnage, substance now qualifies for Annex III exemption. No testing required any longer.
Diammonium sodium hexakis(nitrito-N)rhodate (CAS 64164-17-6)	X	X	X	Low water solubility / liable to sediment rapidly from suspension – ICE recommended
Diamminedichloropalladium (CAS 13782-33-7)	X	X	X	Low water solubility / liable to sediment rapidly from suspension – ICE recommended
Palladium (II) di(4-oxopent-2-en-2-oate) (CAS 14024-61-4)	X	-	X	N/A
Platinum dichloride (CAS 10025-65-7)		X	X	Low water solubility / liable to sediment rapidly from suspension – ICE recommended
Tetraammineplatinum dinitrate (CAS 20634-12-2)	X	X	X	Supplied as solution, max. conc. 6.6%. Makeup of 20% solution from solid is not possible since solid is not isolated (explosivity); suggest to test 6.6% solution in BCOP test.
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate (CAS 68478-92-2)	(X)	(X)	(X)	Data sharing under discussion with Silicones sector. Suggest to put testing on hold. (Will decompose in aqueous solution. Consider waiver possibility. Predicted to be a marked irritant.)
Dihydrogen hexahydroxyplatinate (CAS 51850-20-5)	X			

Irritation

- CRO selection/ Practicalities
  - EPISKIN, ICE, potential in-vivo: LAB, Hungary
  - BCOP: only possible at Harlan, suggest to conduct potential in-vivo follow up at Harlan as well

Acute and repeated dose toxicity requirements

- Acute oral
  - Testing recommendations: slide Paul
- Acute inhalation/dermal
  - Depending on data from
    - Dustiness (is inhalation relevant at all?)
    - Bio-elution (is dermal uptake possible at all?)
    - Irritation (no testing possible for irritants)
    - Practicalities (can stable testing atmosphere be created?)
- Repeated dose
  - Route of exposure/ dose selection, based on data from acute tests



7. Next steps - Timeline

2013 Registrations

	Highest tonnage	DL	Dossier
Diammonium hexachloropalladate *(Intermediate)*	• SCC: 100-1000 tpa • Non-SCC: 10-100 tpa	• 2013 • 2018	• Available information • Full dossier
Diammonium hexachloroplatinate *(Intermediate)*	• SCC: 100-1000 tpa • Non-SCC: 10-100 tpa	• 2013 • 2018	• Available information • Full dossier
Diamine dichloropalladium *(Substance)*	• 100-1000 tpa	• **2013**	• **Full dossier**

Required by 31 May 2013

- 1 full dossier
- 2 intermediate dossiers (reporting available information)
- Caveat: need robust documentation of SCC!
  - Responsibility of the concerned company(ies)
  - WCA and PMC have to assume SCC compliance

