



CALENDAR:

17-19 October 2017:
PMC Autumn back to
back meetings,
Brussels

5-6 December 2017:
PMC General
Assembly, Brussels

5-6 June 2018:
EPMF/PMC General
Assemblies, Liège
(Belgium)

Dear Members,

We hope you enjoyed a nice summer despite a quite heavy agenda due to the finalisation of our last registration dossiers which will be submitted by the Lead Registrants before the Christmas break.

It was a “silver summer”: the beginning of the summer was focused on the submission of the updated silver dossier reflecting the outcome of the Substance Evaluation; we received three new CLH proposal in the context of biocides; the consultation on the EOGRTs testing proposal just started; and, finally, the kick-off of the silver WG on EQS lead by Sweden.

The work and approval process continued on the remaining PGMs dossiers in preparation of the submission by the Lead registrants.

In parallel, the discussions on the reorganisation of EPMF and PMC continued to ensure a smooth transition process in 2018.

In this issue you will find more information about our summer activities!

Enjoy the reading of PMC REACH News.

Best regards,

France

Autumn days are here again ...





PMC Administrative update

Overview of PMC already registered substances

Name of the substance	Identification numbers		LR	Registered by LR
	CAS	EC		
Silver	7440-22-4	231-131-3	Aurubis	Nov 2010
Silver nitrate	7761-88-8	231-853-9	Ames	Nov 2010
Disilver oxide	20667-12-3	243-957-1	Ames	Oct 2010
Silver carbonate	534-16-7	208-590-3	Johnson Matthey	Mar 2012
Disilver(1+) sulphate	10294-26-5	233-653-7	Johnson Matthey	Mar 2012
Silver chloride	7783-90-6	232-033-3	Agfa Gevaert	Mar 2013
Silver bromide	7785-23-1	232-076-8	Agfa Gevaert	Mar 2013
Silver iodide	7783-96-2	232-038-0	Agfa Gevaert	Mar 2013
Gold	7440-57-5	231-165-9	C. Hafner	Apr 2016
Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate	68365-87-7	269-858-3	Johnson Matthey	Jun 2016
Balsams, copaiba, sulfurized, mixed with turpentine, gold salts (UVCBI)	68990-27-2	273-589-7	Heraeus	Apr 2016
Silver cyanide	506-64-9	208-048-6	Saxonia Edelmetalle	Nov 2016
Potassium dicyanoaurate	13967-50-5	237-748-4	Umicore Galvanotechnik GmbH	Oct 2016
Palladium	7440-05-3	231-115-6	Umicore NV/SA	Jan 2017
Palladium dichloride	7647-10-1	231-596-2	BASF	Jan 2017
Dihydrogen tetrachloropalladate(2-) (in solution)	16970-55-1	241-047-9	Heraeus	May 2017
Diamminedichloropalladium	14323-43-4	238-269-3	Heraeus	Jan 2017
Dichlorobis(triphenylphosphine)palladium	13965-03-2	237-744-2	Heraeus	Jan 2017
Palladium (II) di(4-oxopent-2-en-2-oate)	14024-61-4	237-859-8	Heraeus	Jan 2017
Palladium(II) acetate	3375-31-3	222-164-4	Heraeus	Oct 2016
Palladium monoxide	1314-08-5	215-218-3	Heraeus	Jan 2017
Tetraamminepalladium (II) nitrate	13601-08-6	237-078-2	Johnson Matthey	Jan 2017
Tetraamminepalladium(2+) dichloride	13815-17-3	237-489-7	Umicore AG&Co.KG	Mar 2017
Tetraamminepalladium(2+) dihydroxide	68413-68-3	270-241-6	Heraeus	May 2017
Tetrakis(triphenylphosphine)palladium	14221-01-3	238-086-9	Umicore AG&Co.KG	Mar 2017
Palladium sulphate	13566-03-5	236-957-8	Heraeus	May 2017
Tetraamminepalladium(2+) diacetate	61495-96-3	262-819-1	Umicore AG&Co.KG	Apr 2017
Disodium tetrachloropalladate	13820-53-6	237-502-6	BASF	Jan 2017
Palladium dinitrate (UVCBI)	10102-05-3	233-265-8	Heraeus	Apr 2017
Palladium dihydroxide	12135-22-7	235-219-2	Umicore AG&Co.KG	Apr 2017
Diammonium hexachloropalladate	19168-23-1	242-854-9	Johnson Matthey	Mar 2017
Dipotassium hexachloropalladate	16919-73-6	240-974-6	C. Hafner	Feb 2017
Platinum	7440-06-4	231-116-1	Vale	Jun 2017
Tetraammineplatinum dichloride	13933-32-9	237-706-5	Johnson Matthey	Feb 2017
Tetraammineplatinum dinitrate (in solution)	20634-12-2	243-929-9	Umicore AG&Co.KG	Aug 2017
Platinum dioxide	1314-15-4	215-223-0	Umicore AG&Co.KG	Mar 2017
Platinum dinitrate (UVCBI)	18496-40-7	242-383-9	Heraeus	Jun 2017
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate (UVCBI)	68478-92-2	270-844-4	Heraeus	Feb 2017
Dihydrogen hexahydroxyplatinate	51850-20-5	257-471-2	Johnson Matthey	Jun 2017
Iridium	7439-88-5	231-095-9	Johnson Matthey	May 2016
Hexachloroiridic acid, Hydrogen hexachloroiridate (IV) (UVCBI)	16941-92-7	241-012-8	Heraeus	June 2016
Diammonium hexachloroiridate	16940-92-4	241-007-0	Johnson Matthey	May 2016



Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium	25470-96-6	247-015-0	Johnson Matthey	Oct 2016
Carbonylhydrotris(triphenylphosphine)rhodium	17185-29-4	241-230-3	Umicore AG&Co.KG	Mar 2017
Dicarbonyl(pentane-2,4-dionato-O,O')rhodium	14874-82-9	238-947-9	Umicore AG&Co.KG	Sep 2017
Rhodium trichloride, hydrate	20765-98-4	606-630-8	Heraeus	Sep 2017
Di- μ -chloro-bis(hapto-1,5-cyclooctadiene)dirhodium(I)	12092-47-6	235-157-6	Heraeus	Sept 2016
Tris(triphenylphosphine) rhodium (I) chloride	14694-95-2	238-744-5	Umicore AG&Co.KG	Mar 2017
Rhodium triiodide	15492-38-3	239-521-5	Umicore AG&Co.KG	July 2017
Dirhodium trioxide	12036-35-0	234-846-9	Umicore AG&Co.KG	July 2017
Rhodium (III) acetate (UVCB!)	42204-14-8	255-707-9	Umicore AG&Co.KG	July 2017
Rhodium trihydroxide	21656-02-0	244-508-2	Heraeus	July 2017
Triammonium hexachlororhodate	15336-18-2	239-364-2	Vale	July 2017
Diammonium sodium hexakis(nitrito-N)rhodate	64164-17-6	264-713-0	Vale	July 2017
Tris(nitrato-O)nitrosylruthenium	34513-98-9	252-068-8	Umicore AG&Co.KG	Feb 2017
Rhenium	7440-15-5	231-124-5	KGHM Metraco	Sept 2013
Perrhenic acid (in solution)	13768-11-1	237-380-4	Heraeus	Nov 2013
Ammonium perrhenate	13598-65-7	237-075-6	Heraeus	Jul 2013
Sodium rhenate (in aq. solution)	13472-33-8	236-742-9	Climax Molybdenum	Mar 2014
Potassium perrhenate	10466-65-6	233-953-8	Heraeus	Aug 2013
Refinables (ALL)				Nov 2010



PMC Technical update

Ag and compounds

Substance Evaluation of Ag metal (nano): The silver REACH dossier has been updated and submitted by the 13 July deadline set in the final decision. PMC concluded that the ecotoxicity testing of the smallest silver nanoform covered by the REACH registration dossier demonstrated that the nanoform of silver is less toxic than ionic silver and therefore further fate testing is currently not needed. The eMSCA now has until July 2018 to evaluate the new information and they will conclude either that no further data is needed or they will draft a new decision indicating that further information is still needed to address the concern.

