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Objet : Inorganic Phosphates REACH dossier update

To all members of the REACH SIEFs for the inorganic phosphate substances listed below.

15th March 2010

This email provides updated information for the relevant SIEF members concerning the REACH Registration Dossier development for the approx 40 inorganic phosphates covered by the « IP Consortium » and listed below.

It updates the information already circulated by email to the SIEFs 9/2009, 12/2008, 5/2009.

For further information and access to documents cited below:

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

Contact:

ip@reachcentrum.eu

Dossier development status and work ongoing

By developing these dossiers together, and in close cooperation with Consortia covering other related substances (in particular FARM) significant time and cost savings will be achieved through grouping of substances and read-across.

As already indicated, the initial data gap assessment (contracted to HARLAN) for these substances was completed mid 2009. Our past emails requested all SIEF members to communicate to us any data or studies in their possession and not already included in the list of studies identified by the IP Consortium, list which was made available to the SIEFs 12/2008 and again 9/2009. The information received has been taken into account in the attached summary data gap assessment and studies list.

Following this, progress is ongoing with the following tasks:

- finalisation of **substance identity (sameness)**, including specifications of **composition, impurities, granulometry and when applicable pH** of aqueous solutions
- updating study plans as a function of further information becoming available, results of studies delivered to date, ongoing assessment of available literature and data, progress of dossier writing
- dossier writing for 2010 Registration dossiers only. The objective for these dossiers is to have draft finalised IUCLID and CSR (see "CSR submission" below) files available for discussion within the IP Consortium by April 2010
- preparation of **GHS C&L classification proposals** for all IP substances: completed except where pending results of specific studies
- **tables of uses and applications** which the IP Consortium intends to cover in the Joint Registration dossier for each substance: for some substances tables are now on the Consortium website, for others they will be placed there soon.

Also, the studies identified as necessary to complete the Registration Dossier have been launched as follows:

1) For all substances, whatever the Registration deadline:

- physico-chemical studies, where Reach-conform data was not available and where waivers are not possible, where necessary for each substance but where possible for only one substance within different "groupings" of phosphate types (in order to minimise study costs by read-across and grouping). These studies are largely completed and draft reports have been circulated to IP Consortium members.
- studies necessary to clarify GHS classification for a number of substances (2010 GHS classification deadline for all substances irrespective of tonnage). These studies have been agreed within the IP Consortium and are now underway.

2) For 2010 Registration deadline substances only:

- where unavoidable, missing toxicology, genotoxicology and ecotoxicology studies, again using grouping and read-across to minimise testing necessary. These studies have been agreed within the IP Consortium and are now underway.

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 the IP substances for your approval** (at present, one text, but before signature we will issue one agreement text for each IP substance). This text is based closely on the standard industry text proposed by Cefic and now used by many SIEFs. Please note that no reply or comment from you by 15th April 2010 is considered as acceptance of this SIEF Agreement for the substances for which you are a SIEF member.

Signature of the SIEF Agreement will be done using the specific electronic signature tool which ReachCentrum will open in early May 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 : we nonetheless recommend that you should consider joining the Consortium if you wish to be directly involved with following the dossier registration preparation work.

CSR submission

For "Not Classified" substances (under GHS), the IP Consortium intends to include the CSR (Chemical Safety Report) within the Joint Registration dossier, because this will be very simple.

For "Classified" substances, a standard model CSR will be made available by the Consortium, taking into account the uses and applications covered by the Consortium (see documents), but the CSR will 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. In this case, updating the CSR to include new uses will therefore be the responsibility of each registrant

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Documents now made available

The following documents are now available on the Consortium website indicated above

- **SIEF Agreements for your approval** (model document, the same text will be used to produce a specific agreement contract for each IP substance for signature) = NEW

