

# **Inorganic phosphate SIEF Agreement signature and LoA purchase procedure**

24<sup>th</sup> August 2010

**To all companies interested to REACH Register the 21 inorganic phosphate substances listed below by 2010.**

**This email explains the procedure for purchase of LoA (Letter of Access) for these substances.**

**The following steps are obligatory and necessary conditions for obtaining LoA:**

- **Online procedure using ReachCentrum online LOAShop**  
<http://loashop.reachcentrum.eu>
  - à **signature of the SIEF Agreement Contract** for each IP Consortium substance you intend to Register in 2010  
*(no online signature, no possibility to purchase LoA)*
  - à **complete details of your affiliates, represented parties for ORs**
  - à **commit to purchase LoA, and request for invoice**
- **Payment of invoice** covering the full “conservative” estimated dossier cost, see below *(Token will not be issued until full payment is received)*

The online signature and payment system is online as of mid July and each of these steps can be done as of now.

**We recommend that you engage the above steps rapidly**, in order to allow sufficient time for emission of invoices, receipt and validation of payment and Token emission, and then for your own company dossier submission. If you delay the online procedures or the payment, you risk not having time to submit correctly your own company dossier, pay ECHA Fees and receive your Registration Number before the 1/12/2010 Registration deadline, particularly in the case of incidents or saturation with the ReachCentrum LOAShop or with the ECHA website, or incidents with payment references or transfers, or any other non foreseeable incident. The Inorganic Phosphate Consortium takes no responsibility for consequences in such cases.

**For further information and access to documents:**

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

**For online SIEF Agreement Contract signature and LoA purchase:**

<http://loashop.reachcentrum.eu>

Contact: [ip@reachcentrum.eu](mailto:ip@reachcentrum.eu)

## **SIEF Agreement Contract sign up**

**It is in your interest to sign up to the SIEF Agreement Contract as rapidly as possible (for each IP substance you intend to register):**

- Risks of missing Registration deadline if you delay, as indicated above.
- On signature, we will send to you documentation to facilitate Registration preparation: “IP Registration Notes” concerning organisation of dossier preparation for different sections of IUCLID, spectra and analysis recommendations for inorganic phosphates, model spectra waiver texts, etc

- You will be able to communicate information concerning affiliates, companies for which you are acting as Only Representative. This information is obligatory for obtaining Letter of Access
- As soon as you have completed this information, you will be able to commit online to purchase LoA
- If you have completed the online procedure and your payment has been received, then you will receive the Token (and so be able to submit your company's own Registration mini-dossier) and an electronic (PDF) Letter of Access as soon as the Lead Company submits the Joint Registration dossier (planned for September for most IP 2010 dossiers)

### **“Conservative” estimated dossier cost and recalculations as a function of cost share**

As per the Dossier Estimate Tool circulated to the SIEFs 6/9/2009 and since made permanently available and updated on the IP public website, the LoA purchase cost will be calculated using a “conservative” estimate of cost share based on the number of Consortium Member registrants only (total dossier cost divided by number of IP Consortium Members intending to register the substance in 2010 plus one external LoA purchaser).

**The total amount payable, including LOAShop handling fee, will be indicated online in the LOAShop system.**

This probably leads to a “conservative” estimate of dossier cost PER REGISTRANT, in that it is likely that more than one non-Member will purchase LoA, and therefore that the actual dossier cost share in this case will finally be lower (cost divided by higher number of registrants). Therefore, the dossier cost share will be recalculated after the 2010, 2013 and 2018 submission deadlines, and reimbursements if due will at these times be made to all registrants having purchased LoA.

Reimbursements will be made by bank transfer within 2 months of each of the three registration deadlines, subject to the conditions indicated below.

The following provisions (reserves) will be added to dossier cost before calculating the reimbursements:

- Estimated cost for submitted Testing Proposals, where applicable
- 5% of dossier cost as a provision for possible future management costs arising after submission (dealing with questions from ECHA, dossier updates ....)

