

Precious Metals and
Rhenium Consortium
Rhenium Work Group
conference call

27 October 2011, 15h00 CET

Participants

- Angela Alderman, Johnson Matthey
- Caroline Braibant, EPMF
- Roland Brasch, Heraeus
- Michael Husakiewicz, Lipmann Walton
- Ken Kloska, Climax Molybdenum
- Marie-Laure Ledrich, Traxys
- Klaus Rothenbacher, EPMF
- Marc Simon, Traxys
- Rüdiger Thiele, Heraeus
- Paul Whitehead, WCA
- Minako Takamiya-Allen, WCA

Agenda

1. Welcome and introduction
2. Scope adjustments/confirmation
3. Progress of testing programme
4. Next steps and likely need for CSA/CSR
5. ID Cards and IUCLID 5 filling
6. Overall project progress, timeline and budget
7. AOB, next meeting/call, closing remarks

1. Welcome and introduction

- Confidentiality and Competition Law
- Participants
- Approval of the Agenda
- Actions of the last meeting
- Approval of the minutes

Actions last meeting

- *in vivo* mutagenicity test not subject to testing proposal
 - REACH regulation indicates only Annex IX and X tests require testing proposal
 - ECHA statistics indicate all testing using vertebrate animals should be subject to testing proposal
 - *In vitro* results for APR indicate no need for *in vivo* test
- LAB contract and sample done
- CSR required on the basis of classification
- List of studies used to derive and support Re classifications + cost done
 - Will be circulated as annex to today's meeting minutes
 - C. Braibant to prepare LtU and revert to Re WG

2. Scope

Name	Type of Dossier	Tonnage band	Registration deadline	Volunteer Lead Registrant
Rhenium	Substance	1-10 t/a	2018	KGHM Ecoren
Perrhenic acid (in solution)	Substance	1-10 t/a	2018	Heraeus
Ammonium perrhenate	Substance	10-100 t/a	2018	Heraeus
Sodium rhenate (in aq. solution)	SCC Intermediate	1-10 t/a	2018	Climax Molybdenum
Potassium perrhenate	Non-SCC Intermediate	1-10 t/a	2018	Heraeus
Dirhenium heptasulphide	SCC intermediate	1-10 t/a	2018	Johnson Matthey

3. Progress of testing programme

Mammalian toxicity study programme for ammonium perrhenate (APR)

(Appendix APR tox study status update 2011_10_25)

- LLNA (Harlan), HLM (Covance), MLA (Covance), Isolated chicken eye (LAB): either finalised, draft report issued or experiment completed.
 - *In vivo* eye irritation study (Harlan): Due to the negative result for ICE. Programme in progress, draft report to be issued in mid Jan 2012.
 - Further *in vivo* mutagenicity studies are considered unnecessary; negative results for HLM and MLA.
- Reprotox study (CRL): Analytical result in 40%PEG400/water - by the beginning of Nov; draft result of the range-finding study (RFS) - by the end Nov*; unaudited draft report for the main study - in May 2012* onwards.

* Cf. discussions on vehicle selection

Other endpoints to be fulfilled

Mammalian toxicity

- Potentially acute oral toxicity study in 40%PEG400/water may be performed, due to the reliability of currently available study in vegetable oil. Dose(s) depending on the result of range-finding study/main study for OECD 422.
- Bio-elution testing in the gastric and sweat fluids for read-across (rhenium metal) – programme is dealt with under PGM project.
- Toxicokinetic behaviour (APR) – paper exercise

Physico-chemical property

- Particle size distribution (Harlan or DMT) – programme in progress (potassium perrhenate)

4. Next steps and CSR?

CSA/CSR

- CSA needs to be submitted for APR ; highest tonnage band: 10 – 100 tpa (last updated 27/06/11).
- Exposure assessment (EA) and risk characterisation (RC) need to be performed if APR meets the criteria for classification as dangerous (PBT/vPvB criteria do not apply to inorganic substances).
- Available results do not indicate APR to be a dangerous substance so far, including newly available results for skin sensitisation, *in vitro* genotoxicity and *in vitro* eye irritation.

