

Caroline Braibant

From: Caroline Braibant
Sent: mardi 30 avril 2013 14:29
To: 'Brasch, Roland'
Cc: Audrey Rondepierre; Klaus Rothenbacher; 'Hannakam, Marcus'; 'Thiele, Ruediger'; 'Grohnert, Peter'
Subject: RE: Substance sameness between solids and solutions & Annex V of the REACH regulation

Dear Roland,

Your summary is a good one and highlights the 'sameness' context very well, thank you.

We are having this checked internally from a legal standpoint and propose to pick it up again at the next PGM WG meeting (19 Jun 2013).

Meanwhile, can you update us on whether you have sent the samples for testing or not?

We would like to know what to tell the test house and what results to expect before the meeting in June (other PMC Members prefer testing both the solid and the solution/liquid).

Cheers,

Caroline

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From: Brasch, Roland [<mailto:roland.brasch@heraeus.com>]
Sent: mardi 16 avril 2013 12:40
To: Caroline Braibant
Cc: Audrey Rondepierre; Klaus Rothenbacher (rothenbacher@epmf.be); Hannakam, Marcus; Thiele, Ruediger; Grohnert, Peter
Subject: RE: Substance sameness between solids and solutions & Annex V of the REACH regulation

Dear Caroline,

Thanks for your feedback on our proposal. We appreciate your open remarks because we have to admit that our proposal is not robust enough if it is judged only on base of the REACH requirements as defined in the REACH legislation.

For clarification of Heraeus' point of view we'd like to raise this topic again. To avoid misunderstandings we want to point out, that the following remarks refer exclusively to the sameness discussion in general.

Our proposal for PGM compounds with more than one existing version (**solid and solution**) bases on the following reflections:

- a) Each version of the PGM compounds exists each as a result of a process step. We see three process steps (grades):

Grade 1: The **“solution”**, which is the PGM compound, **dissolved** in diluted acid as a result of a chemical reaction (reaction mass)

Composition: PGM compound (ion or complex form) + solvent/stabilizer in various concentration ranges

Physical state: **liquid**

Type of substance: **UVCB**

Grade 2: PGM compound, **isolated** from reaction mass in grade 1

Composition: PGM compound (hydrated or anhydrous form)

Physical state: **solid**

Type of substance: **mono-constituent substance**

Grade 3: PGM compound grade 2, **intentionally redissolved** in diluted acid

Composition: PGM compound (ion and complex form) + solvent/stabilizer in various concentration ranges

Physical state: **liquid**

Type of substance: **mixture**

- b) The diluted acid in grade 1 and 3 is essential and acts as solvent/stabilizer. Otherwise the PGM compound would hydrolyze.
- c) Some PGM compounds react with the solvent/stabilizer.
- d) Phys-chem and hazard properties of solution are also driven by the solvent/stabilizer.
- e) No difference between phys-chem and hazard properties of the solutions in grade 1 and grade 3 but differences between solutions and solid.

With focus on the registration of PGM compounds with more than one existing versions under the same EC number and due to the formal “sameness” between grade 3 and grade 1, it is in our opinion reasonable to identify the hazard properties of the solutions on base of the properties of the pure components, which are the PGM compound itself and the stabilizer/solvent.

This “mixture-approach” would

- lead to a more robust data set.
- allow a classification of the solutions by using existing regulations/rules for the classification of mixtures under CLP and transportation regulations.

For Heraeus – and again: the aim is the registration of PGM compounds with more than one existing “versions” under the same EC number - the “mixture-approach” seems to be practical and at least as robust as the alternative approach, namely the determination of hazard properties of the PGM compound by testing the solutions, where also uncertainties have to be taken into consideration (e.g. because of the influence of the stabilizer/solvent, various concentration ranges of PGM compound and stabilizer/solvent, definition of a representative sample, aging effects, ...).

By following the “mixture-approach” and by using existing mixing rules we cannot see a deviation from REACH and CLP obligations relative to safety and environment. But admittedly this approach does not match completely the traditional REACH registration route (but neither does the alternative approach). The most serious issue we see in this matter is the formal REACH-borderline between grade 1 and grade 2. We are aware that this borderline is the reason why e.g. Annex V is not applicable from a legal point of view. But perhaps some arguments for Annex V exemptions can at least be used to justify our approach. So we are of the opinion that, based on reasonable evidence we should try to cross this borderline backwards from grade 2 to grade 1. The consequence would be a registration route based on the pure PGM compound in combination with the following challenges:

1. To exclude the **“solution”** version from the dossier but to include a **“dissolved”** version,
2. To claim solid and dissolved version to be identical (instead of solid and solution)
3. Prove of substance sameness
4. To assess the risks of the substances generated by reacting with the stabilizer/solvent (= the dissolved version) through the assessment of the precursors of the reaction (= the solid version).

As a summary we currently see two approaches to the one-dossier-registration of PGM compounds with more than one existing version. They are: solid vs. solution and solid vs. dissolved version. Both approaches have advantages and disadvantages and either deviates from the normal REACH registration procedure. In either approach expert judgment will play an important role.

From the pure REACH perspective either approach is not robust. And in extreme cases we have to think about an option three.

We see definitely need for clarification and therefore will ask you to organize an exchange with the PGM experts group.

