

To all members of the REACH SIEF for phosphoric acid EC# 231-633-2.

29th May 2010

This email provides updated information concerning the REACH Registration Dossier development for Orthophosphoric acid, EINECS 231-633-2, CAS 7664-38-2.

It updates the information already circulated by email to the SIEF on 9/11/2009 and 21/10/2009.

For further information and access to documents cited below:

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

Contact: Phosphoricacid@reachcentrum.eu

Dossier development status and work ongoing

The data gap was completed in October 2009, with 355 studies identified, assessed and Klimisch scored. The list of these studies is available on the above website for consultation. You are asked to make known to us any relevant study or information, in your possession or of which you are otherwise aware, which is not included in this list.

The IUCLID dossier is now partly completed and undergoing examination by the Lead Company, pending delivery of several studies for genotox and ecotox endpoints ordered (new studies or study purchase) early 2010.

The IUCLID dossier is being prepared to cover all types of phosphoric acid, from fertilizer grade to pure phosphoric acid, and will include the solid form – please see the proposed "Sameness" document, attached. This approach is subject to the acceptance of the submitted dossier by ECHA.

GHS classification of phosphoric acid is already harmonised by Classification & Labelling included for the substance in Annex VI. Modification of this Annex is a complex process, and we propose to NOT consider launching it (if considered necessary) until after submission and acceptance of the phosphoric acid REACH dossier. The Classification and Labelling will therefore be as in Annex VI unchanged.

We strongly suggest that you download and examine the documents available on the website cited above, and send any comments to us as rapidly as possible. In order to complete the dossier within the 2010 deadline, it may not be possible to take into account any comments received after end June 2010.

Change of Lead Registrant

For internal company reasons, GPN no longer wishes to ensure the role of Lead Registrant for phosphoric acid, and after agreement, this has been handed over to FMC Foret. The dossier management is therefore transferred from the FARM to the IP (Inorganic Phosphates) Consortium.

Please note that no reply or comment from you by end June 2010 is considered as acceptance of this change of Lead Registrant and of management by the IP Consortium under the IP Consortium financial conditions.

The IP Consortium is currently preparing REACH Registration for some 40 inorganic phosphate substances, and by developing these dossiers together with phosphoric acid, time savings and dossier quality will be achieved through grouping of substances and read-across.

SIEF Agreements

Regarding Consortium and SIEF administration and relations, the IP Consortium has noted the proposal by Cefic to use a SIEF Agreement as the standard basis for organising SIEF – Consortium relations and responsibilities. **You will therefore find (at the website above) the proposed text of the SIEF Agreement for IP substances for your approval** (at present, one "model" text is online, but before opening to signature we will issue one specific agreement text for each IP substance, including phosphoric acid). This text is based on the standard industry text proposed by Cefic and now used by many SIEFs.

The SIEF Agreement text specifies in detail the financial conditions for purchase of Letter of Access (dossier cost share, Advantage Compensation Payment, share of general Consortium and dossier

administration and management costs, etc). Please note that no reply or comment from you by end June 2010 is considered as acceptance of this SIEF Agreement.

Signature of the SIEF Agreement will be done using the specific electronic signature tool which ReachCentrum will place online in mid June 2010.

Signature of the SIEF Agreement will be necessary to obtain access to the Joint Registration dossier and is independent of the option of joining or not the IP Consortium (it is not necessary to join the IP Consortium to purchase Letter of Access, but it is necessary to sign the SIEF Agreement).

Covered uses, Guidance on Safe Use, CSR submission

The proposed list of covered uses and applications is available for consultation at the IP Consortium website as referenced above.

A standard model word text CSR (and Guidance on Safe Use, IUCLID section 11) for phosphoric acid will be made available by the IP Consortium (to all companies purchasing Letter of Access), taking into account the uses and applications covered by the Consortium (see above), but these will then be submitted separately as part of each registrant's company specific registration information. The standard CSR can thus be either submitted as provided, or extended by each registrant to include its own or its downstream users specific uses or applications.

The reason for this, is to ensure that possible updating of the CSR to include future new uses, after Registration, will be the responsibility of each registrant (Lead Registrant intervention will not be necessary).

Budget estimation tool :

You will also find on the website a budget estimation tool for Registration Dossier participation (excel tool, updated 5/2010, for different IP substances including phosphoric acid). This includes approximate costs of company owned and third party owned study costs, estimated on the basis of the current dossier development status and on the basis of standard value estimates.

This tool gives you an estimate of the cost of Access to the phosphoric acid dossier (and/or other IP substance dossiers if required), but assuming that only the relevant IP Consortium Members plus your company purchase access. Obviously the cost will be lower if further SIEF members also purchase access, as dossier and administration costs will then be shared between more participants.

This cost tool is a very approximate estimate only, as final costs will not be known until dossier writing is completed, ordered studies are delivered and invoiced, etc.

For further information and access to documents cited:

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

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