For more info: katrien.arijs@arche-consulting.be

CLH of silver containing active substances (SCAS) under BPR: Three further CLH proposals were submitted by Kemi (Sweden) for silver zeolite (SZ), silver copper zeolite (SCZ) and silver sodium zirconium hydrogen phosphate (SSZHP). For these 3 substances, an environmental classification is proposed (Aq acute 1 and Aq chronic 1) and for SZ and SCZ, a Repr 2 classification is proposed. For the human health classifications, RAC conclusions on silver zinc zeolite (SZZ) have been broadly taken into account so the proposed classifications for these 3 SCAS are favourable to the original proposed classification of SZZ. For the environmental classifications, the same error has been made as for SZZ not fully recognizing the metals classification scheme. It is expected that the 45-day public commenting period for the CLH proposals will start soon and the PMC Secretariat is preparing comments on the Repr classification of SZ and SCZ, taking into account also latest studies, and the environmental classifications. For the latter, Eurométaux will also submit comments.

For more info: katrien.arijs@arche-consulting.be or france.capon@epmf.be

Extended one-generation reproductive toxicity study (EOGRTS) testing proposal on silver acetate: On 27 September, ECHA published the consultation on the EOGRTS on silver acetate (<https://echa.europa.eu/information-on-chemicals/testing-proposals/current/-/substance-rev/17702/term>). Only third parties (not directly involved in the dossier) can send comments by 13 November 2017. After that, the draft decision will be sent to the registrant (so far only to the LR) and a commenting period of 30 days will start. A final decision will be prepared on that basis and communicated to the registrant. The testing proposal and next steps will be discussed during the next silver WG meeting. However, it confirms that if the testing proposal is accepted, the testing could start in 2018.

For more info: katrien.arijs@arche-consulting.be

Potential prioritisation of silver under the Water Framework Directive (WFD): A decision on the relevance of silver for the Watch List (WL) or Priority Substances (PS) list will be made based on (additional) monitoring data and a confirmed PNEC. PNECs are currently being discussed in substance-specific sub-groups and Sweden is taking the lead in the silver sub-group. Both PMC and Eurométaux are participating to this sub-group, and MS participation is limited to Germany, Latvia and Denmark. The PMC Secretariat is continuing its work on building a robust, up to date ecotox dataset for the Ag REACH PNEC and communicated its willingness to share their assessment with Sweden by the end of the year. The information from the European Commission on timeline and process remains vague and PMC intend to send a letter to the Commission requesting clarity.

For more info: katrien.arijs@arche-consulting.be



Au and compounds

Status of TCA: The testing is completed, DNELs have been derived and occupational exposure scenarios drafted. It is estimated to have the draft registration dossier completed by end of October for review by the WG.

For more info: vincent.dunon@arche-consulting.be

Ir and compounds

The REACH registration dossiers for Iridium metal, Diammonium hexachloroiridate and Hexachloroiridic acid have been successfully registered by the Lead Registrants, and co-registrants are kindly invited to register ASAP.

For more info: jelle.mertens@epmf.be

Pd and compounds

The REACH registration dossiers for Palladium metal and all Palladium compounds have been successfully registered by the Lead Registrants, and co-registrants are kindly invited to register ASAP.

For more info: maxime.eliat@arche-consulting.be

PM CN

Status of KAg(CN)₂: Supportive analytics have been performed, confirming the results of the combined repeated dose toxicity study. The registration dossier has been finalised and has already been approved by the WG.

For more info: vincent.dunon@arche-consulting.be

Pt and compounds

The dossiers of Platinum metal and 10 Platinum compounds have been finalised:

-the dossiers of Platinum metal and 6 Platinum compounds have successfully registered by the Lead Registrants. Co-registrants are kindly invited to register ASAP.

-the dossiers of the four Chloroplatinate dossiers will be submitted by the Lead Registrants by end of 2017 to anticipate potential regulatory follow-up actions.



Two dossiers are still under development:

- **Dihydrogen hexahydroxyplatinat, compound with 2-aminoethanol:** DNELs have been drafted and the risk assessment has been finalised. Additional phys-chem testing has been launched to anticipate potential failure of the dossier submission (cfr. PMC's recent experience with ECHA manual completeness check). Preliminary test results are expected by the end of the year. In order to not delay registration, review and approval of the dossier will be initiated early October (not including the ongoing phys-chem test data) to have a dossier available end of 2017 for submission by the Lead Registrant. The phys-chem data will be included once available, and circulated for review and approval separately from the dossier.
- **Diammineplatinum (II) nitrite:** the dossier is finalised (Annex III dossier), and will be circulated for review and approval soon. The PMC internal timing for registration of this substance is Q4 2017.

