Precious Metals Consortium

Precious Metals & Rhenium Consortium

Gold Work Group Meeting

17 October 2017 | Brussels

Precious Metals Consortium

Welcome and introduction

Competition law and confidentiality

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.

DO	DON'T
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.	

Tour de Table & Apologies

Cf. List of participants in agenda

Approval of the draft agenda

1. Welcome and Introduction
2. Phase III: Testing programme
3. Phase IV: Exposure scenario data collection
4. Phase V : Dossier finalisation
5. Budget
6. AOB, next meetings/calls and closing remarks

Approval of minutes from previous WG meeting

- The previous Au Work Group meeting was held on 21 March 2017
- Draft minutes were distributed on 21 April 2017

➔ ***Are the minutes of the WG meeting held on 21 March 2017 approved?***

Status of actions

[A]	WHAT	WHO	STATUS
38	Waiver statement, expert judgement on flammability of TCA based on the oxidation state of the compound	EPMF/ WCA	June ‘17
39	Completion of the gene mutation endpoint by a weight of evidence approach	EPMF/ WCA	June ‘17

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Phase III
Testing Programme

Update on the progress of the TCA testing programme

Test	Laboratory	Start Date	Completion Date	Comments
Dose Range-Finding study	LPT (Study No. 33737)	4th October 2016	November 2016 (In-life phase)	Dose levels selected for this study 0, 30, 100 and 300 mg/kg/day TCA Draft report has been reviewed by OPG and MH in January 2017. Awaiting second draft from LPT
Repeated oral dose/Reproductive toxicity screen – OECD422	LPT (Study No. 33738)	8th November 2016 – start of premating period/oestrus cycle monitoring 23rd November 2016 – Start of dosing	October 2017	**NOAEL = 50 mg/kg/day (TCA solution)**
Formulation analysis method development	LPT	w/b 19th September 2016	Draft report available 28th October 2016	Method validation and results from DRF study samples are appended to the DRF study report (33737) Results of samples from the main study will be appended to the main study report (33738)

Update on the progress of the TCA testing programme

Test	Laboratory	Completion date	Result	Comments	Classification
OECD474 – in vivo micronucleus assay	Covance	Final report issued February 2015	Negative	Formulation prepared by weight therefore dose levels (25, 50 and 100 mg/kg/day) based on unadjusted MTD of 100 mg/kg/day Formulation analysis revealed assays for all groups to be within -11% of nominal All dose levels therefore were below the adjusted MTD of 210 mg/kg/day Analysis of bone marrow smears for gold (Umicore-unreported data) did not detect gold in the target tissue at any dose level Plasma samples from rats on the MTD study (dosed at 168 or 210 mg/kg/day – adjusted for density) were despatched to Umicore for analysis of gold content in an attempt to demonstrate exposure.	Not classified on this study, however, study to be repeated as an Annex IX study. **Bioanalytics included in the Genetic toxicity Summary of the IUCLID dossier**

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Phase IV
Exposure scenario data collection

DNEL derivations for TCA

The DNEL calculations have been conducted only for **worker exposure** (dermal and inhalation).

	TCA	Comments
Point of Departure	50 mg/kg/day (TCA solution) = 35.8 mg/kg/day (TCA)	Lowest NOAEL from OECD422 studies
Inhalation		
Systemic effects **Long-term exposure**	**0.14 mg/m³**	
Dermal		
Systemic effects **Long-term exposure**	**0.04 mg/kg/day**	Assuming 100% dermal absorption, due to likelyhood to damage of the skin.
General Population		
Systemic effects **Long-term exposure**	**0.03 mg/m³**	

Systemic –acute and Local effects – long-term/acute, not derived:

- Waived on the corrosive properties of TCA
- Systemic long-term DNEL together with CLP skin and eye classifications are considered protective of this systemic acute/short-term exposure

Occupational Exposure Scenarios TCA: Hazard Conclusions

Route	Type of effect	Hazard conclusion
Inhalation	Systemic, long-term	**DNEL = 0.14 mg/m³**
	Systemic, acute	Hazard unknown (no further information necessary)
	Local, long-term	High hazard (no threshold derived)
	Local, acute	High hazard (no threshold derived)
Dermal	Systemic, long-term	**DNEL = 0.04 mg/m³**
	Systemic, acute	No hazard identified
	Local, long-term	High hazard (no threshold derived)
	Local, acute	High hazard (no threshold derived)
Eye	Local	High hazard (no threshold derived)

Occupational Exposure Scenarios TCA: Hazard Conclusions

Route	Type of effect	Type of risk characterisation	Comments
Inhalation	Systemic, long-term	Quantitative	Max. RCR = 0.741 (see ES for specific RPE requirements)
	Systemic, acute	Qualitative	Covered by systemic, long-term
	Local, long-term	Qualitative	Respiratory protective equipment (RPE) as precautionary measure
	Local, acute	Qualitative	Respiratory protective equipment (RPE) as precautionary measure
Dermal	Systemic, long-term	Quantitative	Max. RCR = 0.75 (see ES for specific RPE requirements)*
	Systemic, acute	Not needed	Covered by systemic, long-term
	Local, long-term	Qualitative	Gloves protecting from local effects to the skin
	Local, acute	Qualitative	Gloves protecting from local effects to the skin
Combined	Systemic, long-term	Quantitative	Max. RCR = 0.789 (see ES for specific RPE requirements)
Eye	Local	Qualitative	Eye protection from local effects to the eyes

*9.1.12. Worker CS 12: Exposure duration 15-60 minutes included

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Phase V
Dossier finalisation

Project progress and registration target

Dossier	Status
Gold	Registration finalised
Balsams	Registration finalised
Aurio	Registration finalised
Tetrachloroauric acid	Dossier complete by end October

Timings:

- End October review by WG
- End November review by Mgt Cmt
- Half December review by Sub-assembly

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Budget

2017 expenses - status

2017 Budget to be spent	Expenses by 31/08/2017
355 200 €	64 862 €

Opportunities of improvement

What?	Comment	Priority
IUCLID 6 dossiers	Update of the dossier needed as due to the migration of the IUCLID 5 files some sections need to be updated to be compliant with the new format	Low
Read-across	Read-across needs to be documented according to RAAF	Low
Phys-Chem	Some justification of phys-chem endpoints should be reanalysed if still compliant	Low

Tasks and budget projections 2018

	Au metal	Au compounds
Rolling Maintenance	*€ 4.375*	*€ 13.125*
Literature review	€ 1.250	€ 3.750
Update of uses and ES	€ 2.500	€ 7.500
Updates of CSR and IUCLID	€ 625	€ 1.875
Further Improvements	*€ 35.000*	*€ 15.000*
Literature review nano Au	€ 35.000	
Additional Phys-Chem		€ 15.000
REACH Evaluation	-	-
Scientific Manager	*€ 8.882,83*	*€ 8.882,83*
Total	**€ 48.257,83**	**€ 37.007,83**

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Final remarks

Final Remarks

- A.O.B.
- Actions summary
- Conclusions
- Next meeting/conf call:
  - PMC General Assembly meeting: **5-6 December 2017**, **Brussels**
  - Next Au Work Group meetings: **13-15 March 2017, Brussels**
  - + Ad-hoc meetings/conf call



THANK YOU

www.epmf.be | info@epmf.be

Avenue de Broqueville 12, B-1150 Brussels
+32 (0)2 775 63 86

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