From: Klaus Rothenbacher <rothenbacher@epmf.be>
Subject: **PGMs: testing programme update May 2013**
Date: 7 Jun 2013 14:35:06 GMT+02:00
To: Audrey Rondepierre <rondepierre@epmf.be>, mhalhead@halhead.org, nevillep@angloplat.com, Manfred.Probst@c-hafner.de, giovanni.prelazzi@chimet.com, Caroline Braibant <braibant@epmf.be>, bodo.berkner@ferro.com, peter.grohnert@heraeus.com, ruediger.thiele@heraeus.com, angela.alderman@matthey.com, boydda@matthey.com, mark.raffray@matthey.com, christine.bourda@metalor.com, aurelie.normand@metalor.com, francisco.boo@metalor.com, mari.jarvikivi@nornik.fi, info@safimet.com, fehse@saxonia.de, marie-laure.ledrich@luxcontrol.com, guy.ethier@umicore.com, marleen.vandenbergh@umicore.com, Heike.Kinz@eu.umicore.com, roland.winde@eu.umicore.com, Nathalie.Dom@eu.umicore.com, steven.verberckmoes@umicore.com, edwin.broekaert@umicore.com, mike.dutton@vale.com, mike.shepherd@vale.com, Carole.Wilson@vale.com, roland.brasch@heraeus.com, michael.huber@wieland-edelmetalle.de, heik@xstratanickel.no, hstubberud@xstratanickel.no, massimo.blattner@valcambi.com, heinz-guenter.schenzel@c-hafner.de, paul.dinning-1@gbr.dupont.com, Nissanka Rajapakse <Nissanka.Rajapakse@matthey.com>
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▶ 1 Attachment, 62,5 KB

To the PGM WG and TAP

FYI – Please find attached the latest update on our ongoing PGM testing. In summary:

- Initial results for the Corrositex testing programme are available. Unfortunately, the lab did not receive CoAs for all tested substances and therefore cannot issue the corresponding reports yet (inclusion of the CoA is a requirement). We requested the certificates again.
- The sensitisation testing (LLNA assay) is currently ongoing. The 2 missing test substances have still not arrived at the lab
- Our recommendation for CROs to conduct our repeated dose testing (RDT) programme had been agreed. The tests have therefore been initiated now (e.g., sent sample requests, ID card requests for test substances, developing protocols, discussing safe handling issues with labs)
- DDP: the tests on Daphnia reproduction and chronic sediment testing (chironomids) are ongoing. The in-life phase of the range-finding studies has been completed, but detailed results are not reported yet. The results and a recommendation for dose setting are expected in June
- DDP repeated dose testing: the two agreed additional pre-studies are ongoing: a) the palatability study at CiToxLAB has started; and b) the additional dose formulation work at Fraunhofer Dresden (stability of formulations prepared on a daily basis) has been completed. A draft report will be circulated to the PGM WG for discussion

As always, please let me know if you should have any questions.

Kind regards,

Klaus Rothenbacher

From: Audrey Rondepierre [mailto:Rondepierre@epmf.be]
Sent: Dienstag, 7. Mai 2013 16:50
To: mhalhead@halhead.org; nevillep@angloplat.com; Manfred.Probst@c-hafner.de; giovanni.prelazzi@chimet.com; braibant@epmf.be; bodo.berkner@ferro.com; peter.grohnert@heraeus.com;

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Subject: PGMs: testing programme update

To the PGM WG and TAP

FYI – Please find attached an update on our ongoing PGM testing. In a nutshell:

- The PGM testing programme is progressing as planned
- As agreed, we will place the genotoxicity tests at Covance. The scope has been agreed previously. We have received a final quotation and are now ready to start. Sample requests will go out shortly
- The Corrositex testing programme has started. The scope has been agreed, samples have been requested (and most of them were received) and the tests have started at LPT, Munich
- The sensitisation testing (LLNA assay) is currently ongoing. We are missing 2 test substances – they are currently being requested again
- We have made a recommendation for CROs to conduct our big repeated dose testing (RDT) programme. Our recommendation is to split the tests between CiToxLAB (Hungary) and LPT (Germany). Please see the separate mail sent yesterday for more details
- DDP: the agreed ecotox tests on Daphnia reproduction and chronic sediment testing (chironomids) are ongoing. The initial range-finding studies gave unclear results and therefore had to be extended. The main studies will be initiated once this is clarified
- DDP repeated dose testing: the work in formulation development indicated that the dosing formulations are not stable for the time of the study. We are therefore currently evaluating 2 options: a) check if the formulations are stable enough if they are made up freshly every day, and b) evaluate if a dietary study (dosing DDP via the food, rather than via gavage) is an option. This might be our last option in case the formulations are not sufficiently stable. A palatability pre-study has been started to evaluate this.

As always, please let me know if you should have any questions. We will give a more detailed overview at our upcoming PGM WG meeting and you will of course have the opportunity to ask any questions.

Kind regards,

Klaus Rothenbacher

From: Sandra Allen [mailto:sandra.allen@regulatoryscience.com]
Sent: Dienstag, 7. Mai 2013 11:05
To: 'Klaus Rothenbacher'
Subject: RSA Study management update + wca input

HI Klaus,

As discussed wca have sent me their update for April and I have included into the study management spreadsheet.

Regards,

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