These provisions will be added to the reimbursement calculations in 2013 or 2018 if and only if it is by then clear that the relevant expenditure will be partly or fully not required.

No reimbursements will be made where the amount due to a given company is < 500 €

The LOAShop Handling Fee and the Advantage Compensation Payment are not subject to cost share allocation, and so are not concerned by the reimbursements. The Advantage Compensation Payment, however, will be calculated at 5.000 €/substance for the initial LoA purchase payment and will be partially reimbursed after Registration for companies exceeding the 20.000 €/company ceiling fixed by the financial conditions.

It is emphasised that, as specified in the SIEF Agreement contract, the calculated cost of Letter of Access indicated above is not final and that all registrants remain jointly liable to any additional costs resulting from further information or testing requirements (applicable for their tonnage band) requested by ECHA, other unexpected dossier costs or related management costs.

### **SIEF Agreement Contract**

This email updates the information already circulated by email to the SIEFs 9/2009, 12/2008, 5/2009, 30/3/2010.

In particular, the draft SIEF Agreement Contract was made available on our website since March 2010, as indicated in our email of 30/3/2010. No objections have been made to this text and the several detail comments received have been taken into account.

The only significant changes since the model proposed in March (other than specific financial conditions concerning the sign-up and payment indicated above) are the following:

- *Throughout: obligation to sign up to the SIEF Agreement Contract online via LOAShop <http://loashop.reachcentrum.eu> . No manual or paper sign up, contracting or LoA emission will be possible, because it would not be feasible in the delays*
- *In Article I and Annex 1: "Handling Cost: this is a fee of 425 Euros per substance charged by ReachCentrum for emission of token and Letter of Access using the electronic SIEF Agreement sign-up tool". This is additional to the other LoA costs (dossier and administration cost share, Advantage Compensation Payment)*
- *In Annex 1: Payment and Access conditions – calculation of "conservative" estimate of LoA cost, payment before Token emission and reimbursement depending on number of LoA purchased and after provisions for additional costs after Registration deadline, as explained above*

Signature of the SIEF Agreement will be necessary to obtain access to the Joint Registration dossier and does not result in Membership of the IP Consortium.

### **Dossier development status and work ongoing**

The 2010 IP substances are currently at the phase of draft IUCLID finalisation by our service provider (Harlan) and (for classified substances) CSR and risk scenario verification by Lead Companies. A few tests and studies are still pending, in particular to confirm GHS status for several substances.

A Testing Proposal for a 90-day toxicity study will be submitted for one pyrophosphate, to be used (referred) for read-across for all other pyrophosphates.

After checking of these dossiers, our objective is to start dossier submission in late August 2010, and to complete submission of all nearly all 2010 substance dossiers, unless unpredicted issues or delays arise, by end September 2010.

Following comments received after making these documents available on our website after our email of 30/3/2010, the following documents have been updated on the Consortium website.

Please consult these taking into account the indications below:

- SIP substance identity (sameness) specification
- Harmonised GHS classification and labelling
- Tables of uses and applications
- Budget estimate tool

- SIEF Agreement Contract

### **SIP – substance identity (sameness) specifications**

The IP substance sameness (SIP) includes specifications of **composition, impurities, granulometry and when applicable pH** of aqueous solutions.

The SIP is included in the SIEF Agreement Contract.

Each registrant (including the Lead Registrant) will have to specify separately the impurities in their own product, in the company-specific (confidential) part of their Registration submission (IUCLID §1.2). However, REACH is unclear as to how to take into account in the Joint Registration the ranges of purity, impurities, granulometry, pH, of substances as placed on the market by different registrants. The IP Consortium will adopt the following approach.