- revised **proposed substance identity and sameness** for all of the IP substances. Please note that there are significant changes for copper phosphates (IP 36 - 38) and for MCP (Mono Calcium Phosphate = IP21) and for IP10. Please note also that the sameness proposal now includes specifications of granulometry range and (in some cases) pH range. You must verify that your own substances conform to both the composition and impurity specifications in the sameness proposals, and the granulometry and pH ranges where given. If not, they will not be covered by the submitted Joint Registration Dossier and/or you will have to provide specific information or studies to demonstrate that your substances' properties do not modify the dossier conclusions.
- **deadline** (tonnage band) for Registration Dossier preparation by the IP Consortium (included in substance sameness document above)
- updated summary of data gap assessment (Harlan, 12/2009)
- GANT Chart summarising the dossier preparation status (1/2010)
- updated **budget estimation tool for Registration Dossier participation** (excel tool, updated 1/2010). This now 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 (see note below on Budget Calculation).
- updated full list of all relevant studies in our possession (1/2010)
- **GHS Classification and Labelling proposals - for comment**
- proposed **tables of uses** to be covered by the CSR to be prepared by the IP Consortium, one for each substance (for some substances, first draft for comment is now on the Consortium website, others will be placed online soon)

What you should do now :

Please examine all the documents indicated above and send to us any additional information or data in your possession or any comment.

In particular, it is important now to

- a) **examine the SIEF Agreement(s) text.** No reply or comment from you by end April 2010 is considered as acceptance of this text for the SIEFs for which you are a member. Electronic signature will be possible from early May and will be necessary to obtain Letter of Access.
- b) **examine the GHS classification proposals** and make known to us by end April 2010 and disagreements with the proposed classifications, and also indicate and provide details of any specific forms of substances placed on the market which require a different classification and labelling (high concentrations, pH-adjusted preparations, other forms ...)
- c) **examine the proposed uses tables**, if already available or on receiving email notification when they are all online, and indicate any other non-confidential uses or applications (or relevant codes) which are not included in this table

Why join the IP Consortium

Independently of the SIEF Agreement, which covers all registrants wishing to access the Joint Registration, the advantages of joining the IP Consortium now are:

- You will be kept fully informed on a day-to-day basis on the progress and results of work, through being directly involved in the Consortium decision making process and in the Consortium working groups for your concerned substances. SIEF members who are not members of the Consortium will continue to be informed by email or by

other means of progress at key points in the dossier development, within the limits of feasibility and cost of communicating to 38 SIEFs with tens to hundreds of members.

- Specific issues and questions concerning your own products and concerning registration management and administration will be addressed by the Consortium if you become a member (specific issues concerning impurities, mixtures, related substances, analysis required for your own registration submission, administrative information requirements, ...) The Consortium is NOT in a position to answer individual questions or deal with company-specific issues for SIEF members which are not members of the Consortium.
- You can be sure to be ready for participation in the relevant substance(s) Joint Registration(s) within deadlines, by participating in Consortium exchanges and preparation during dossier preparation. This is particularly important for 2010 registration substances. The Consortium will submit the Joint Registration within the deadlines fixed by the REACH Regulation, but (depending on dossier development, study progress, etc) possibly only the minimum time before this deadline.
- Benefit from feedback and learning from the Consortium activities in preparation of Registration for the Consortium substances, and in exchange with Consortia working on related substances (Iron Platform, ZincReach, FARM, STPP Consortium ...)
- Benefit from cost sharing. As specified in the IP Consortium Agreement financial conditions (as made available to all SIEF members in 2008), companies which become Members of the Consortium will benefit from "sharing" of the Registration Dossier development and substance testing costs (as further companies join the Consortium or purchase Letter of Access to the Registration Dossier or to specific studies or data developed by the Consortium). Companies which choose not to become Members of the Consortium, but instead simply to purchase a Letter of Access for Registration will share costs with the number of Consortium Members at the time of their dossier purchase, but will not benefit from future cost sharing (the Letter of Access is given for a specified cost at a given time, this cost not being subject to modification or reimbursements later)

Budget calculation :

It is not feasible for us to indicate today to SIEF members a « cost per dossier », for a given Registration deadline, because the actual cost to each Registrant will depend :

- on the studies necessary for the substance and for its phosphate group, and for each endpoint (depending on tonnage band for registration). The current budget tool is based on the studies identified as necessary to date, but it is possible that further studies may in fact be required depending on the results of the first phase of studies, on ongoing assessment of information or on information which becomes available in the future.

