



Data Sharing Issues

Note to Management Committee, 5 December 2016

1. Introduction

Following article 4.2.2. (n) of the PMC agreement, the Management Committee is in charge of data sharing issues. This note aims at raising a series of issues concerning data sharing and at suggesting a way forward.

2. Existing information used in registration dossiers

Following article 5.1.3. of the PMC agreement, "Rights to use (including to cite, or refer to) existing Information granted by the Consortium to third parties within the context of the REACH Regulation, for instance through a Letter of access, **shall be subject to prior written approval from, and appropriate compensation to the Member(s) who initially provided the Information to the Consortium.**"

LoA have already been sold for dossiers including data provided by 3rd parties (e.g.: silver dossiers) but no written agreement with the owners of these studies have been found. Therefore, the Secretariat decided to ensure compliance with article 5.1.3. of the agreement to review all the "existing studies" used in registration dossiers (cf. annex 1 – Listing of existing studies and ownership). Most of the existing data are owned by PMC members, and the situation can be solved quickly by the signature of a template allowing sub-licensing of the studies (cf. annex 2 – Template Members' consent regarding the granting of the right to use existing Information to third parties).

During this process, the following issues have been identified:

Registration dossier	Study	Owner	Issue
Silver and silver compounds	Sensitization study with silverthiosulphate in guinea pigs (maximization test); Report n° V95.538"	Enhold BV	Data sharing agreement has been signed on 20 August 2010. This agreement allows to PMC members the use of the data for registration for silver and silver compounds BUT does not



			allow sub-licensing. LoA for silver has been sold and are therefore in breach with data sharing agreement with Enhold.
Pt HHPA 2AE	Determination of the vapour pressure of Bis(ethanolammonium)hexahydroxoplatinate solution containing approximately 10% platinum, 2002	Karl Heinz Krebs	No data sharing agreement with this owner and problem of identifying this owner (no website, no contact person etc.). No LoA sold so far.
Pt HHPA 2AE	Hexahydroxoplatinum (IC)Acid. Acute toxicity. Testing the acute toxicity after single administration in rats, report n°2 of 2 originals, 1995	Initiative Umweltrelevante Alst	No data sharing agreement with this owner. Company is based in Frankfurt but no website no contact person. No LoA sold so far.
Pt HHPA 2AE	Potassium hexachloroplatinate (IC). Testing the acute toxicity after single oral administration in rats, 1995	Initiative Umweltrelevante Alst	No data sharing agreement with this owner. Company is based in Frankfurt but no website no contact person. No LoA sold so far.



Palladium, Palladium monoxide	Evaluation of the mutagenic activity of palladium(II)nitrate dihydrate in the Salmonella typhimurium reverse mutation assay and Escherichia coli reverse mutation assay (with independent repeat), 2003	OMG AG Co	No data sharing agreement with this owner. Company is based in Hanau but no website no contact person. No LoA sold so far.
Rhodium trinitrate	Assessment of acute oral toxicity with rhodiumtrinitrate hydrate in the rat (acute toxic class method), 2003	OMG AG Co	No data sharing agreement with this owner. Company is based in Hanau but no website no contact person. No LoA sold so far.
Rhodium trinitrate	Assessment of contact hypersensitivity to rhodiumtrinitrate hydrate in the albino guinea pig (maximisationtest), 2003	OMG AG Co	No data sharing agreement with this owner. Company is based in Hanau but no website no contact person. No LoA sold so far.
Rhodium trinitrate	Evaluation of the mutagenic activity of rhodiumtrinitrate hydrate in the Salmonella typhimurium reverse mutation assay and the Escherichia coli reverse mutation assay (with independent repeat), 2003	OMG AG Co	No data sharing agreement with this owner. Company is based in Hanau but no website no contact person. No LoA sold so far.
Rhodium trinitrate	Rhodium (III)-Nitrate-Hydrate Determination of the immobilisation of Daphnia magna STRAUS, 2003	OMG AG Co	No data sharing agreement with this owner. Company is



