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Envoyé: lundi 19 octobre 2009 13:07
Objet: STPP Joint Registration

Email to STPP SIEFs (Einecs 231-838-7 and 237-004-9)

To all companies in the SIEFs for STPP, that is the following substance:

EINECS	231-838-7 237-004-9
CAS	7758-29-4 13573-18-7 15091-98-2
Names	Pentasodium triphosphate Triphosphoric acid, sodium salt Sodium tri polyphosphate Sodium tri polyphosphate hexahydrate

From: STPP Reach Consortium Secretariat STPP@reachcentrum.eu

Important deadline 30th November 2009

Further information: http://www.reachcentrum.eu/EN/consortium-management/consortium.aspx

As we have already indicated to you, a REACH Registration Dossier for STPP (Sodium Tri Poly Phosphate)[i] has been developed by the STPP REACH Consortium.

This email is to inform you that this dossier is now fully COMPLETED. The STPP Joint Registration has been created in REACH IT (name: Pentasodium Triphosphate_JS) ready for the actual submission. The completed dossier is currently one of a small number of dossiers being used for testing of the pre-release version of the ECHA technical completeness check IT tool. The dossier will be formally submitted (Joint Submission) in December 2009 after this testing is completed.

The reasons for proceeding with this early Joint Submission are as follows:

- the dossier is now complete and ready
- early submission gives maximum time for any further adjustments should any prove necessary before the 2010 deadline
- we wish to ensure submission before ECHA IT systems become crowded with near-deadline submissions, thus avoiding any risks of administrative difficulties
- early submission means that there is a possibility of feedback on the dossier before mid-2010 which would be very useful for finalisation of other inorganic phosphates REACH Registration Dossiers, currently under preparation

In order to fully respect the REACH obligations of information sharing and joint registration, we are therefore informing you now, well in advance, of the timetable necessary for SIEF members to respect if you wish to participate in this Registration,, in order to enable all SIEF members who wish to do so to participate in the Joint Submission.

Context: Dossier testing

This STPP Registration Dossier was informally submitted to to the European Chemical Agency (ECHA) in the Cefic-ECHA "dossier testing" process in February 2009, and detailled comments were received from ECHA on both the IUCLID5 and CSR documents, and then discussed at a meeting with Cefic and ECHA in Helsinki on 20th - 21st April 2009.

These comments led us to complete a number of points in the dossier, including formal completeness aspects, formulation of certain waivers, re-evaluation and completion of certain study information and Key and Weight of Evidence studies referred, etc. This "dossier testing" was not a formal dossier submission and the comments made by ECHA are not contractual and do not anticipate conclusions of formal dossier submission. Nonetheless the exercise has enabled us to complete many aspects of the dossier and to now reasonably expect its acceptance.

Information sharing

We have fully informed the two STPP SIEFs about the development of this dossier, including making available 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 or had in their possession other relevant information. The draft IUCLID5 and CSR summaries, Proposed Classification and Labelling, Substance Identity and Identified Uses have already been made available on request for verification to SIEF members.

The finalised Classification and Labelling proposals, Substance Identity, Identified Uses, IUCLID5 and CSR summaries (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 (click: "STPP Joint Registration")

The draft IUCLID5 summary and CSR Dossier (conclusions for each endpoint and list of studies referenced for each endpoint) have already been made available on request for verification to SIEF members subject to signature of a "commitment and confidentiality" document, defining and committing to confidentiality conditions, and committing to payment of appropriate dossier access costs. The summary and list of referred studies of the finalised dossier are now similarly available.

Dossier cost

Because STPP is such a widely used substance with a long history, there is a very extensive number of relevant studies. Over 1 000 studies were examined for the dossier preparation, and 150 studies are summarised in the IUCLID file.

The full 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), is estimated as:

462 860Euros ex VAT

The final cost to purchase access to the dossier will be different for companies deciding or not to join the initial Joint Submission within the deadlines indicated below.

In all cases, the base cost to obtain Access to the dossier will be as follows:

- (482 860 Euros / N) + 20.000 Euros[ii] ex VAT, where N is the number of companies participating in the joint registration at the deadline date indicated above
- As an example: if N = 10, this cost will be 68 286 Euros ex VAT
 If N = 15, this cost will be 52 191 Euros ex VAT

NOTE: for companies in lower tonnage bands (<1000) tonnes the dossier cost to be shared will be lower (certain endpoint studies and waiver writing costs not required [iii]). The calculation above assumes N companies registering in the >1000 tonnes band, the cost share calculation is modified appropriately if some of the companies sharing the costs are in lower tonnage bands.

There are two options for purchasing dossier access:

- A) Participation in Joint Registration as per deadline below: the initial cost will be calculated above, but if other companies purchase access later, a partial refund will be made
- B) After the deadline below, purchase of a Letter of Access. In this case, the cost will be fixed as above and no late partial refunds will be made.