- on the number of companies finally purchasing (for IP Consortium Members) or having agreed to access the Joint Registration at the time of purchase (for companies not members of the IP Consortium), for the given substance, because relevant dossier and testing costs are shared

- but also on the number of companies purchasing access to the Joint Registration for other IP substances, or purchasing access to the given substance dossier for read-across, because of sharing of the general consortium costs and the costs for studies which are read-across for a group or for several groups of substances

The Excel tool attached therefore allows you to enter the IP Consortium substance or substances which your company is interested in registering, and calculates an estimated cost to your company total for joining the IP Consortium and obtaining access to the

Registration Dossiers for these substances. This calculation assumes that NO OTHER FURTHER COMPANIES will join the IP Consortium or purchase dossier access, either for these substances or for any other Consortium substances (that is : costs are shared between the existing Consortium members plus your own company only). Obviously, it is very likely that a number of further companies will join the Consortium for registration of these or other substances, in which case the dossier costs to your company will be reduced (very, very approximately) "in proportion".

Important notes :

- 1) **Registration deadlines:** For substances for which IP Consortium Members have a later Registration deadline than 2010 (that is <1,000 tonne/year) indicated in the sameness proposals document, the Registration Dossier will NOT be prepared for 2010. If you have an earlier deadline than the one indicated below, it is essential that you communicate this to us IMMEDIATELY so that we can discuss how you can take over leadership of the dossier preparation in order to achieve an earlier date.
- 2) **Information exchanges:** It is a legal obligation for all parties (SIEF members, third parties .) to make known to the SIEF all data and studies relevant for REACH Registration. The IP Consortium is respecting this obligation, as far as is feasible, by making available to the SIEF the list of all studies in our possession or known to us (already done since end 2008, now updated). Please communicate rapidly to us details of any other relevant data or studies in your possession or of which you are aware.
- 3) **Polymers.** After due assessment, the IP Consortium Members consider that a number of inorganic phosphate substances are « polymers » within the definition of REACH (see list below). Consequently, we are not preparing REACH Registration Dossiers for these substances, will not be registering them, and will not contribute financially or in any other way to Registration Dossiers or to any other related activities engaged by other parties.
- 4) **Other inorganic phosphates not covered by the IP Consortium:** A number of inorganic phosphates are NOT covered by the IP Consortium because the dossier preparation for them is being led by the other consortia with which the IP Consortium is collaborating (see list below), or simply because they are not produced by Consortium Members or because their Registration is being managed otherwise. If you are intending to register inorganic phosphates NOT covered by the IP Consortium or by one of these consortia, we would be very interested in exchanging information and data in order to maximise read-across and reduce testing and dossier costs. Please contact us indicating the substance(s) concerned, registration deadlines, and the data you have in your possession.

List of substances covered by the IP Consortium

Registration deadline	IP N°	Chemical name(s)	EINECS N°	CAS N°(s)
1,000++	2	Sodium dihydrogenorthophosphate	231-449-2	7558-80-7
		Monosodium phosphate-anhydrous		13472-35-0
		Monosodium phosphate-dihydrate		10049-21-5
		Monosodium phosphate-monohydrate		
1,000++	3	Disodium hydrogenorthophosphate	231-448-7	7558-79-4
		Disodium phosphate-anhydrous		10028-24-7
		Disodium phosphate-dihydrate		