			based in Hanau but no website no contact person. No LoA sold so far.
Rhodium trinitrate	Rhodium(III)-nitrate-hydrate Determination of the acute toxicity for the fish <i>Cyprinus carpio</i>	OMG AG Co	No data sharing agreement with this owner. Company is based in Hanau but no website no contact person. No LoA sold so far.
Rhodium trinitrate	Rhodium(III)-nitrate-hydrate. Determination of the growth inhibition of the green algae <i>Desmodesmus subspicatus</i> .	OMG AG Co	No data sharing agreement with this owner. Company is based in Hanau but no website no contact person. No LoA sold so far.
Tris(triphenylphosphine) rhodium (I) chloride	Determination of the water solubility of Chloro-tris(triphenylphosphin)-rhodium(1), 2001	OMG AG Co	No data sharing agreement with this owner. Company is based in Hanau but no website no contact person. No LoA sold so far.
Tris(triphenylphosphine) rhodium (I) chloride	Tris(triphenylphosphine)rhodium(I)chloride. Determination of the immobilisation of <i>Daphnia magna</i> STRAUS, 2003	OMG AG Co	No data sharing agreement with this owner. Company is based in Hanau but no website no contact



			person. No LoA sold so far.
Ru trichloride	Final Report DK 813 Ruthenium (III) chloride-hydrate Determination of the immobilisation of Daphnia magna STRAUS	OMG AG Co	No data sharing agreement with this owner. Company is based in Hanau but no website no contact person. No LoA sold so far.
Karstedt Concentrate	Pt-divinyltetramethyldisiloxane bacterial mutation assay (S. typhimurium and E. coli), 2004	OMG AG Co	No data sharing agreement with this owner. Company is based in Hanau but no website no contact person. No LoA sold so far but will be soon to Reconcile members.
Ru acetate	Ruthenium acetate - Acute toxicity to Daphnia magna	British Pretroleum Chemicals	No data sharing agreement with this owner. The study was provided by a PMC member. No LoA sold so far.
Rh trichloride	In vitro mammalian cell gene mutation assay (thymidine kinase locus/TK+/-) in mouse lymphoma L5178Y cells with rhodium (III) chloride hydrate, solution, 2007	Dr. Knoell	No data sharing agreement with this owner. The study was provided by a PMC member. No LoA sold so far.



	<p>In vitro mammalian micronucleus assay in Chinese Hamster V79 cells with rhodium (III) chloride hydrate, solution, 2007</p> <p>Mammalian micronucleus test of murine peripheral blood cells with rhodium (III) chloride hydrate, solution, 2007</p>		
Rh trinitrate	Mammalian micronucleus test of murine peripheral blood cells with rhodium (III)-nitrate-hydrate	Dr. Knoell	No data sharing agreement with this owner. The study was provided by a PMC member. No LoA sold so far.

The Secretariat suggests **the following steps** to address these data sharing issues:

- **January 2017:** organize a conference call of the Management Committee to discuss the issues listed above (date to be fixed)
- **January 2017:** send to the PMC data owners the letter to be signed regarding Members' consent on the granting of the right to use existing Information to third parties
- **By end of Q1 2017:** solve the different pending issues to ensure a smooth and compliant data sharing with SIEF members.

3. Data sharing outside the EU – K-REACH

As a follow-up of the Management Committee meeting of 21st November 2016, the Secretariat assessed the possibility to share REACH data outside the EU and especially with companies having to comply with K-REACH.



