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De : "IP Consortium" <ip@reachcentrum.eu>
Envoyé : dimanche 6 septembre 2009 21:57
Joindre : IP consortium costs calculation 31-8-09.xls; IP3 proposal and testing plan 7-2009.pdf; IP2 data gap assessment 31-8-09.pdf; IP4 Consortium List of Studies 31-8-09.pdf; IP1 Substance sameness survey 31-8-09.pdf
Objet : Inorganic Phosphates Reach Registration

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

6th September 2009

This email provides updated information for the relevant SIEF members concerning the REACH Registration Dossier development for the 38 inorganic phosphates covered by the « IP Consortium » and listed below. By developing these dossiers together, significant time and cost savings will be achieved through grouping of substances and read-across.

As already indicated by emails to the concerned SIEFs (12/2008, 5/2009), a data gap assessment and elaboration of preliminary study plans were contracted to HARLAN for these 38 substances late 2008. This first phase of work is now complete. 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 and made available to the SIEFs end 2008. The information received has been taken into account in the attached data gap assessment and studies list.

As a result of this preliminary assessment, a first series of substance tests has been launched (end July 2009), intended to ensure that full sets of data for physico-chemical properties are available (either per substance or per group, as considered necessary). In particular, full data is being developed, conform to REACH endpoint study protocol specifications, for solubility and hydrolysis, because these are essential to underpin arguments on toxicity, ecotoxicity and exposure. A second phase of tests already identified as unavoidable will be launched shortly, in order to fill important gaps in the data for each group of phosphates.

It is hoped that further testing will not then be necessary, but this will only be confirmed as a function of the results coming from the currently launched tests, and the consistency of these results with the intended substance groupings for read-across.

We attach to this email, for the 38 IP Consortium substances, **FOR COMMENT OF ALL CONCERNED SIEF MEMBERS** :

- proposed « substance identity » (sameness survey, pdf n°1)
- deadline for Registration Dossier preparation by the IP Consortium (included in sameness survey)
- summary of data gap assessment as completed by Harlan (8/ 2009, pdf n°2)
- study proposal and Dossier writing cost estimate (Harlan 7/2009, pdf n°3)
- budget estimation tool for Registration Dossier participation (excel)
- full list of all relevant studies in our possession to date (8/2009, pdf n°4)

For further details of the Inorganic Phosphates Consortium and full information concerning financial conditions, dossier access, and other issues, and for the process of obtaining the list of available studies and information currently in our possessions, please see :

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

What you should do now :

- Verify the proposed Substance Identity (sameness) in the document attached for all substances you intend to register, and send any comment or proposed modification to us at ip@reachcentrum.eu by 30th September 2009 latest. We will consider that “no reply” means acceptance of the proposal.
- Inform us immediately if you have a higher tonnage band than that indicated in the Substance Identity document. Unless otherwise confirmed, the Joint Registration dossier will not be submitted by the IP Consortium before the deadline corresponding to the tonnage band indicated in this document.
- Verify the list of studies, the summary of the data gap assessment and the study plan, for all substances for which you are susceptible to hold or be aware of data or studies, and inform us immediately at ip@reachcentrum.eu of any relevant information not included in or taken into account in these documents. We remind you that it is your legal obligation under REACH to inform the SIEF of all relevant information in your possession, even for substances you do not intend to register.
- Decide whether and for which substances you wish to join the IP Consortium, referring to the budget estimation tool and to the full details of the Consortium available via <http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/ip-reach-consortium.aspx>) In particular, please refer to the financial and administrative conditions of the IP Consortium Agreement, available on request from ip@reachcentrum.eu

Why join the IP Consortium

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 sub substances. SIEF members who are not members of the Consortium will be informed by email or by other means of progress at regular periods, 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 (impurities, mixtures, related substances, analysis required for your own registration submission ...) and concerning registration management and administration will be addressed by the Consortium. The Consortium is not in a position to answer individual questions from other SIEF members.
- Be sure to be ready for participation in the relevant substance(s) Joint Registration (s) within deadlines. This is particularly important for 2010 registration substances. The Consortium will submit the Joint Registration within the deadlines.
- 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, 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 later)

Budget calculation :

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

- on the studies necessary for the substance and for its phosphate group. The current budget tool is based on the studies identified as necessary by the July 2009 data gap assessment, but it is possible that further studies may in fact be required depending on the results of the first phase of studies
- on the number of companies joining the IP Consortium and entering the Joint Registration, for the given substance, because relevant dossier and testing costs are shared between IP Consortium Members
- but also on the number of companies joining the IP Consortium and entering the Joint Registration for other substances, 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 Consortium for Registration of these substances. This calculation assumes that NO OTHER FURTHER COMPANIES will join the Consortium, 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 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), the Registered 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 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 (attached). 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 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 and the data you have in your possession.