		Disodium phosphate-dodecahydrate		10039-32-4
		Disodium phosphate-heptahydrate		7782-85-6
1,000++	4	Trisodium orthophosphate	231-509-8	7601-54-9
		Trisodium phosphate-anhydrous		10101-89-0
		Trisodium phosphate-dodecahydrate		15819-50-8
		Trisodium phosphate-hexahydrate		10361-89-4
		Trisodium phosphate-decahydrate		60593-58-0
		Trisodium phosphate-0,5-hydrate		60593-59-1
		Trisodium phosphate-octahydrate		
1,000++	5	Disodium dihydrogenpyrophosphate	231-835-0	7758-16-9
		Sodium pyrophosphate		
		Sodium acid pyrophosphate		
100-1,000	6	Trisodium hydrogen diphosphate	238-735-6	14691-80-6
		Trisodium pyrophosphate		26573-04-6
		Trisodium pyrophosphate-monohydrate		16457-94-6
		Trisodium pyrophosphate-nonahydrate		
1,000++	7	Tetrasodium pyrophosphate	231-767-1	7722-88-5
		Tetrasodium pyrophosphate-decahydrate		13472-36-1
100-1,000 (2010 Registration as "Intermediate" only)	8	Trisodium trimetaphosphate	232-088-3	7785-84-4
		Sodium trimetaphosphate		
1,000++	10	Sodium metaphosphate	233-343-1	10124-56-8
		<i>Sodium hexametaphosphate</i>		
1,000++	12	Potassium dihydrogenorthophosphate	231-913-4	7778-77-0
		Monopotassium phosphate		
1,000++	13	Dipotassium hydrogenorthophosphate	231-834-5	7758-11-4
		Dipotassium phosphate		16788-57-1
		Dipotassium phosphate-trihydrate		78436-04-1
		Dipotassium phosphate-hexahydrate		
100-1,000	14	Tripotassium orthophosphate	231-907-1	7778-53-2
		Tripotassium phosphate		27176-10-9
		Tripotassium phosphate-monohydrate		22763-03-7
		Tripotassium phosphate-trihydrate		22763-02-6
		Tripotassium phosphate-heptahydrate		78436-05-2
		Tripotassium phosphate-nonahydrate		
1,000++	55	Phosphoric acid, potassium salt (2:1)	238-961-5	14887-42-4
		Potassium pentahydrogen bis(phosphate)		
1,000++	15	Tetrapotassium pyrophosphate	230-785-7	7320-34-5
		Tetrapotassium pyrophosphate-monohydrate		79102-70-8
		Tetrapotassium pyrophosphate-trihydrate		7790-67-2
1,000++	16	Pentapotassium triphosphate	237-574-9	13845-36-8
		Potassium tripolyphosphate		66904-52-7
		Potassium tripolyphosphate-dihydrate		
1,000++	21	Calcium bis(dihydrogenorthophosphate)	231-837-1	7758-23-8
		Monocalcium phosphate anhydrous		10031-30-8
		Monocalcium phosphate 1-hydrate		
1,000++	22	Calcium hydrogenorthophosphate	231-826-1	7757-93-9
		Dicalcium phosphate anhydrous		7789-77-7
		Dicalcium phosphate 2-Hydrate		
1,000++	23	Tricalcium bis(orthophosphate)	231-840-8	7758-87-4
		Beta-tricalcium phosphate		
1,000++	24	Hydroxylapatite	215-145-7	1306-06-5
		Hydroxyapatite		
		Tricalcium phosphate		

		Pentacalcium hydroxide tris(orthophosphate)	235-330-6	12167-74-7
100-1,000	25	Calcium dihydrogenpyrophosphate	238-933-2	14866-19-4
		Calcium acid pyrophosphate		
10 - 100	26	Dicalcium pyrophosphate	232-221-5	7790-76-3
		Calcium pyrophosphate		
100-1,000	27	Iron orthophosphate	233-149-7	10045-86-0
		Ferric-III orthophosphate		
100-1,000	28	Tetrairon tris(pyrophosphate)	233-190-0	10058-44-3
		Ferric-III pyrophosphate		
1,000++	29	Magnesium hydrogenorthophosphate	231-823-5	7757-86-0
		Dimagnesium phosphate anhydrous		7782-75-4
		Dimagnesium phosphate 3-hydrate		
		Magnesium hydrogen phosphate trihydrate		
10-100	30	Trimagnesium bis(orthophosphate)	231-824-0	7757-87-1
		Trimagnesium phosphate 4-hydrate		
		Trimagnesium phosphate 5-hydrate		
		Trimagnesium phosphate 8-hydrate		
100-1,000	31	Magnesium bis(dihydrogenorthophosphate)	236-004-6	13092-66-5
		Monomagnesium phosphate 4-hydrate		
100-1,000	57	Magnesium pyrophosphate	236-595-0	13446-24-7
1-10	58	Magnesium dihydrogenpyrophosphate	244-016-8	20768-12-1
1-10	33	Trimanganese bis(orthophosphate)	237-997-9	14154-09-7
		Trimanganese phosphate 3-hydrate		
1-10	34	Manganese bis(dihydrogen phosphate)	242-520-2	18718-07-5
		Monomanganese phosphate		
1-10	35	Manganese hydrogen phosphate	257-147-0	51349-94-1
		Dimanganese phosphate 2-Hydrate		
1-10	36	Tricopper bis(orthophosphate)	232-254-5	7798-23-4
		Tricopper (II)-phosphate		
100-1,000	37	Diphosphoric acid, copper salt	233-279-4	10102-90-6
		Copper (II)-pyrophosphate		
10-100	37B	Dicopper pyrophosphate	239-250-2	15191-80-7
10-100	38	Dicopper hydroxide phosphate	235-285-2	12158-74-6
		Copper (II)-hydroxyphosphate		
1,000++	39	Aluminium tris dihydrogenphosphate	236-875-2	13530-50-2
		Monobasic aluminium phosphate		
100-1,000	40	Aluminium orthophosphate	232-056-9	7784-30-7
		Aluminium phosphate trihydrate		22784-12-9
		Tribasic aluminium phosphate		
100-1,000	41	Aluminium dihydrogen triphosphate	237-714-9	13939-25-8
		Aluminium tripolyphosphate		
100-1,000	43	Phosphoric acid, aluminium sodium salt	232-090-4	7785-88-8
		Sodium aluminium phosphate 1:3:8		
		Sodium aluminium phosphate 3:2:8		
		Sodium aluminium phosphate		
100-1,000	44	Boron orthophosphate	236-337-7	13308-51-5
		Boron phosphate		
100-1,000	46	Pentapotassium pentasodium bis(triphosphate)	246-156-5	24315-83-1
		Sodium potassium tripolyphosphate		
1,000++	47	Disodium fluorophosphate	233-433-0	10163-15-2

