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Envoyé : lundi 8 mars 2010 14:24
Objet : STPP Reach Registration information for all SIEF members - Eines 231-838-7 and 237-004-9

8th-March-2010

Email to all members of the two STPP SIEFs

Conditions of access to the REACH dossier submission for STPP

(Sodium Tri Poly Phosphate Eines 231-838-7 and 237-004-9)

From: STPP Reach Consortium Secretariat STPP@reachcentrum.eu

Acting on behalf of the STPP Lead Registrant (FMC Foret) and of the other STPP Reach Consortium Members, as specified in the Consortium Agreement.

Further information: <http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/stpp-reach-consortium.aspx>

Dossier status

This email is to inform you that the REACH joint registration dossier is now fully COMPLETED, has been SUBMITTED and has been formally accepted by ECHA : the successful ECHA Submission Report and dossier Reference Number have been received and tokens can now be emitted for companies purchasing access, as soon as full payment is made to the Consortium (REACH IT Joint submission name: Pentasodium Triphosphate_JS).

Dossier content update

Since our email of 19th October 2009, the Consortium received communication of a number of additional studies. In particular, we received a 28 day mammal inhalation toxicity study dating from the early 1970s. We considered it necessary to examine this information in detail before submitting the REACH joint registration.

This 28-day STPP inhalation toxicity report shows significant mortalities at medium and high inhalation dosages for one (only) of the three species of mammal tested. However, histopathological examination of tissues from the animals was not carried out, so that it is not possible to establish whether these mortalities were due to toxicity of STPP or to experimental issues, and no clear conclusion can be drawn from this study. We have therefore classified this study as Klimisch 3. The study data does not result in "Classification" of STPP. Nonetheless, a waiver based on route-to-route extrapolation (from oral to inhalation), as previously planned, is not now possible in the STPP registration dossier for the chronic inhalation toxicity endpoint. The dossier has therefore been modified for the inhalation toxicology endpoint, and a 90-day study inhalation toxicity study on rats is now proposed as a "Testing Proposal", accompanied by a note explaining why such animal testing is not considered by the Consortium to be justified.

This does not therefore finally modify the budget of the dossier as currently finalised, but it does mean that all registrants should be aware that additional study

costs may become necessary later if ECHA decides that the proposed 90-day inhalation toxicity study is justified and should be carried out. In which case, all registrants will have to share the additional cost of this study, if applicable according to their tonnage bands.

As a consequence of the above, the joint registration was submitted by the Lead Company FMC Foret in February 2010.

Information sharing

We have fully informed the two STPP SIEFs (EINECS N°: 231-838-7 and 237-004-9) by email of 19/10/09 about the development of this dossier and financial conditions for dossier access, in addition to making this information available on the Consortium's public website. We have also made available on-line a summary of work organisation and a full list of relevant studies and information in our possession, thus enabling all SIEF members to indicate to us if they were aware of or had in their possession other relevant information. The draft IUCLID5 and CSR summaries, proposed Classification and Labelling, Substance Identity and Identified Uses were made available on request for verification to all SIEF members.

The finalised Classification and Labelling proposals, Substance Identity, Identified Uses, and summaries of the IUCLID5 and CSR as submitted (as well as full information concerning the dossier access and confidentiality conditions) are now available at: <http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/stpp-reach-consortium.aspx>

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Financial conditions for dossier Letter of Access

The principle of financial conditions explained in our email of 19th October has been accepted by a number of SIEF members who have signed the relevant documents and made the initial deposit payment.

Because STPP is such a widely used substance with a long history, there are a large number of relevant studies. Over 1 000 studies were examined for the dossier preparation, and some 175 studies summarised in the IUCLID file.

The total cost of the dossier preparation (cost of access to required studies, dossier writing, consortium administration, etc.), up to and including dossier submission (not including ECHA fees), has been maintained within the budget announced in our email of 19/10/2009 (482 860 Euros ex VAT) and is finally:

- 480 199 Euros ex VAT

The cost of Dossier Access has therefore been fixed, as defined in the communicated financial conditions, as follows:

For > 1,000 tonnes tonnage band:

480 199 Euros / (number of companies committing to the Joint Registration by the deadline fixed in our 19/10/2009 email = 10) + 20.000 Euros*, ex VAT
= 68 020 Euros ex-VAT

* Advantage Compensation Payment - see Consortium Agreement financial conditions.

