# PMC REACH NEWS

**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,

Q2 2017 has been dedicated to the finalisation of the approval of most of the Pt dossiers (except HPPA 2 aminoethanol which is still under preparation). The nanosilver testing came to an end with positive results showing that the toxicity of nanosilver is not higher than the toxicity of silver nitrate which will allow us to send the outcome of the Evaluation to ECHA in July 2017.

The new EPMF-PMC website: www.epmf.be is now fully available including the members pages where the latest versions of the registration dossiers submitted to ECHA, as all the meetings documents are available. Please feel free to send us your feedback if any!

In June 2017, the Assembly met in Pforzheim and was focused on the future of PMC after 2018. To know more, I invite you to read our Q2 2017 newsletter.

Enjoy the reading of PMC REACH News.

We wish you a happy summer break!

Best regards,

France

# PMC Administration

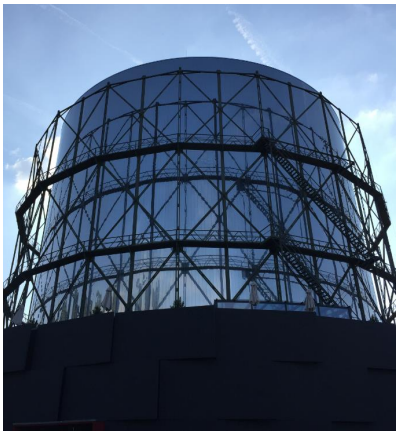
## Overview of PMC already registered substances

| 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 ***(UVCB!)*** | 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 ***(UVCB!)*** | 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 |
| Platinum dioxide | 1314-15-4 | 215-223-0 | Umicore AG&Co.KG | Mar 2017 |
| Platinum dinitrate ***(UVCB!)*** | 18496-40-7 | 242-383-9 | Heraeus | Jun 2017 |
| Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate ***(UVCB!)*** | 68478-92-2 | 270-844-4 | Heraeus | Feb 2017 |
| Iridium | 7439-88-5 | 231-095-9 | Johnson Matthey | May 2016 |
| Hexachloroiridic acid, Hydrogen hexachloroiridate (IV) ***(UVCB!)*** | 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 |
| 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 |
| 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 |

## Outcome of the Assembly meeting

The assembly meeting was organized in Pforzheim in June 2017. This was an opporunity to contribute to the 250th anniversary of the German Jewellery industry. As usual, the Secretariat updated the Assembly on the administrative issues (approval of the 2016 audited accounts, presentation of the status of the 2017 accounts, the status of registration etc.) and on the ongoing projects. The future of PMC after 2018 was the main discussion point. The Assembly agreed on the principle to merge EPMF and PMC after 2018 with a single governance. This proposal will help to build a stronger association in preparation of the next challenges to be addressed by the Precious Metals industry. The new structure will be menu driven leaving to the members the choice of the platforms they want to contribute to. The structure and the cost sharing formula will be adapted on that basis and should be validated by the PMC Assembly in December 2017. 2018 will be a transitional year and the new structure will be fully operational in 2019.

The dinner of the PMC was organized in the Gasometer in Pforzheim. We had the privilege of receiving Mrs. Sybille Schüssler, Mayor of Pforzheim, who did an introductory speech after the welcome speech of Dr. Heinz-Günter Schenzel (C. Hafner), co-Chair of the PMC.

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# PMC Technical matters

## Ag and compounds

**Substance Evaluation of Ag metal (nano)**: The ecotoxicity testing and physico-chemical characterisation of the smallest silver nanoform covered by the REACH registration dossier is finalised and demonstrated that the nanoform of silver is less toxic to algae, *Daphnia* and soil microorganisms than ionic silver. PMC therefore believes that the read-across use of toxicity values from ionic to nanosilver as a ówworst caseô approach is justified and scientifically defensible, and futher fate testing is currently not needed. The data collection on the uses of the two silver nanoforms covered by the REACH registration dossier is also finalised and showed limited use / release to the environment of nanosilver. A meeting with the eMSCA was held end of May to present the results and the silver REACH dossier has been updated and will be submitted by the 13 July deadline set in the final decision. After submission, the eMSCA will have 12 months 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 info is still needed to address the concern.

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**CLH of silver containing active substances (SCAS) under BPR**: It is expected that the commenting period for the CLH proposals for silver zeolite, silver copper zeolite and silver sodium hydrogen zirconium phosphate will start soon. The CLH proposal for elemental silver has been postponed and will probably be available for commenting after summer 2017. For silver copper zeolite, PMC is considering joint commenting with ECI.

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**Potential prioritisation of silver under the Water Framework Directive (WFD)**: During the review of the Priority Substances (PS) list for the WFD, silver has been shortlisted as a potential candidate for prioritisation / EQS derivation. JRC has drafted an EQS dossier for silver, with a proposed EQS that is 4 times lower than the REACH PNEC. The legislative process for review of the PS list has been postponed but it is still expected that by the end of 2017, JRC will re-assess the relevance of substances to be included in the Watch List or PS list and need for EQS derivation. PMC will contribute to this process through Eurométaux and is currently building a robust, up to date silver ecotoxicity dataset to assess the need for a PNEC revision.

