PGM Project Progress

WCA Environment Ltd
& bibra

Presentation outline

- Overall Project Progress
- Phys-chem and environmental sections
- Mammalian toxicology section
- REACH requirements
- Category approach
- Testing strategies
- Laboratories
- CSA/CSR
- IUCLID 5
- Exposure
- Timelines
- Budget
- Key decisions

Current status

- Phase I = complete
- Phase II = in progress and ahead of the schedule in the proposal
- Phase III = in progress and ahead of the schedule in the proposal

Overall Project Progress

Phase I:

- Complete - Literature searches; preliminary data gap analysis; formal report of findings.

Phase II:

- Identification and review of all relevant studies, and preparation of robust summaries and Klimisch scores for each critical study;
- Construction of a matrix with the available information for each category;
- Evaluation of the physicochemical parameters for each category and assess category viability;
- Evaluation of the mammalian and ecotoxicity data for category justification;
- Evaluation of the relevant information for individual substance registration;
- Identification of potential read-across;
- Identification of test waivers;
- Application of REACH derogations (in particular related to Annex III);
- Recommendation of testing strategies; and
- Production of a draft report.

Progress: Phys-chem and Environmental Sections

PHASE II: TEST DEROGATION ASSESSMENT						
	Platinum	**Palladium**	**Iridium**	**Osmium**	**Rhodium**	**Ruthenium**
Acquire publications and proprietary reports	✓	✓	✓	✓	✓	✓
Assign Klimisch scores	✓[a]	✓[a]	✓[a]	✓[a]	✓[a]	✓[a]
Apply Annex XI / read across / waivers if gaps	✓[a]	✓[a]	✓[a]	✓[a]	✓[a]	✓[a]
Check viability of categories	In progress	In progress	In progress	In progress	In progress	In progress
Identify real data gaps	✓	✓	✓	✓	✓	✓
Assign value to proprietary data	?	?	?	?	?	?
Develop test plan (incl. adaptations and new testing)	In progress	In progress	In progress	In progress	In progress	In progress
Check PBT/vPvB	NA	NA	NA	NA	NA	NA
PHASE III: TEST PROGRAMME DESIGN						
	Platinum	**Palladium**	**Iridium**	**Osmium**	**Rhodium**	**Ruthenium**
	In progress	In progress	In progress	In progress	In progress	In progress

Progress: Mammalian Toxicology

- Around **185 study reports** have been identified from those forwarded by PMC members as **key** (i.e. specifically on substances to be registered)
- Initial **Robust Study Summary** drafts, including reliability (Klimisch) scoring, have now been developed (in IUCLID 5 template format) on **over 130** of these - currently undergoing internal **bibra** review
- About **111** additional unpublished studies (forwarded by PMC members) have been identified (on other PGM substances, outside those being registered) that may be useful for **read-across** or **weight-of-evidence** approaches
- Preliminary assessment of **Phase I** search results indicates that there are relatively few published data on many of the PGM substances being registered.

Progress: Mammalian Toxicology

- Data gap analysis - possibilities for read-across / data-waiving
  - "early days"
  - Review and evaluation of available data suggests there are extensive opportunities to minimize testing
  - Additional searching for data on compounds outside those being registered may reduce the need for testing even further.

REACH Requirements

Tonnage and Type	REACH Annex requirement
1-10 tonne substance	VII
10-100 tonne substance	VII and VIII
100-1000 tonne substance	VII, VIII and IX
1-10 tonne intermediate	Data already available
10-100 tonne intermediate	Data already available
100-1000 tonne intermediate	Data already available

- **Physicochemical Endpoints**

Annex VII: State of the substance at 20°C and 101.3 kPa; Melting/freezing point; Boiling point; Relative density; Vapour pressure; Surface tension; Water solubility; Partition coefficient n-octanol/water; Flash-point; Flammability; Explosive properties; Self-ignition temperature; Oxidising properties; Granulometry (particle size distribution).

Annex VIII: No further requirements

Annex IX: Stability in organic solvents and identity of relevant degradation products; Dissociation constant; Viscosity

- **Mammalian Toxicology Endpoints**

Annex VII: Skin irritation *in vitro;* Eye irritation *in vitro;* Skin sensitisation *In vitro;* gene mutation study in bacteria; Acute toxicity, oral route.

Annex VIII: Skin irritation *in vivo;* Eye irritation *in vivo; In vitro* cytogenicity in mammalian cells; *In vitro* gene mutation study in mammalian cells; Acute toxicity, inhalation; Acute toxicity, dermal route; Short-term repeated dose toxicity oral/dermal/inhalation; Reproduction toxicity; Developmental toxicity; Assessment of toxicokinetic behaviour (based on required studies).

Annex IX: Sub-chronic toxicity study (90 day) oral/dermal/inhalation; Development toxicity study; Other reproduction toxicity study

- **Ecotoxicology Endpoints**

Annex VII: Short-term toxicity testing on aquatic inverts (preferably *Daphnia*); Growth inhibition study on aquatic plants (preferably algae).

Annex VIII: Short-term toxicity testing on fish.

Annex IX: Long-term toxicity testing invertebrates (*Daphnia*); Long-term toxicity testing fish; Short-term toxicity to terrestrial invertebrates; Effects on soil microorganisms; Short-term toxicity to terrestrial plants

- **Environmental Fate Endpoints**

Annex VII: Biodegradation in water: screening tests

Annex VIII: Activated sludge respiration inhibition testing; Hydrolysis as a function of pH and identification of degradation products; Adsorption/desorption screening study (HPLC method).