Ag

Au

Ir

Os

Pd

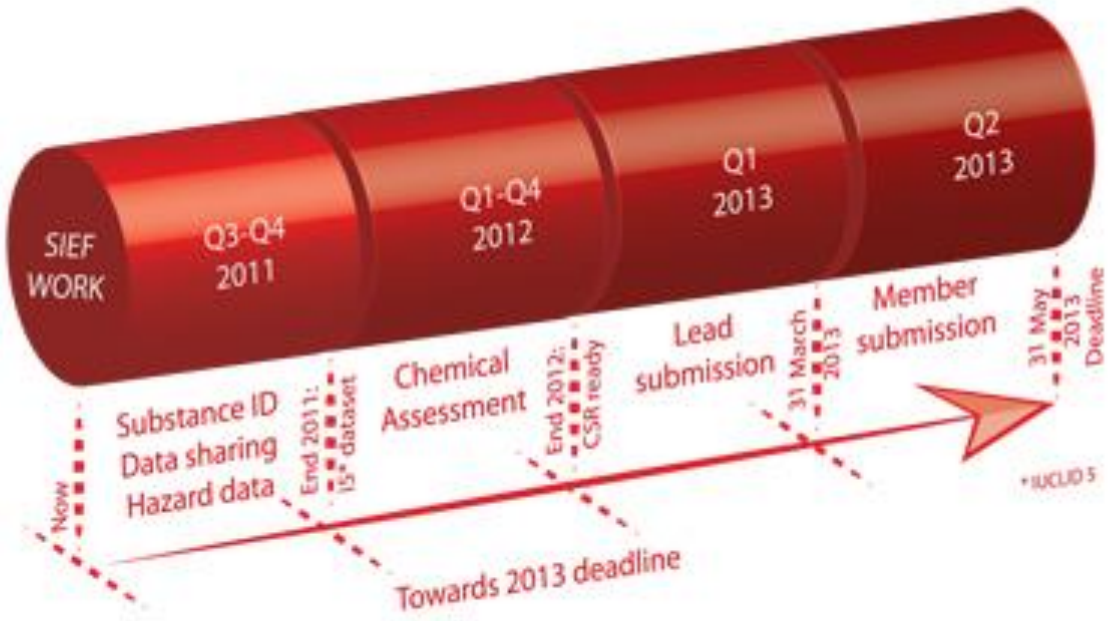
Pt

Re

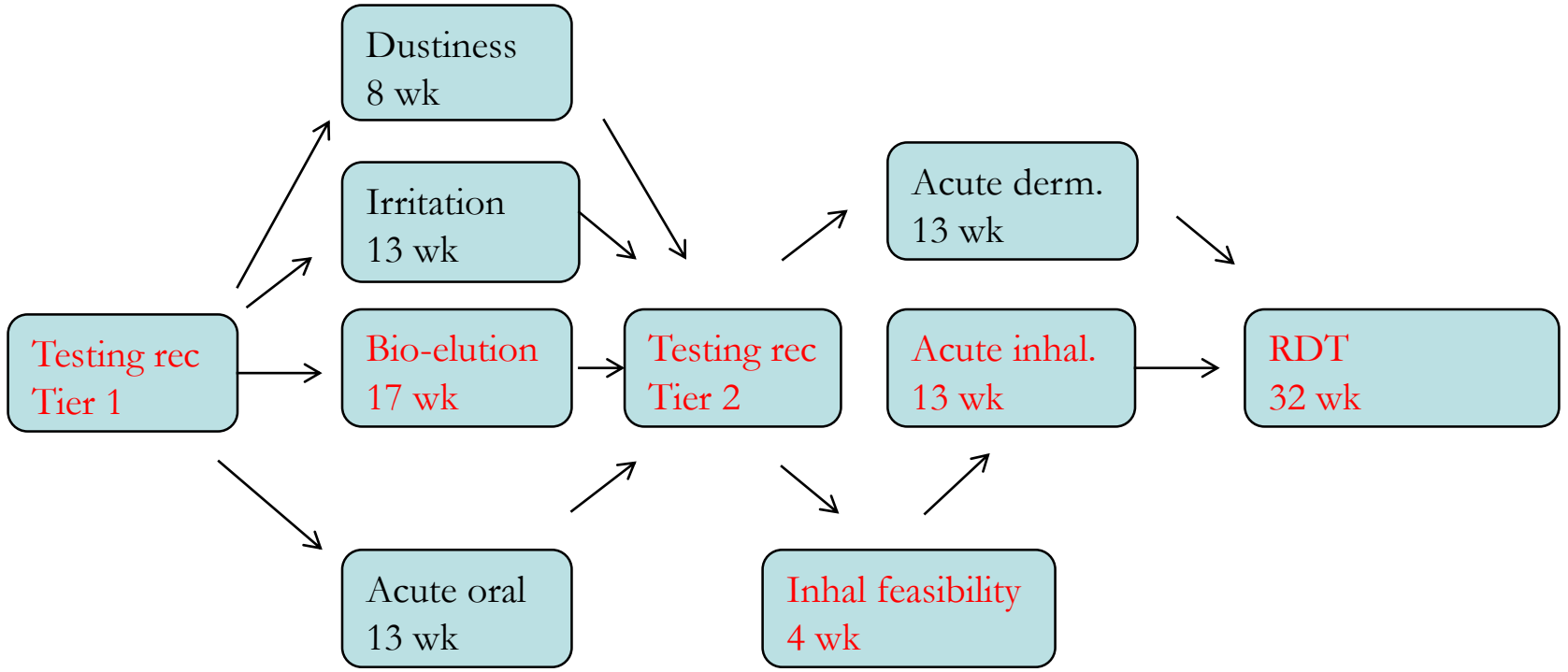
Rh

Ru

Timeline for successful submission
(from ECHA website)