Kind regards

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From: Caroline Braibant [<mailto:braibant@epmf.be>]
Sent: Freitag, 5. April 2013 16:36
To: Brasch, Roland
Cc: Audrey Rondepierre; Thiele, Ruediger; Grohnert, Peter; rothenbacher@epmf.be
Subject: RE: Substance sameness between solids and solutions & Annex V of the REACH regulation

Dear Roland, Rüdiger and Peter,

Thanks for this complement of information.
I copy Klaus so he is included in the exchange.

Please find below my personal views, based on my interpretation of substance identification and REACH registration requirements:

- I believe we cannot claim an exemption from registration for the solution 'versions' of our compounds because they are manufactured, imported (M/I), and/or placed on the market (cf. comment in red in your e-mail below). So unless I am mistaken, Annex V plays no role in our analysis...(?)
- As regards considering the solution as a mixture, then we have to fully exclude the solution 'version' from the registration dossier which can only cover substances (mixtures are not to be registered, only their components). This does not match your proposal below to cover the solid and the solution in the same dossier and furthermore it does not resolve the case where (some) companies M/I or place on the market only the solution (then they would not be covered by any registration).
- Considering the solution as a mixture may however resolve your issue around using the classification of the solid to deduct the classification of the solution (with e.g. MeClas). But in order to do so you have to demonstrate that it is the same species when 'reading-across' the classification from the solid to the solution – and this is something which remains unclear, no (?)

- You say we could prove substance sameness on the basis of expert judgement – we have tried and this has not worked out, which is why we are undergoing parallel testing for skin corrosion (solid and solution) – do you have objective criteria that could be used to argument this expert judgement and discussed with the PGM WG?

Finally, and as I said when we met, I believe it is too late to retract from the on-going testing programme and it is a matter of responsible care/due diligence to actually continue with the tests and generate the data.

Once we have the data, we can then try and obtaining a specific derogation from packaging group I to packaging group II with the relevant transport authorities, as this was probably done for the acids themselves.

If you wish, I can find out which other metal sectors have the same issue (we are probably not the only ones transporting acidic solutions) and we can organise this ASAP.

I am sorry I cannot support your proposal but it is in my view not robust enough and looks like deviating from obligations relative to safety of workers and the environment which is exactly what REACH and CLP aim to address... I do not claim this is the objective of Heraeus of course, but believe that it will look like it to any lawyer or authority (who would have no clue about speciation issues in PGM compounds to start with) we would ask the question to... You are naturally free to seeking advice on this and come back to us once you have more certainty that the (updated) proposal could meet all regulatory requirements.

Feel free to raise this again with Klaus; we would be happy to organise an exchange with the PGM experts so you can have their views and not only PMC secretariat ones.

I wish you a nice evening anyway, and cross my fingers that the skin corrosion tests will not be as bad as anticipated ;-)

Cheers,

Caroline

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From: Brasch, Roland [mailto:roland.brasch@heraeus.com]
Sent: jeudi 4 avril 2013 15:41
To: Caroline Braibant (braibant@epmf.be)
Cc: Audrey Rondepierre (rondepierre@epmf.be); Thiele, Ruediger; Grohnert, Peter
Subject: Substance sameness between solids and solutions & Annex V of the REACH regulation

Dear Caroline,

I would like to come back to the substance sameness discussion and in this context to Annex V of the REACH regulation, a topic that we briefly talked about during our last week's meeting.

In principle the sameness-question and the related consequences can be extended to all substances which are sold both as solids and in solution. Although some companies obviously do not isolate the solids but put the substance on the market only as solution.

In Heraeus' opinion solids and solutions should be considered as identical and the solutions should be regarded as mixtures (solid + solvent + stabilizer). We are well aware that in some cases the dissolved substances – e.g. due to complex formation – have different characteristics than the solids. In this case the sameness between solid and solution cannot be demonstrated by simply comparing the corresponding spectra.

At this point we wonder whether Annex V of the REACH regulation might be helpful. According to ENTRY 4 (pg 3) of the attached "Guidance for Annex V Exemptions from the obligation to register" do "substances ... which result from a chemical reaction that occurs when ... a stabilizer, ... solvent, ... functions as intended ... not need to be registered *provided it is not itself (the material resulting from the chemical reaction between the substance+the solvent/stabilizer, i.e. our substance...) manufactured, imported, and/or placed on the market.*

So - as a proposal - the registration route for the above mentioned substances could consider

- solid and dissolved substance as identical.
By different characteristics between solid and dissolved substance: prove of substance sameness based on expert judgment and/or referring to Annex V exemptions.
- 2 compositions:
 - o Solid
 - o Solution (worst-case-solution, max. PM-content, max. acid-content)
- the determination of the tonnage band is based on the solid form of the PGM compound, even in solutions.
- hazardous material properties and classification to be determined by the solid only.
For the solutions: Allocation of hazardous material properties by expert judgment; classification by using MECLAS. No separate testing of solutions!

Of course we have to admit that we are no lawyers. Even in German language the wording of Annex V is difficult to understand and allows multiple variations of interpretation. But we think it is worth to check whether we can benefit or not.

In addition we propose to contact e.g. a consultant with experience in this special matter for support. Perhaps we could have a PGM WG workshop. Or to ask other consortia, which might be in the same situation as we are.

What do you think?

Kind regards,

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