For further details of the Inorganic Phosphates Consortium see :

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

Contact:

ip@reachcentrum.eu

List of substances covered by the IP Consortium

| IP ref | Chemical name(s) | EINECS N° | CAS N°(s) |
|--------|--|-----------|------------|
| 2 | Sodium dihydrogenorthophosphate | 231-449-2 | 7558-80-7 |
| | Monosodium phosphate-anhydrous | | 13472-35-0 |
| | Monosodium phosphate-dihydrate | | 10049-21-5 |
| | Monosodium phosphate-monohydrate | | |
| 3 | Disodium hydrogenorthophosphate | 231-448-7 | 7558-79-4 |
| | Disodium phosphate-anhydrous | | 10028-24-7 |
| | Disodium phosphate-dihydrate | | 10039-32-4 |
| | Disodium phosphate-dodecahydrate | | 7782-85-6 |
| | Disodium phosphate-heptahydrate | | |
| 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 | | |
| 5 | Disodium dihydrogenpyrophosphate | 231-835-0 | 7758-16-9 |
| | Sodium pyrophosphate | | |
| | Sodium acid pyrophosphate | | |
| 6 | Trisodium hydrogen diphosphate | 238-735-6 | 14691-80-6 |
| | Trisodium pyrophosphate | | 26573-04-6 |
| | Trisodium pyrophosphate-monohydrate | | 16457-94-6 |
| | Trisodium pyrophosphate-nonahydrate | | 7722-88-5 |
| 7 | Tetrasodium pyrophosphate | 231-767-1 | 13472-36-1 |
| | Tetrasodium pyrophosphate-decahydrate | | |
| 8 | Trisodium trimetaphosphate | 232-088-3 | 7785-84-4 |
| | Sodium trimetaphosphate | | |
| 10 | Sodium metaphosphate | 233-343-1 | 10124-56-8 |
| | <i>Sodium hexametaphosphate</i> | | |
| 12 | Potassium dihydrogenorthophosphate | 231-913-4 | 7778-77-0 |
| | Monopotassium phosphate | | |
| 13 | Dipotassium hydrogenorthophosphate | 231-834-5 | 7758-11-4 |
| | Dipotassium phosphate | | 16788-57-1 |
| | Dipotassium phosphate-trihydrate | | 78436-04-1 |
| | Dipotassium phosphate-hexahydrate | | |
| 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 | | |
| 55 | Phosphoric acid, potassium salt (2:1) | 238-961-5 | 14887-42-4 |
| | Potassium pentahydrogen bis(phosphate) | | |

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|----|---|-----------|------------|
| 15 | Tetrapotassium pyrophosphate | 230-785-7 | 7320-34-5 |
| | Tetrapotassium pyrophosphate-monohydrate | | 79102-70-8 |
| | Tetrapotassium pyrophosphate-trihydrate | | 7790-67-2 |
| 16 | Pentapotassium triphosphate | 237-574-9 | 13845-36-8 |
| | Potassium tripolyphosphate | | 66904-52-7 |
| | Potassium tripolyphosphate-dihydrate | | |
| 21 | Calcium bis(dihydrogenorthophosphate) | 231-837-1 | 7758-23-8 |
| | Monocalcium phosphate anhydrous | | 10031-30-8 |
| | Monocalcium phosphate 1-hydrate | | |
| 22 | Calcium hydrogenorthophosphate | 231-826-1 | 7757-93-9 |
| | Dicalcium phosphate anhydrous | | 7789-77-7 |
| | Dicalcium phosphate 2-Hydrate | | |
| 23 | Tricalcium bis(orthophosphate) | 231-840-8 | 7758-87-4 |
| | Beta-tricalcium phosphate | | |
| 24 | Hydroxylapatite | 215-145-7 | 1306-06-5 |
| | Hydroxyapatite | | |
| | Tricalcium phosphate | 235-330-6 | 12167-74-7 |
| | Pentacalcium hydroxide tris(orthophosphate) | | |
| 25 | Calcium dihydrogenpyrophosphate | 238-933-2 | 14866-19-4 |
| | Calcium acid pyrophosphate | | |
| 26 | Dicalcium pyrophosphate | 232-221-5 | 7790-76-3 |
| | calcium pyrophosphate | | |
| 27 | Iron orthophosphate | 233-149-7 | 10045-86-0 |
| | Ferric-III orthophosphate | | |
| 28 | Tetrairon tris(pyrophosphate) | 233-190-0 | 10058-44-3 |
| | Ferric-III pyrophosphate | | |
| 29 | Magnesium hydrogenorthophosphate | 231-823-5 | 7757-86-0 |
| | Dimagnesium phosphate anhydrous | | 7782-75-4 |
| | Dimagnesium phosphate 3-hydrate | | |
| | Magnesium hydrogen phosphate trihydrate | | |
| 30 | Trimagnesium bis(orthophosphate) | 231-824-0 | 7757-87-1 |
| | Trimagnesium phosphate 4-hydrate | | |
| | Trimagnesium phosphate 5-hydrate | | |
| | Trimagnesium phosphate 8-hydrate | | |
| 31 | Magnesium bis(dihydrogenorthophosphate) | 236-004-6 | 13092-66-5 |
| | Monomagnesium phosphate 4-hydrate | | |
| 33 | Trimanganese bis(orthophosphate) | 237-997-9 | 14154-09-7 |
| | Trimanganese phosphate 3-hydrate | | |
| 34 | Manganese bis(dihydrogen phosphate) | 242-520-2 | 18718-07-5 |
| | Monomanganese phosphate | | |
| 35 | Manganese hydrogen phosphate | 257-147-0 | 51349-94-1 |
| | Dimanganese phosphate 2-Hydrate | | |
| 36 | Tricopper bis(orthophosphate) | 232-254-5 | 7798-23-4 |
| | Tricopper (II)-phosphate | | |
| 37 | Diphosphoric acid, copper salt | 233-279-4 | 10102-90-6 |
| | Copper (II)-pyrophosphate | | |
| 38 | Dicopper hydroxide phosphate | 235-285-2 | 12158-74-6 |
| | Copper (II)-hydroxyphosphate | | |
| 39 | Aluminium tris dihydrogenphosphate | 236-875-2 | 13530-50-2 |
| | Monobasic aluminium phosphate | | |
| 40 | Aluminium orthophosphate | 232-056-9 | 7784-30-7 |
| | Aluminium phosphate trihydrate | | 22784-12-9 |
| | Tribasic aluminium phosphate | | |
| 41 | Aluminium dihydrogen triphosphate | 237-714-9 | 13939-25-8 |
| | Aluminium tripolyphosphate | | |
| 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 | | |
| 44 | Boron orthophosphate | 236-337-7 | 13308-51-5 |