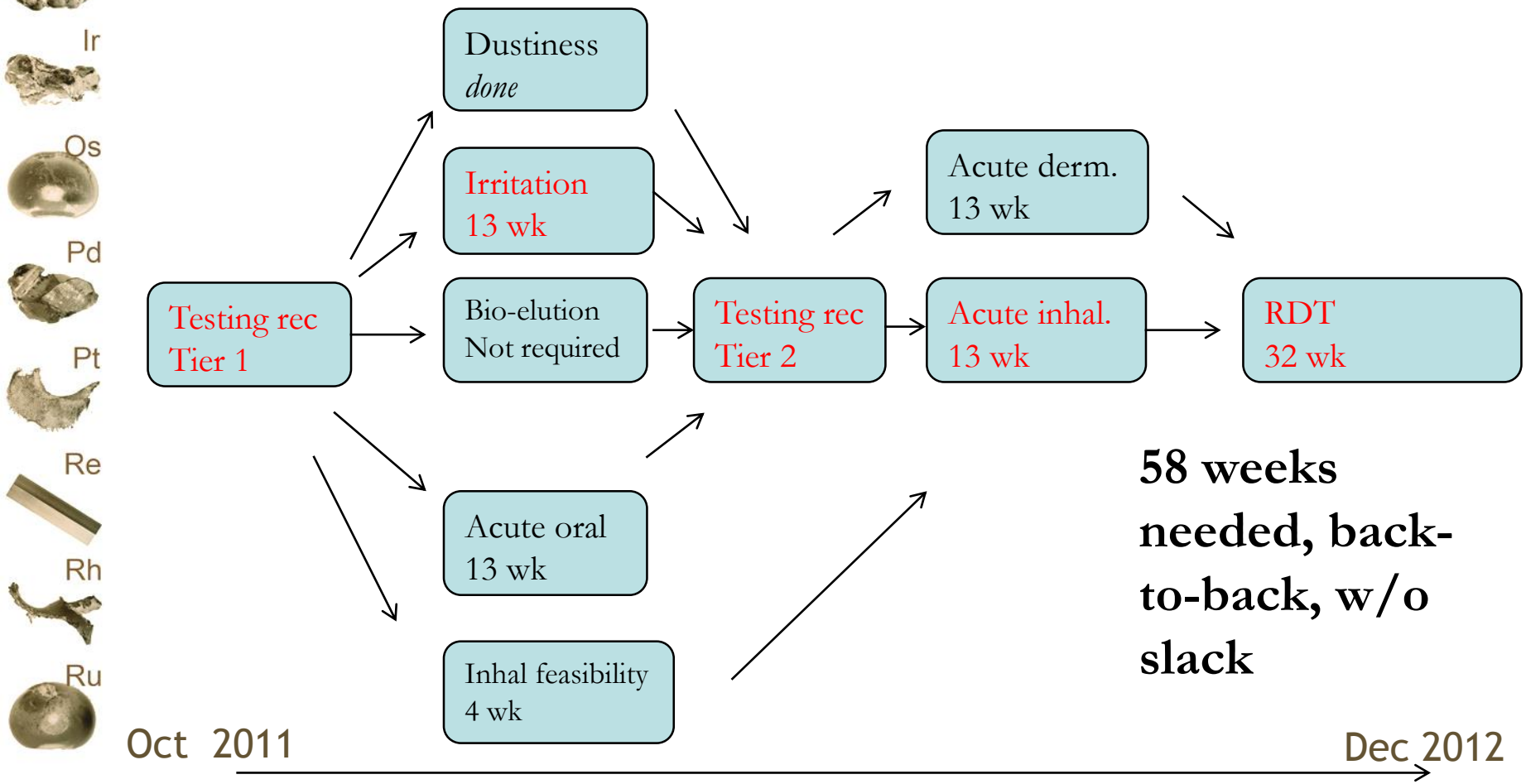
Timeline "normal track" testing - Likely too long for 2013 deadline



66 weeks needed, back-to-back, w/o slack

Oct 2011 → CSR

Timeline fast-track - for 2013 deadline



Options Diamine dichloropalladium

Substance 100-1000 → 2013 registration

- OPTION 1: Prepare full dossier by 2013
  - Determine critical path
  - Fast track testing ca 58 weeks, w/o allowing for slack time
  - Discuss options to accelerate
    - Speed up irritation testing
    - Determine feasibility (can a stable test atmosphere be created at all?) in advance
    - Conduct inhalation in parallel with oral study?
- OPTION 2: Prepare as much as technically feasible and update afterwards
  - Consider risks; e.g., tentative DNEL = higher assessment factor = lower margin of safety

Options Diammonium hexachloroPt and Pd

Intermediates 100-1000 t/a SCC registrations by 2013, followed by 10-100 t/a non-SCC registrations before 2018

- OPTION 1: Prepare 'all available information' dossiers by 2013 and update afterwards
  - Legal compliance ensured
  - Double registration preparation/submission work (unless updates are foreseen anyway)
- OPTION 2: Prepare full 10-100 t/a dossiers by 2013 and no need to update afterwards
  - Legal compliance ensured
  - No double registration preparation/submission (unless updates are foreseen anyway)