- The Registration Dossier, and in particular the hazard assessments will address the pure substance, but **will also cover the substance (as placed on the market) if and only if purity and impurities, granulometry and pH (if applicable) are conform to the levels indicated in the Consortium SIP.**
- If a Registrant's substance does not conform to the IP sameness SIP specifications then the Registrant **MUST** justify that the differences do not modify the IUCLID 5 and CSR conclusions and do not require a different Classification and Labelling or different exposure scenarios. This is your legal obligation and responsibility.
- Such information must be provided in the company specific (confidential) registration dossier, and may result in additional Fees being payable to ECHA.

### **Harmonised GHS C&L classification for all IP substances (2010, 2013 and 2018 registration substances).**

The table online now specifies for which substances the IP harmonised classification is now "final" (will not be reconsidered in 2010 and has already been or will be notified by IP companies or including in REACH Registration), or is "still pending" (awaiting confirmation or clarification by studies still ongoing)

We remind you that for all substances which your company is NOT registering in 2010 (even if IP is submitting the Joint Registration in 2010), the notification within the deadline of your company's GHS Classification and Labelling and the conformity of your packaging are your own company's responsibility.

### **Tables of uses and applications**

The uses and applications which the IP Consortium intends to cover in the Joint Registration dossier (2010 substances only) are indicated in the tables already circulated to the SIEFs and updated on the Consortium website.

The SIEFs were already consulted on these tables and information transmitted to the Consortium has been taken into account. If you nonetheless find uses which you think are NOT covered, you should indicate these to us as soon as possible: it may or may not be possible to take into account in the Joint Submission at this late stage.

Please note that we will **NOT** take into consideration tables or lists of uses transmitted: we will only take into consideration specific proposals for additions or modifications, based on

the proposed tables online, formulated precisely as “add XXX code under YYY use and sector” or similar, and sent to us with short appropriate explanation.

### **CSR submission**

For "Not Classified" substances (under GHS), the IP Consortium will include the CSR (Chemical Safety Report, and IUCLID \$11 Guidance for Safe Use) within the Joint Registration dossier, because these will be simple and are unlikely to be subject to future modification.

For "Classified" substances, a standard model CSR (and IUCLID \$11 Guidance for Safe Use) will be made available by the Consortium (to all companies having paid for LoA), taking into account the uses and applications covered by the Consortium (see above), but the CSR (and IUCLID \$11) will be then submitted separately as part of each registrant's company specific registration information. The standard CSR can thus be either submitted as provided, or can be extended by each registrant to include its own or its downstream users specific uses or applications. In this case, any future updating of the CSR to include new uses will therefore be the responsibility of each registrant.

### **For further information and access to documents:**

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

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## **List of substances which will be registered for 2010 by the IP Consortium**

**Substances NOT listed below will NOT be registered in 2010 by the IP Consortium.**

NOTE: the Joint Registration Dossier will be submitted using the substance name and EINECS number in **bold and marked with \*** below ONLY. The other names and EINECS numbers given below will be indicated in the Dossier as being covered because considered to be the same substance.

IP	Chemical name(s)	EINECS N°(s)	CAS N°(s)	Lead Registrant
2	<b>Sodium dihydrogenorthophosphate *</b> Monosodium phosphate	<b>231-449-2 *</b>	7558-80-7, 13472-35-0, 10049-21-5	Thermphos International
3	<b>Disodium hydrogenorthophosphate *</b> Disodium phosphate	<b>231-448-7 *</b>	7558-79-4, 10028-24-7, 10039-32-4, 7782-85-6	Thermphos International
4	<b>Trisodium orthophosphate *</b>	<b>231-509-8 *</b>	7601-54-9, 10101-89-0, 15819-50-8, 10361-89-4, 60593-58-0, 60593-59-1	Thermphos International
5	<b>Disodium dihydrogenpyrophosphate *</b>	<b>231-835-0 *</b>	7758-16-9	Thermphos International