WILL NOT BE REGISTERED BY "IP" CONSORTIUM

-----> considered to be POLYMERS

	9	Polyphosphoric acids, sodium salts	272-808-3	68915-31-1
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	11	Grahams salt	233-782-9	10361-03-2
		Sodium metaphosphate insoluble		
	17	Potassium metaphosphate		7790-53-6
		Potassium polyphosphate		
		Polyphosphoric acids, potassium salts		
		Kurroll's salt		
	20	Polyphosphoric acids, ammonium salts	269-789-9	68333-79-9
		Ammonium polyphosphate		14728-39-3
	32	Magnesium dimetaphosphate	237-000-7	13573-12-1
	42	Aluminium metaphosphate	237-415-3	13776-88-0
	45	Sodium calcium polyphosphate	245-490-9 233-782-9	23209-59-8
		Metaphosphoric acid, calcium sodium salt		85049-55-4
		Polyphosphoric acid calcium sodium salt		
	49	Polyphosphoric acid(s)	232-417-0	8017-16-1
	50	Pyrophosphoric acid(s)	219-574-0	2466-09-3

**WILL NOT BE REGISTERED BY "IP" CONSORTIUM
-----> covered by "STPP" consortium**

	0	Sodium tripolyphosphate	231-838-7	7758-29-4
		Pentasodium triphosphate		13573-18-7
		Sodium triphosphate		
		Sodium tripolyphosphate-hexahydrate		
	1	Triphosphoric acid, sodium salt	237-004-9	15091-98-2
		Sodium triphosphoric acid		

**WILL NOT BE REGISTERED BY THE "IP" CONSORTIUM
-----> covered by "FARM" consortium**

	48	Phosphoric acid	231-633-2	7664-38-2
		Orthophosphoric acid		
	18	Ammonium dihydrogenorthophosphate	231-764-5	7722-76-1
		Phosphoric acid, ammonium salt	233-330-0	10124-31-9
		Monoammonium phosphate		
	19	Diammonium hydrogenorthophosphate	231-987-8	7783-28-0
		Diammonium phosphate		
	51	Urea phosphate	225-464-3	4861-19-2
		Carbamide phosphate	224-534-0	4401-74-5
		Triple Super Phosphate	266-030-3	65996-95-4

**WILL NOT BE REGISTERED BY THE "IP" CONSORTIUM
-----> covered by "ZincReach" consortium**

	52	Zinc bis(dihydrogen phosphate)	237-067-2	13598-37-3
		Monozinc phosphate 2-Hydrate		
	53	Trizinc bis(orthophosphate)	231-944-3	7779-90-0
		Trizinc phosphate 2-hydrate		
	54	Dizinc pyrophosphate	231-203-4	7446-26-6
		Zinc pyrophosphate		