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## Au and compounds

**Status of TCA**: Due to some additional testing the completion of the **OECD 422** study was delayed. This has an impact on the further workprogress and therefor the registration deadline is extended to **Q4 2017**. Over the summer it is estimate to complete the occupational exposure work and have the dossier ready for review in autumn.

***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 registered by the Lead Registrant, and co-registrants are kindly invided 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 invided to register ASAP.

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

## PM CN

**Status of $KAg(CN)_2$:** The review process for the registration dossier of $KAg(CN)_2$ has been initiated. Some supporting analytics are still ongoing, though should not impact the results of the dossier. Additions or changes will be communicated prior the finalisation of the dossier.

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

## Pt and compounds

Five dossiers including the Platinum metal have been finalised and sucessfully registered by the Lead Registrants. Co-registrants are kindly invided to register ASAP

The four Chloroplatinate dossiers have been finalised and approved but will only be submitted by the Lead Registrants by end of the year to anticipate potential regulatory follow-up actions.

The dossier for Tetraammineplatinum dinitrate was rejected by ECHA during the manual completeness check process (waiver for ôExplosive Propertiesôwas not considered valid). PMC secretariat is in contact with the Lead Registrant to agree on a best way forward to complete the dossier.

Two dossiers are still under development:

- **Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol**: a draft study report for repeated dose toxicity is sent to the study monitor on 16 June 2017. The study results will be forwarded to the PGM Tox Experts soon for discussion. Afterwards, DNELs will be drafted and the occupational risk assessment will be finalised. The PMC internal timing for registration of this substance is Q4 2017.
- **Diammineplatinumm (II) nitrite:** this study was put on hold in 2016 and restarted in 2017. This substance will be registered as an Annex III dossier. The dossier is currently under development. The PMC internal timing for registration of this substance is Q4 2017.

**Karstedt Concentrate**: The study report for the repeated dose toxicity assay has been discussed by the PGM Tox Experts. Based on the available data, it was agreed that Karstedt Concentrate needs an additional classification as Repro2 (H361d) and that a testing proposal for an Extended One Generation Reproductive Toxicity Study (OECD443) needs to be included in the dossier. PMC secretariat will communicate the Repr2 classification to the SIEF (end June), update the classification in our inventory on the website and communicate to the Downstream Users (August). The DNELs for this compound have been derived and approved by the PGM Tox Experts. The exposure assessment is currenlty being performed, and a first draft version is expected early July 2017. The REACH dossier for this compound will be updated for all these changes in Sept-Oct 2017.

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

**Analysis of Alternatives to Chloroplatinates:** the final report has been issued on 19 June 2017 and is available on the PMC members pages. The next steps will be to assess the internal shadow RMOa report and updated it based on the outcome of the AoA exercise.

***For more info:*** france.capon@epmf.be

## Re and compounds

**Dirhenium heptasulphide dossier** will be submitted if requested by the LR. The next literature review is planned for end 2017.

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

## Refinables

PMC Secretariat is following ongoing UVCB substance identity (SID) discussions between ECHA and Eurométaux and checking SID determination for each one of the Refinables. A workshop with ECHA on substance identification took place on 31 March to find a workable and acceptable solution for the industry and ECHA. Unfortunately, this meeting was not delivering the exepcted solution and a follow-up meeting will be organized on 30 June 2017 with Christel Musset and Commission to try to solve the issue at a higher level.

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

## Rh and compounds

Four dossiers have already been finalised and registered by the Lead Registrants (<April 2017).

The dossiers for Rhodium metal and 9 Rhodium compounds have been drafted, and have been reviewed and approved by the Working Group and Management Committee. The final approval stage as Sub-Assembly level is ongoing). Due to late approval responses at Working Group level, these dossiers are a bit delayed. If approval timings at Sub-Assembly level are respected, the dossiers should be ready for registration by the Lead Registrants mid July 2017.

Some bioelution assays in artificial gastric bodyfluid with 5 Rh(III) compounds are currently running. Intention is to estimate and compare their bioaccessibility when taken up orally and reaching the stomach. Once the results are available, a discussion will be held at PGM Tox Expert level to re-assess the approach currently taken for Rh(III) genotoxicity (if required).

For Rhodium sulphate, phys-chem testing is currently running to fill remaining datagaps. The registration dossier for this compound is intended to be available for registration by the Lead Registrant before the end of 2017.

***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 testing reports for repeated dose toxicity and reproductive toxicity screening for Ruthenium trichloride and TetradoRu have been released and results have been discussed at PGM Working group level. The DNELs have been derived, and exposure scenarios have been drafted.

The dossiers for Ruthenium metal and 4 Ruthenium compounds have been drafted, and are currently under review by the Working Group. The dossiers are intended to be send out for approval by the Working group on 7 July 2017. The dossiers should be ready for registration by the Lead Registrants Q3 2017.

For Ruthenium trihydroxide, phys-chem testing will be initiated soon to fill remaining datagaps. The registration dossier for this compound is intended to be available for registration by the Lead Registrant before the end of 2017.

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## SVHC Roadmap

The main activity in Q2 2017 have been related to the assessment of different monitoring tools which could falicilate the screening of our substances of interest. A recommendation on the best tool to be used should be available over summer.

Another important activty is related to the review of the PbO use/occurrence in the precious metals refining and recycling in the context of the intermediates interpretation. Indeed, ECHA, Cefic and Eurometaux launched 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 is under preparation for 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 Amendement
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 ï 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