	Sodium (acid) pyrophosphate			
6	<b>Trisodium hydrogen diphosphate *</b>	<b>238-735-6 *</b>	14691-80-6, 26573-04-6, 16457-94-6	Thermphos International
	Trisodium pyrophosphate			
7	<b>Tetrasodium pyrophosphate *</b>	<b>231-767-1 *</b>	7722-88-5, 13472-36-1	Thermphos International
8	<b>Trisodium trimetaphosphate *</b>	<b>232-088-3 *</b>	7785-84-4	BK Giuliani
	Sodium trimetaphosphate			
10	<b>Sodium metaphosphate *</b>	<b>233-343-1 *</b>	10124-56-8	BK Giuliani
12	<b>Potassium dihydrogenorthophosphate *</b>	<b>231-913-4 *</b>	7778-77-0	Prayon
	Monopotassium phosphate			
13	<b>Dipotassium hydrogenorthophosphate *</b>	<b>231-834-5 *</b>	7758-11-4	Prayon
	Dipotassium phosphate			
55	<b>Potassium pentahydrogen bis(phosphate) *</b>	<b>238-961-5 *</b>	14887-42-4	Prayon
15	<b>Tetrapotassium pyrophosphate *</b>	<b>230-785-7 *</b>	7320-34-5, 79102-70-8, 7790-67-2	BK Giuliani
16	<b>Pentapotassium triphosphate *</b>	<b>237-574-9 *</b>	13845-36-8, 66904-52-7	BK Giuliani
	Potassium tripolyphosphate			
21	<b>Calcium bis(dihydrogenorthophosphate) *</b>	<b>231-837-1 *</b>	7758-23-8, 10031-30-8	Chemische Fabrik Budenheim
	Monocalcium phosphate			
22	<b>Calcium hydrogenorthophosphate *</b>	<b>231-826-1 *</b>	7757-93-9, 7789-77-7	Chemische Fabrik Budenheim
	Dicalcium phosphate			
60	MCP-DCP Reaction Mass <b>MDCP *</b>	<b>233-283-6 *</b>	10103-46-5	Roullier
23	<b>Tricalcium bis(orthophosphate) *</b>	<b>231-840-8 *</b>	7758-87-4	Chemische Fabrik Budenheim
	Beta-tricalcium phosphate			
24	Bone Ash	270-423-5, 215-145-7, <b>235-330-6 *</b>	68439-86-1, 1306-06-5, 12167-74-7	Chemische Fabrik Budenheim
	Hydroxylapatite			
	Tricalcium phosphate			
	<b>Pentacalcium hydroxide tris(orthophosphate) *</b>			
29	<b>Magnesium hydrogenorthophosphate *</b>	<b>231-823-5 *</b>	7757-86-0, 7782-75-4	Chemische Fabrik Budenheim
	Dimagnesium phosphate			
39	<b>Aluminium tris dihydrogenphosphate *</b>	<b>236-875-2 *</b>	13530-50-2	Chemische Fabrik Budenheim
	Monobasic aluminium phosphate			
47	<b>Disodium fluorophosphates *</b>	<b>233-433-0 *</b> 231-552-2	10163-15-2, 7631-97-2	BK Giuliani
48	<b>Ortho phosphoric acid *</b> Phosphoric acid	<b>231-633-2 *</b>	7664-38-2	FMC Foret

**Note :** the three substances STPP, MAP, DAP are NOT being registered by this Consortium (IP) but by other Consortia (STPP Consortium, FARM). LoA purchase can be also made via the ReachCentrum LOAShop <http://loashop.reachcentrum.eu> under the financial conditions defined by the relevant Consortia. This is indicated for information only, and is independent of the IP Consortium.

IP	Chemical name(s)	EINECS N°(s)	CAS N°(s)
Not applicable	Sodium tripolyphosphate (STPP)	231-838-7, 237-004-9	7758-29-4, 13573-18-7, 15091-98-2
	Pentasodium triphosphate		
	Ammonium dihydrogenorthophosphate	231-764-5, 233-330-0	7722-76-1, 10124-31-9
	Monoammonium phosphate (MAP)		
	Diammonium hydrogenorthophosphate	231-987-8	7783-28-0
	Diammonium phosphate (DAP)		