Thus, the final cost of purchasing dossier access is likely to be higher for companies which decide NOT to participate in the Joint Registration according to the deadlines below. This is because of the additional administrative work, cash flow costs and financial risk which will result for the Consortium, which will have completed its principal operations once the Joint Submission is completed.

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 STPP only, and for use for no other purposes and for no other substances.

Please note that in the case of additional studies or other information being requested by ECHA after submission, the resulting additional costs must be shared between all registrants (where concerned according to tonnage bands), and will be additional to those indicated above.

The above figures do not include ECHA registration fees.

Joint Submission deadlines

To participate in the Joint Registration submission your company must respect the following deadlines:

- as of now the information pack of documents which includes the items mentioned below can be downloaded from http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/stpp-reach-consortium.aspx (click: "STPP Joint Registration")
 - a. STPP REACH Consortium Commitment and Confidentiality Form.
 - b. STPP REACH Consortium Agreement (includes detail of financial and confidentiality conditions),
 - c. updated list of all relevant studies in our possession,

- d. summary of the STPP IUCLID dossier
- e. summary of the STPP CSR, including GHS classification, substance sameness and Identified Uses
- 2) DEADLINE -: 30th November : return signed Commitment and Confidentiality Form and make payment of initial deposit of 30.000 Euros. By this date, payment must be effectively received by ReachCentrum (STPP Consortium Secretariat, bank account details below) as well as the following original signed documents: STPP REACH Consortium Commitment and Confidentiality Form (includes agreement to substance identity and proposed Classification and Labelling), STPP REACH Consortium Agreement (acceptance of confidentiality, financial and other conditions), dossier summary (agreement to IUCLID dossier content and CSR conclusions).
- 3) Approximately 15th December: **final invoices will be issued** by ReachCentrum, calculated on the basis of N = number of companies having paid the deposit and signed the commitment by the above deadline, along with formal notification of admission to the STPP Reach Consortium. **At the same time, the initial dossier joint submission will be made to ECHA by lead company FMC Foret**.
- 4) As soon as you pay the final invoice (total dossier cost as calculated above minus the 30 000 Euros deposit already paid) then (a) your company's name and details will be added as a member of the Joint Sumission to the Lead Registrant dossier (section 1.5) (b) an up-to-date "Token" to confirm your membership in the REACH IT STPP Joint Submission will be sent to you, thus enabling confirmation by your company as a member of this Joint Submission in REACH IT. You can then proceed with your own company's specific submission at whatever date you choose, as a function of your tonnage band registration deadline.. Please note that your company will only be included into the joint registration dossier, and the "Token" will only be sent, after the full final payment is received by the Consortium Secretariat ReachCentrum.

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 Commitment and Confidentiality 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: spectra, substance composition, with analysis methods .). Harlan will only submit your registration after receiving this questionnaire with the full necessary information, and after receiving payment. Harlan have offered to carry out this service for 4.500 ? ex VATper company. This is a separate contract with Harlan independent of the STPP Consortium, payable to Harlan not to the Consortium.

Next steps

If you wish to register STPP under REACH, please download now from http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/stpp-reach-consortium.aspx (click: "STPP Joint Registration") the documents indicated in (1) above and return these, with the initial payment of 30.000 Euros by 30th November 2009

We remind you of the importance, as mandatory under REACH, that you:

- inform us if your company has any data, information or studies relevant to Reach Registration of STPP. The updated list of all studies and information in our posession is available as indicated above to enable you to verify that you do not know of other relevant information in your posession or elsewhere.
- verify your agreement to the proposed Classification and Labelling, Substance Identity and Identified Uses (available as above) and indicate to us in case of comments or disagreement.

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Bank account details for payments to STPP Reach Consortium Secretariat:

All payments MUST include as references: "STPP" <u>and</u> your Pre-Registration number.

All payments must be made in Euros and must be net of any taxes or other costs.

Name of account holder: ReachCentrum SPRL

Address of account holder: Av. E. Van Nieuwenhuyse 6 - 1160 Brussels -

Belgium

VAT Number: BE 0882 099 291

Bank Name and address: Fortis Bank - Avenue Louise 200, 1000 Brussels,

Belgium

Account Number: 001-4924627-13

IBAN code: BE08 0014 9246 2713

BIC (SWIFT) code: GEBABEBB

- [i] *EINECS numbers 231-838-7 and 237-004-9, CAS numbers 7758-29-4, 13573-18-7 and 15091-98-2
- [ii] Advantage Compensation Payment see Consortium Agreement financial conditions
- [iii] For companies in lower tonnage bands, certain studies are not required. Removing the value of these studies and the cost of their summary and inclusion into the dossier gives the following % of costs for lower tonnage bands:

100-1000 tonnes = 68% 10-100 tonnes = 40% <10 tonnes = 24%

That is, if the dossier cost share including Advantage Compensation Payment is XXX? for a >1,000 tonne company, then the cost share will be 68% x XXX? for a 100-1,000 tonne company, etc.