Exposure modelling

(In relation to new ECHA guidance)

- APR does not currently meet the criteria for classification as dangerous for phys/chem, environment or mamm tox.
- If the new mamm tox tests were to result in a classification
 - ✓ Human health assessment will be performed.
 - ✓ Environmental assessment will also need to be considered although no classification effects were observed in the algal test.

5. ID Cards and IUCLID 5 filling

ID Cards

- Prepared for each substance and intermediate



Sections 1 and 3 in IUCLID

- Company specific information needs to be put into the relevant section of IUCLID. Confidentiality issues need to be taken into account.
- PMRC/wca will collect the information for the generic composition data (Section 1.2) and use information (Section 3.5), by February 2012. An excel template will be circulated shortly.



Microsoft Excel
Worksheet

6. Overall project progress

- LLNA, ICE, genotox (MLA, HLM), and RFS* (draft result only) available by face-to-face meeting in Dec 2011.
- Unaudited draft report for reprotox study in May 2012* onwards – assessing necessity of EA and RC, performing toxicokinetic assessment for APR.
- Currently available dataset for APR does not incur necessity of EA and RC.
- IUCLID 5 data (generic composition and use information) will be collected by February 2012.
- Significant budget increase (cf. next slides).
- Dossiers should be available for review by October 2012 (current schedule*).

* Cf. discussions on vehicle selection

Budget (1) - summary

Phase	Consultancy fees to 30.9.11	Budget	Budget remaining	Invoiced	Paid	Amount outstanding
Phase I	4,883.93	4,883.93	-	4,883.93	4,883.93	-
Phase II	23,200.00	23,200.00	-	23,200.00	23,200.00	-
Phase III - CLP	9,958.75	10,000.00	41.25	9,906.25	9,906.25	52.50
Phase III - ITS	13,148.75	19,000.00	5,851.25	13,148.75	13,148.75	-
Study monitoring	13,058.75	11,400.00*	(1,658.75)*	-	-	13,058.75
Phase IV	617.50	10,000.00	9,382.50	617.50	617.50	-
Phase V	4,390.00	19,135.00	14,745.00	4,390.00	3,505.00	-
Ad Hoc Work	180.00	705.00	525.00	180.00	180.00	-
TOTAL	69,437.68	98,323.93	28,886.25	56,326.43	56,326.43	13,111.25

* Budget increase of £10,800 required

Budget (2)

AMENDMENT TO THE BUDGET – MAMMALIAN STUDY MONITORING

- The following additional costs were not provided for in the original forecast:
 - ICE test (BCOP cancelled),
 - Vehicle preparation issues for reprotox study,
 - Bio-elution testing (Re metal),
 - Potential acute oral tox study.

Budget (3)

- The following actions have required more time than anticipated.
- Protocol/contract/draft report approval and signature. Iterations and communication CRO → WCA → PMC → WCA → CRO.
- Sample availability and shipment delays.
- The increase in indicative budget is based on 2 days per month for 8 months (anticipated length of study programme).

Overall timeline

Project Phase	Task	Timelines
III	Phys/Chem testing	31.12.11
	- Particle size distribution	
	Mammalian toxicity testing and report preparation	
	- Bio-elution testing	
	- <i>In vitro</i> / <i>in vivo</i> eye, skin sens, genotox	20.01.12
IV	- Reprotox, (acute tox)	31.05.12 (draft results)
	(Environmental modelling)	
	Composition, use pattern	01.11.11 - 28.02.12
	Occupational modelling and S. 9 & 10 CSR	01.04.12 - 31.07.12
V	CSA/CSR (as required)	07.12 - 31.10.12
	(PNECs)	
	DNELs	01.04.12 - 30.06.12
	Dossiers available for review by the lead registrants*	<u>31.10.12</u>

* Subject to the progress of study programme

7. AOB, next call/meeting, and conclusion

AOB?

Next meetings/calls

- Brussels, 6 December 2011 as from 4:30 pm CET
 - Evening meeting
 - After the PMC Assembly meeting
- Other calls and meetings tentatively foreseen in:
 - Feb 2012
 - Jun 2012

Closing remarks

Thank you!!!