So far, PMC Secretariat received the following requests:

Company	Substances	Requested data	Comments
Korea Chemicals Management Association	Potassium dicyanoaurate (PGC, CAS No. 13967-50-5) Potassium dicyanoargentate(CAS No. 506-61-6)	Water solubility Melting/Freezing point Density Particle size analysis Acute toxicity-oral/inhalation Ames test, bacterial reverse mutation assay Skin irritation/corrosion Skin sensitization Acute toxicity on fish Acute toxicity on preferred species daphnia	Potassium dicyanoaurate is not in the priority list.
Korea Chemicals Management Association	Silver nitrate(7761-88-8) Silver cyanide(506-64-9)	Water solubility Melting/Freezing point Boiling point Vapor pressure Octanol/water partitioning coefficient Density particle size analysis Acute toxicity-oral Amestest(bacterial reverse mutation assay) Skin irritation/corrosion Skin sensitization Acute toxicity on fish Ready biodegradability Acute toxicity on preferred species Daphnia	



Nam & Nam International Co., Ltd/NAM & NAM Europe GmbH	Dihydrogen hexahydroxyplatinate, compound with 2- aminoethanol (1:2) (EC No. 268-717-3/CAS No. 68133-90-4)	Water solubility Melting/freezing point Boiling point Vapor pressure Partition coefficient Density Granulometry Acute toxicity(oral) Ames Skin irritation Skin sensitization Acute toxicity(fish) Ready biodegradability Acute toxicity(Invertebrates)	Dihydrogen hexahydroxyplatin ate, compound with 2- aminoethanol (1:2) is not in the priority list.
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Based on the 1st priority list of substances to be registered by 1er July 2018, data sharing requests are expected for:

- Potassium dicyanoargentate (CAS: 506-61-6)
- Silver cyanide (CAS: 506-64-9)
- Silver nitrate (CAS: 7761-88-8)

On 21st November, a conference call has been organized with other metals consortia representatives who need to organize data sharing for K-REACH. Some templates of License to Use are already available and shared by our colleagues (e.g.: Co Cs, Pb Cs and Sb Cs), which could facilitate our work. However, key questions must be addressed upfront to define some important principles for the data and cost sharing. Please find here below a list of these questions and related recommendations for decision by the Management Committee:

- Do we prefer to sell LtU to individual co-registrants of a substance or to the Lead Registrant/Consortia-like structures representatives?
 - o For sake of efficiency, **the Secretariat recommends to favour the negotiation and the selling of the data to a consortium.** To ensure fair data sharing costs, we should take into account the number of co-registrants and the potential for the Cs to sublicense the data (in the context of LoA) – some draft agreements allowing this are available.
- Do we prefer to sell comprehensive data set or each study individually?
 - o For sake of efficiency, **the Secretariat recommends to favour the selling of a comprehensive data set** to avoid unnecessary administrative burden and organize this based on the tonnage band and K-REACH related requirements. If 3rd party refuses the proposal, an assessment of the added value for PMC of a pick and choose approach versus administrative burdens will be required.
- Do we intend to provide support on read-across approach followed and on metals specific issues in general?



- If this is an important issue, due to the PMC internal deadline for REACH 2018, it is difficult to provide such a type of support. **The Secretariat recommends to provide when needed RAAF documents to explain our read-across approach and to join forces with the other consortia when needed to ensure the application of the metals methodology.**
- How do we plan to estimate the LtU fee?
 - Based on the exchanges with the other consortia, **the Secretariat recommends to take into account the costs related to the studies (lab, consultants and HR internal resources) and some administrative fees for the K-REACH data sharing (e.g. 10% of the total costs).** All the other costs included in the PMC WP (e.g. exposure scenarios, uses identification etc.) cannot be taken into account except if explicitly required. For the cost sharing, it is suggested to follow the same approach than in the PMC and EU LoA and apply different factors depending on the requirements.
N.B.: NIER (The National Institute of Environmental Research in Korea) has published indicative prices for the different studies required. It would be recommended to compare these recommendations with the PMC costs.

The **next steps** for this project are:

- **January 2017:** discussion and agreement by the Management Committee on the key principles for data sharing outside the EU (same conf call than the one for the previous issue).
- **February 2017:** preparation of the cost sharing proposals and agreements and approval by the Management Committee
- **March 2017:** negotiation with the partners in Korea