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|----|--|-----------|------------|
| | Boron phosphate | | |
| 46 | Pentapotassium pentasodium bis(triphosphate) | 246-156-5 | 24315-83-1 |
| | Sodium potassium tripolyphosphate | | |
| 47 | Disodium fluorophosphate | 233-433-0 | 10163-15-2 |

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Substances NOT covered by the IP Consortium:

| POLYMERS : | | |
|---|------------|------------|
| The IP Consortium will not prepare or participate in preparation of a Registration Dossier for the following substances which the Consortium considers to be "polymers" under the definitions of REACH | | |
| | EINECS N° | CAS N°(s) |
| Polyphosphoric acids, sodium salts | 272-808-3 | 68915-31-1 |
| Grahams salt | 233-782-9 | 10361-03-2 |
| Sodium metaphosphate insoluble | | |
| Potassium metaphosphate | 232-212-6 | 7790-53-6 |
| Potassium polyphosphate | | |
| Polyphosphoric acids, potassium salts | | |
| Kurroll's salt | 273-317-7 | 68956-75-2 |
| Polyphosphoric acids, ammonium salts | 269-789-9 | 68333-79-9 |
| Ammonium polyphosphate | | 14728-39-3 |
| Magnesium dimetaphosphate | 237-000-7 | 13573-12-1 |
| Aluminium metaphosphate | 237-415-3 | 13776-88-0 |
| Sodium calcium polyphosphate | 245-490-9 | 23209-59-8 |
| Metaphosphoric acid, calcium sodium salt | 233-782-9 | |
| Polyphosphoric acid calcium sodium salt | | 85049-55-4 |
| Polyphosphoric acid(s) | 232-417-0 | 8017-16-1 |
| Pyrophosphoric acid(s) | 219-574-0 | 2466-09-3 |
| NOT IP Consortium : covered by the STPP Consortium | | |
| See: http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/stpp-reach-consortium.aspx | EINECS N° | CAS N°(s) |
| Sodium tripolyphosphate | 231-838-7 | 7758-29-4 |
| Pentasodium triphosphate | | |
| Sodium triphosphate | 237-004-9 | 13573-18-7 |
| Sodium tripolyphosphate-hexahydrate | | |
| Triphosphoric acid, sodium salt | | |
| Sodium triphosphoric acid | 15091-98-2 | |
| NOT IP Consortium : covered by the FARM Consortium | | |
| See: http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/farm-reach-consortium.aspx | EINECS N° | CAS N°(s) |
| Phosphoric acid | 231-633-2 | 7664-38-2 |
| Orthophosphoric acid | | |
| Ammonium dihydrogenorthophosphate | 231-764-5 | 7722-76-1 |
| Phosphoric acid, ammonium salt | 233-330-0 | 10124-31-9 |
| Monoammonium phosphate | | |
| Diammonium hydrogenorthophosphate | 231-987-8 | 7783-28-0 |
| Diammonium phosphate | | |
| Urea phosphate | 225-464-3 | 4861-19-2 |
| Carbamide phosphate | 224-534-0 | 4401-74-5 |

| NOT IP Consortium : covered by ZincReach Consortium | | |
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| See: www.reach-zinc.eu | EINECS N° | CAS N°(s) |
| Zinc bis(dihydrogen phosphate) | 237-067-2 | 13598-37-3 |
| Monozinc phosphate 2-Hydrate | | |
| Trizinc bis(orthophosphate) | 231-944-3 | 7779-90-0 |
| Trizinc phosphate 2-hydrate | | |
| Dizinc pyrophosphate | 231-203-4 | 7446-26-6 |
| Zinc pyrophosphate | | |