



Karstedt Concentrate: Meeting Reconcile-PMC (MCC, Brussels, 15 February 2017, 11 - 14.10)

1. Participants list:

Jean Michel Stein (Bluestar Silicones), Karl Evans (Dow Corning – *via phone*), Peter Fisk (PFA) Inneke Claes and Andrea Bonavita (ReachCentrum), Michael Thiel (Chairman PGM WG, BASF), Roland Brasch (Heraeus - Lead Registrant Karstedt Concentrate), France Capon (*only discussion on LoA and future actions*), Maxime Eliat and Jelle Mertens (PMC)

The below minutes reflect the main suggestions and discussion points of the meeting, and need to be considered together with the slides that have been presented and sent to all participants

2. Introduction

The participants were welcomed to the meeting, reminded of the confidentiality and competition law obligations, and introduced via a tour-de-table.

3. Content of the REACH Dossier

1. Substance ID

SID card has been reviewed by Reconcile and PMC and agreed in March 2016.

2. Use information

The uses reflect the collated information as provided by the Reconcile and PMC member companies.

The Reconcile members will check whether all uses are adequately covered.

It was suggested by Reconcile to include an exposure assessment, although the substance is not classified for any environmental or mammalian tox endpoint. Reason would be that no full testing batch is available (e.g. missing data for sediment and soil, although not being a formal REACH annex VII-VIII data requirement). The assessment might be done on a quantitative or qualitative basis. PMC will check with its Tox Experts and other REACH consortia if including an exposure assessment for non-classified substances (registered <100 tpa) is required. For clarification to PMC, Reconcile is invited to provide the justification and reference in the ECHA Guidance why an exposure assessment would be required.



3. Phys-Chem hazards

It is suggested to:

- perform a density test for Karstedt Concentrate, rather than including a waiving statement + read-across data from the solvent;
- revise the vapour pressure endpoint via including QSAR data for a high molecular weight compound rather than data from the solvent;
- revise the partitioning coefficient endpoint (avoid the inclusion of high logKow value of 5.96);
- revise water solubility, as the value (0.035 g/L) is considered too high (potentially related to lower pH value?). Suggestion to waive this data source (Gregory 2014) via WoE, and use the values obtained via the Fraunhofer studies (cfr. acute aquatic toxicity and hydrolysis endpoints).

4. Environmental fate

Coverage of the hydrolysis endpoint via waiving statement is agreed (no modifications suggested). A remark was raised that the dose selection is too high, so that an excess test substance was added and the test setup should rather be considered a water solubility test than a proper hydrolysis test.

For biodegradation, Reconsile has test data available for the ligand (28-day test). Inclusion of this data in the dossier will be considered by PMC. The endpoint coverage via a waiver is agreed.

For adsorption/desorption, only values for Pt are included (via read-across between all PMC Pt dossiers). Reconsile has a ligand specific logKoc value available (lower value than the one obtained via a generic QSAR tool). Inclusion of the data as supporting data will be considered by PMC.

5. Ecotoxicity

Reconsile agrees to waive full tests based on the DRF results. Reconsile has acute toxicity data available for the ligand (algae/daphnids/fish), and PMC will consider including these data as supporting evidence.

Toxic KC threshold values are available for toxicity to micro-organisms, and a PNEC STP = 0.1 mg/L is included in the dossier. It will be reconsidered by PMC if this would imply inclusion of an exposure assessment.

6. Mammalian toxicity

No suggestions/comments were made on coverage of the various mammalian toxicity endpoints, except for the OECD422 study. For the OECD422 assay, Reconsile has ligand specific data available (*already shared with PMC*), and this study will be considered by the PMC Tox Experts when discussing the outcome of the OECD422 study with KC. It is acknowledged that some effects are similar while other effects clearly are not. Indicative timing for this internal PMC discussion is <Feb 2017.



7. PBT Assessment

It is suggested to focus the assessment on KC, rather than including a waiving statement for Pt (being inorganic) and a ligand specific assessment:

- P: use KC hydrolysis data;
- B: use waiving statement based on MW KC;
- T: use KC test data.

It is agreed that KC is not PBT/vPvB.

4. Dossier status and further steps/timing

The KC registration dossier has been submitted by the LR, including all data available up to end Dec 2016, and the dossier has been accepted by ECHA in February 2017, in compliance with the deadline set by Reconcile of 31 March 2017.

The dossier will need to be updated:

- when a classification is required (cfr. OECD422 study), exposure scenarios need to be developed and the internal PMC timing to resubmit the dossier is end June 2017;
- when no classification is required (cfr. OECD422 study), the dossier needs to be resubmitted to include all data of this OECD422 study. No internal PMC timing has been set for this scenario.

The various suggestions made in the earlier sections, will be considered by PMC for inclusion in the dossier. The decision to update the dossier and the timing will be defined as soon as the Reconcile co-registrants will be part of the Joint Submission via LoA. This can be done before the 2018 registration deadline. The risk for the dossier to be screened and picked up in 2017 is limited:

- The screening process for 2017 is already done and will only start again end of the year;
- The dossier/substance does not meet the screening criteria.

5. LoA discussion

ReachCentrum sent a series of comments to PMC 23 December 2016 and these comments have been addressed by return email and review during the meeting.

The remaining pending actions are:

- Send to Reconcile more information on the so called "administrative costs" and how these costs are shared (post-meeting note: done by FC on 16 Feb);
- Discuss with PMC Management Committee (FC, 15 March 2017).

The possibility to have same approach for Toll Manufacturers than for Affiliates of a company (Reconcile will check if one of their members is in this situation).

The clause on enforceability which should apply to all parties.

France Capon will come back to Reconcile after the Management Committee meeting with proposals.