



Precious Metals
Consortium

Precious Metals & Rhenium Consortium

Gold Work Group

6 October 2016 | Brussels, Belgium

11:30 – 12:00



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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: <ul style="list-style-type: none"> - 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 : <ul style="list-style-type: none"> - 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

[See participants list in supplementary documents]

Approval of the draft agenda

1. Welcome and Introduction
2. Phase I: Inventory & Classification
3. Phase II: Data gap analysis & Integrated Testing Strategy
4. Phase III: Testing programme
5. Phase V: Dossier finalisation
6. Budget
7. AOB, next meetings/calls and closing remarks

Approval of minutes from previous WG meeting

- The previous Au Work Group meeting was hold on 16 April 2016
- Draft minutes were distributed on 2 May 2016

→ Are the minutes of the WG meeting held on 16/04/2016 approved?

Status of actions

[A]	WHAT	WHO	STATUS
32	A full reimbursement of the OECD 474 of TCA with Covance will be pursued	EPMF	May '16
33	A new OECD 422 study with TCA will be initiated	EPMF/WCA	June '16
34	The study design of the new OECD 422 study with will have to be reconsidered, avoiding similar problems as with Covance	WCA/WG	Aug '16
35	Drafting of a justification for reimbursement of both the OECD 474 and 422, to be sent to Covance.	EPMF/WG/ WCA	
36	Drafting a new time line for the registration of TCA and circulate to the WG and the consultants.	EPMF	June '16
37	Ask a new study monitoring quotation to WCA for the OECD 422 study.	EPMF	April '16





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Phase I Inventory & Classification

Inventory and latest classifications

IUPAC Name	Gold	Tetrachloroauric acid	Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate	Balsams, copaiba, sulfurized, mixed with turpentine, gold salts
CAS nr	7440-57-5	16903-35-8	68365-87-7	68990-27-2
EINECS nr	231-165-9	240-948-4	269-858-3	273-589-7
REACH category	Mono-constituent	Mono-constituent	Mono-constituent	UVCB
Dossier prepared	Substance	Substance	Substance	Non-SCC Intermediate
Highest tonnage band	10-100 t/a	10-100 t/a	1-10 t/a	1-10 t/a
Registration deadline	2018	2018	2018	2018
Lead Registrant	C. Hafner	Johnson Matthey	Johnson Matthey	Heraeus
Classification	None	Acute tox. 4 (H302: Harmful if swallowed) Skin corr. 1B (H314: Causes severe skin burns and eye damage) Eye dam. 1 (H318: Causes serious eye damage) Aquatic chronic 2 (H411) Met. Corr. 1 (H290: May be corrosive to metals)	Flam. Solid Cat 1 (H228)	Flam. Solid Cat 1 (H228)



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Phase II Data gap analysis & ITS

Data gap analysis TCA hydrate

- TCA hydrate will be registered and TCA solution will be regarded as a mixture

Endpoint	Comments
Melting/freezing point	75°C (Otto <i>et al.</i> , 2014)
Boiling point	Waived, column 2 (Otto <i>et al.</i> , 2014)
Water solubility	$c_s > 1076$ g/L
Flammability	Waived, expert judgment
Self-ignition temperature	Waived, column 2
Granulometry (particle size distribution)	27.5% (w/w) < 1000 µm Particle size of this fraction: ≥ 200 µm (optical)

Otto, K., Oja Acik, I., Krunks, M., Tõnsuaadu, K., & Mere, A. (2014). Thermal decomposition study of H₂AuCl₄·3H₂O and AgNO₃ as precursors for plasmonic metal nanoparticles. *Journal of Thermal Analysis and Calorimetry*, 118(2), 1065–1072.



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Phase III Testing Programme

Test programme – Physicochemical Analyses, TCA

Test	Laboratory/ Endpoint	Status	Date	Comments
Water solubility (OECD 105)	Siemens/ Annex V	Draft	Aug 2016	$c_s > 1076 \text{ g/L}$
Particle Size Distribution (OECD 110)	Siemens/ Annex V	Draft	Aug 2016	27.5% (w/w) < 1000 μm Particle size of this fraction: $\geq 200 \mu\text{m}$ (optical)

Repeated Test programme – Mamtox TCA Repeat dose toxicity and associated studies

Test	Laboratory	Start Date	Completion Date	Comments
Dose Range-Finding study	LPT	4 th October 2016	November 2016	2 nd Draft Study Plan with WG for review 15/09/2016) Dose levels selected for this study 0, 30, 100 and 300 mg/kg/day TCA Draft report for review estimated January 2017
Repeated oral dose/Reproductive toxicity screen – OECD422	LPT	8 th November 2016 – start of pre-mating period/oestrus cycle monitoring 23 rd November 2016 – Start of dosing	January 2017	Draft report for review estimated April 2017
Formulation analysis method development	LPT	w/b 19 th September 2016	Draft report available 28 th October 2016	Awaiting study plan for review and approval – due w/b 19 th September 2016