Annex IX: Simulation testing on ultimate degradation in surface water; Soil simulation testing (for substances adsorbing to soil); Soil simulation testing (for substances adsorbing to sediment); Identification of degradation products; Bioconcentration in (one) aquatic species, preferably fish; Further studies on adsorption/desorption

Category approach

- Reduces costs
- Reduces need for testing
- Solubility
- Oxidation state
- Toxicity of the counter ions

OSMIUM

- Issues
- No data
- Intermediate assumed to be used under 'strictly controlled conditions'
- Report available data
- If registration intention changes -> substance then read across would be required
- Osmium tetraoxide – data available but not a good substance for read-across due to mammalian toxicology issues

Phase III: Testing Strategies

- **Why do we need solubility data?**
  - REACH requirement
  - This endpoint cannot be waived
  - Costs already minimised by using a category approach
  - Solubility data may be important in making justifications for read-across
- **Choice of test substances and methods**
  - Based on indicative solubilities supplied by Johnson Matthey
  - T/D testing for substances expected to be sparingly soluble (indicative solubilities of µg/l)

Draft ITSs

- In progress for platinum, palladium, rhodium, ruthenium and iridium
- Minimise testing – waivers and read-across where appropriate
- Data gap matrices have been generated (see handout)
- Tables showing the number of tests required
- Attempt to minimise number of laboratories used

Example ecotoxicological data gap matrix

This type of table will be in the text of the ITS with the full matrix in the Appendix

Category	Pt (0)	Pt (2)		Pt (2a)			Pt (4)								Pt (4A)	Pt (X)	
CAS numbers	7440-06-4	10025-65-7	18496-40-7	13933-32-9	20634-12-2	14286-02-3	16941-12-1	26023-84-7	51850-20-5	1314-15-4	10025-99-7	68133-90-4	12285-90-4	16921-30-5	16919-58-7	68478-92-2	52672-74-9
Short-term toxicity testing on aquatic inverts (preferably *Daphnia*)																	
Growth inhibition study on aquatic plants (preferably algae)																	
Short-term toxicity testing on fish																	

Key	
	Testing required
	Testing requirement dependent on outcome of other tests or read-across to data not yet available because the test on the read-across substance has not been commissioned or performed
	Data available, adaptation available, read-across to available data
	Intermediate - data not a requirement

Laboratories

- Been in contact with a number of laboratories (mainly for water solubility testing):
  - Aqura
  - Intertek
  - Wildlife International
  - Harlan (has now been discounted)
- Information on costs, sample sizes, security facilities and timelines (see handout)
- ITRI and CANMET have been contacted specifically about T/D testing

Transformation and Dissolution testing

- For sparingly soluble substances (indicative solubility <µg/l)
- provide an indication of the solubility of the metal and of any transformation of the metal to an environmentally stable ion or substance.
- carried out at three different pHs
- information throughout 28 days
- What will we do with these data?

Phase IV: CSA/CSR

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES – **Individual companies and WCA**
2. MANUFACTURE AND USES – **Individual companies and WCA**
3. CLASSIFICATION AND LABELLING - **WCA and bibra**
4. ENVIRONMENTAL FATE PROPERTIES - **WCA**
5. HUMAN HEALTH HAZARD ASSESSMENT - **bibra**
6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES – **WCA and bibra**
7. ENVIRONMENTAL HAZARD ASSESSMENT - **WCA**
8. PBT AND VPVB ASSESSMENT – **WCA and bibra**
9. EXPOSURE ASSESSMENT - **WCA**
10. RISK CHARACTERISATION - **WCA**

Phase IV: CSA/CSR cont.

- Not as straightforward as pressing a button!
  - Certain sections of IUC5 do not get transferred automatically into the CSR format
  - WCA have generated templates for these sections which are inserted
  - Formatting issues
  - Internal and external reviews and subsequent changes

Phase IV: CSA/CSR cont.

- **Individual company inputs**
  - See Handout with fields from Chapter 1 of IUC5
  - Exposure data
- **Category Justification Documents**
  - Information on impurities and composition required from each company

Phase V: IUCLID 5

- Bibliographic input
  - Before full bibliographic details can be entered onto IUC5 letters of access required
- IUCLID Hosting?
  - Email IUC files around – not very secure, more potential for errors
  - Dedicated server or virtual server

Exposure

- Questionnaire
  - Word format
  - Refined version of the multimetallic questionnaire
  - Mechanism of distribution
  - Deadlines/Timelines

Exposure data will be required for the following substances:

Name	CAS Number	Registration Intention	Classified under Annex I
Hexachloroplatinic acid	16941-12-1	10-100 tonne substance	yes
Dipotassium tetrachloroplatinate	10025-99-7	1-10 tonne substance	yes

For all other substances, the need for exposure data will be decided at a later date and will depend on whether classification is required.

Potential Impacts on Timelines

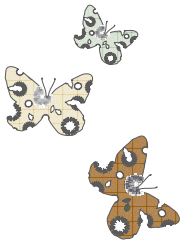
- Review process
- review turn-around for Pilot Phase II
- Obtaining samples from lead registrants
- Laboratory times – not completely within PMC or our control
- Laboratory capacity – wait until after the 2010 registration deadline when capacity may increase?

Budget

Queries

- Use of data from substances that are no longer being registered
- e.g. Ecotox data for 134620-00-1. If not used then there are no data for category Pd2a.

Key decisions



- IUCLID 5
- Testing recommendations
- Testing Labs
- Exposure