Karstedt Concentrate: The OECD422 study, EOGRTS testing proposal, DNEL derivation and occupational exposure assessment have been finalised and reviewed by the registrants. The dossier is currently being finalised, and will be circulated for review and approval soon. Re-submission of the updated REACH dossier is foreseen end 2017.

For more info: maxime.eliat@arche-consulting.be

Re and compounds

No specific activities around the Re dossiers over the summer. The next literature review for Re and Re compounds is planned for end 2017.

For more info: katrien.arijs@arche-consulting.be

Refinables

Discussion between Eurometaux and ECHA are still ongoing regarding the substance identity. Currently H el ene Magaud, of the computational unit of ECHA, is assigned to find a solution together with Eurometaux on how to improve the reporting in the IUCLID dossier. Further updates will follow on the outcomes of these discussions and will help defining the 2018 workplan for refinables.

For more info: vincent.dunon@arche-consulting.be

Rh and compounds

The dossiers of Rhodium metal and 13 Rhodium compounds have been finalised. The dossiers of 12 Rhodium compounds have been successfully registered by the Lead Registrants. Co-registrants are kindly invited to register ASAP.

The bioelution assays in artificial gastric bodyfluid with 5 Rh(III) compounds are finalised, and draft test reports are expected early October. The results will be circulated to the PMC members, and discussed during the Back-to-Back meetings mid October.



Two dossiers are still under development:

-dirhodium trisulphate: the required phys-chem testing has been finalised. The dossier is being updated, and will be circulated for review and approval soon. The registration dossier will be available Q4 2017.

-rhodium tris(2-ethylhexanoate): the required phys-chem testing will be initiated soon. Due to extending timelines for testing, the registration dossier will likely be available for review and approval early 2018 (approval via fast track procedure). The dossier will be available for registration well ahead of the May 2018 deadline.

For more info: jelle.mertens@epmf.be

Ru and compounds

One dossier has already been finalised and registered by the Lead Registrant (Feb 2017).

The dossiers for Ruthenium metal and 4 Ruthenium compounds have been finalised and are at their final approval stage by the Sub-Assembly. The dossiers will be available for registration Q4 2017.

One dossier is still under development:

-Ruthenium trihydroxide, the required phys-chem testing has been finalised. The dossier is being updated, and will be circulated for review and approval soon. The registration dossier will be available Q4 2017.

For more info: jelle.mertens@epmf.be

SVHC Roadmap

- **Chemycal monitoring tool:** in September, PMC contracted Chemycal to monitor the list of priorities substances for the precious metals industry. This list is based on substances registered by the PMC and a group of substances having been identified as critical for the production of precious metals. The SVHC Roadmap WG will discuss in October the best way to communicate the outcome of this monitoring exercise.
- **Intermediate guidance on the use of PbO in precious metals industry:** as you probably remember, ECHA, Cefic and Eurometaux launched in Spring a new technical project to assess the intermediate use of substances in complex matrices. The case of PbO in the precious metals industry has been presented to the authorities in May 2017 and an internal guidance have been prepared over summer to summarize the PMC interpretation. This guidance is under validation and will be sent to ECHA in October, in preparation of a second discussion in November 2017.

For more info: france.capon@epmf.be or jelle.mertens@epmf.be



Acronyms

Afa: Application for Authorisation
BPR: Biocidal Products Regulation
CARACAL: Competent Authorities for REACH and CLP
CLH: Classification & Labelling Harmonization
CoRAP: Community Action Rolling Plan
CRO: Contract Research Organization
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
e-MS: Evaluating Member State
EOGRTS: Extended One-Generation ReproToxicity Study
EQS: Environmental Quality Standards
ESTF: European Silver Task Force
ILA: International Lead Association
LoA: Letter of Access
LR: Lead Registrant
MSC: Member States Committee
MSCA: Member State Competent Authority
OEL: Occupational Exposure Limite
OHS: Occupational Health and Safety
PfA: Proposal for Amendment
PNEC: Predicted No-Effect Concentration
PMC: Precious Metals & Rhenium Consortium
RAC: Risk Assessment Committee
RMM: Risk Management Measure
RMOA: Risk Management Option Analysis
SCAS: Silver Containing Active Substances
STOT RE: Specific Target Organ Toxicity – Repeated Exposure
SVHC: Substance of Very High Concern
TCA: Tetrachloroauric Acid
UVCB: substance of Unknown or Variable composition, Complex reaction products or Biological materials
WFD: Water Framework Directive
WG: Work Group