Test programme – Mamtox TCA Repeat dose toxicity

Test	Laboratory	Completion date	Result	Comments	Classification
OECD474 – in vivo micronucleus assay	Covance	Final report issued February 2015	Negative	<p>Formulation prepared by weight therefore dose levels (25, 50 and 100 mg/kg/day) based on unadjusted MTD of 100 mg/kg/day</p> <p>Formulation analysis revealed assays for all groups to be within -11% of nominal</p> <p>All dose levels therefore were below the adjusted MTD of 210 mg/kg/day</p> <p>Analysis of bone marrow smears for gold (Umicore-unreported data) did not detect gold in the target tissue at any dose level</p> <p>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.</p>	<p>Not classified on this study, however, study to be repeated as an Annex IX study.</p> <p>Testing proposal to be submitted</p>



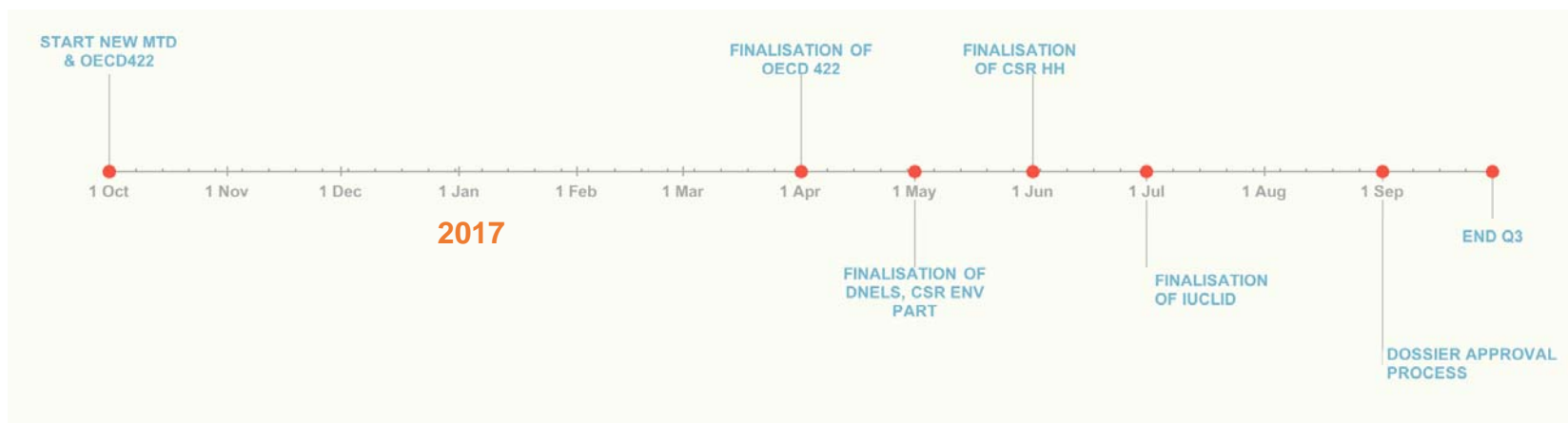
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Phase V Dossier finalisation

Overview Registration Progress

Dossier	Status
Gold	Registration finalised
Balsams	Registration finalised
Aurio	Registration finalised
Tetrachloroauric acid	Registration finalised by Q3 2017

Timeline TCA





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Budget

Budget 2017

	Budget to be spent	Budget to be invoiced
Au-specific costs	355.200 €	201.200 €
Au REACH registration	275.000 €	121.000 €
Phase 1: Literature search, data gap analysis and recommendations	0 €	0 €
Phase 2: In-depth data gap analysis and integrated testing strategy	0 €	0 €
Phase 3: Experimental studies (testing programme including cost of samples)	210.000 €	56.000 €
Phase 4: Generation of Chemical Safety Reports	59.000 €	59.000 €
Phase 5a: Generation of IUCLID 6 Files and Registration Dossiers	5.000 €	5.000 €
Phase 5b: IUCLID 5 Hosting System	1.000 €	1.000 €
Au REACH dossier maintenance	5.000 €	5.000 €
Phase 5a: Generation of IUCLID 6 Files and Registration Dossiers	5.000 €	5.000 €
Au REACH evaluation	0 €	0 €
Au REACH classification & labelling	0 €	0 €
Au internal and external fixed Scientific Manager	14.200 €	14.200 €
Au building reserves	61.000 €	61.000 €



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Final Remarks

Final Remarks

- A.O.B.
- Actions summary
- Conclusions
- Next meeting/conf call:
 - PMC General Assembly meeting: **6-7 December 2016, Brussels**
 - Next Au Work Group meeting: **21-23 March 2017, Brussels**
 - + Ad-hoc meetings/conf call



THANK YOU

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