For lower tonnage bands:

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|-------------------|-------|-----------------------|
| • 100-1000 tonnes | = 68% | = 46 254 Euros ex-VAT |
| • 10-100 tonnes | = 40% | = 27 208 Euros ex-VAT |
| • <10 tonnes | = 24% | =16 325 Euros ex-VAT |

Note: the prices for the lower tonnage bands are based on the price for >1,000

tonnes tonnage band, multiplied proportionally by the number of endpoints required.

This cost **does NOT include**: the possible cost of taking into account any further studies which may be communicated to us in the future, nor any modifications of the dossier which could result from such information, nor any administrative costs of updating the dossier if this becomes necessary in the future. It does not include the costs of carrying out the study submitted as Testing Proposal, nor of any other additional testing ECHA may require after examination of the dossier. All such additional costs must be shared between all registrants (where concerned according to tonnage bands), and will be additional to those indicated here. Note that other than the above provisions, this is a fixed dossier access cost, and that no partial refund will now be given if further companies purchase access to the dossier.

The above conditions are in application of the STPP Consortium Agreement financial conditions already communicated to the SIEF since last year. This Agreement specifies in full the conditions for cost sharing, administrative costs and for valuation and accounting of existing studies and new information, based on standard prices and cost share principles and on the REACH Guidance Document (data sharing).

The Access Rights are accorded for use for REACH Registration of the single substance STPP only, and for use for no other purposes and for no other substances.

If you are acting as an Only Representative for two (or more) different companies, then the above cost must be paid two (or more) times.

The above figures do not include ECHA registration fees.

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How to proceed to purchase dossier access

- 1) **Full information is available** at <http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/stpp-reach-consortium.aspx> (click: "STPP Joint Registration") including
 - a. STPP REACH Dossier Purchase Form,
 - b. STPP REACH Consortium Agreement (includes detail of financial and confidentiality conditions applicable),
 - c. updated list of all relevant studies in our possession,
 - d. summary of the STPP IUCLID dossier, including substance sameness (composition, impurities, granulometry)
 - e. summary of the STPP CSR, including GHS classification and Identified Uses
- 2) To obtain dossier access, you must **return the signed Dossier Purchase Form** (on paper) to the STPP Consortium Secretariat, as indicated above.
- 3) On receiving this Form, the STPP Consortium Secretariat will send you an **invoice** for the full dossier access cost indicated above, according to your tonnage band, and bank details and instructions for making payment. You will also receive indicative instructions outlining the information (analysis, spectra ...) you will have to provide in your individual company-specific registration dossier (to join the Joint Registration).
- 4) **As soon as full payment is received by the Consortium Secretariat (ReachCentrum)** then (a) an up-to-date "Token" will be sent to you to confirm your access to the REACH IT STPP Joint Registration, and (b) a Letter of

Access will be sent to you (signed by the Consortium Secretariat on behalf of the Lead Registrant and the other Consortium Members).

- 5) You can then proceed with your own company's specific submission at whatever date you choose.

Please note that the "Token" will only be sent, after the full final payment is received and verified by the Consortium Secretariat ReachCentrum. **You should therefore return the signed Forms well in advance of your registration deadline to enable sufficient time for the above procedures** (invoicing, payment) and for your own registration submission, ECHA fee payment, etc. The STPP Consortium accepts no liability for any problems resulting from the above administrative procedure, nor from any incidents which might delay this (problems in bank transfer, delayed deliveries ...)

Please note:

If you wish your STPP registration (including company-specific information) to be submitted by the Consortium service provider, Harlan, rather than submitting it yourself, then you should indicate this as requested in the Dossier Purchase Form. Harlan will then contact you sending the specific STPP Joint Submission Questionnaire, which specifies information and required documentation necessary for your company's registration. Harlan will only submit your registration after receiving this questionnaire with the full necessary information, after receiving payment for this specific service, and after confirmation from the Consortium Secretariat that the dossier access cost indicated above has been paid and a Token emitted. Harlan have offered to carry out this service for 4.500 ? ex VAT per company. This is a separate contract with Harlan independent of the STPP Consortium, payable to Harlan not to the Consortium. Again you should allow adequate time for this before your registration deadline.

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