

Chris Thornton

De: Inorganic Phosphates REACH Consortium [ip@reachcentrum.eu]
Envoyé: lundi 24 mai 2010 09:41
À: Thornton
Objet: REACH merging of SIEFs for Bone ash EC 270-423-5 and Hydroxylapatite 215-145-7 pentacalcium hydroxide tris(orthophosphate) 235-330-6

**To all members of the REACH SIEF Bone ash, EC# 270-423-5
And Hydroxylapatite SIEF EC# 215-145-7**

15th May 2010

In agreement with SONAC, it is considered that Bone Ash is the same substance under REACH as IP24: Hydroxylapatite / pentacalcium hydroxide tris(orthophosphate). It is therefore proposed to merge (*see NOTE below) the two SIEFs

SONAC emailed members of the Bone Ash SIEF in October 2009 indicating that they were volunteering to be Lead Company for Bone Ash. After discussion with the Inorganic Phosphates Consortium, SONAC will NOT Register Bone Ash separately because SONAC and the IP Consortium Members consider it to be the same substance as IP24: hydroxylapatite / pentacalcium hydroxide tris(orthophosphate), EINECS 215-145-7.

It is therefore proposed to "merge" (*) the SIEFs for Bone Ash and Hydroxylapatite.

The Lead Company for the single Registration will be Chemische Fabrik Budenheim with registration deadline 2010 (> 1,000 tonnes).

The REACH Registration Dossier development and management will be carried out by the Inorganic Phosphates Consortium (IP), which is also managing Registration for some 40 other inorganic phosphates and phosphoric acid. 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. Full information about the Consortium, including draft SIEF Agreement Contract, financial and dossier access conditions, list of substances covered, etc, is available at:

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

Contact: ip@reachcentrum.eu

Please note that no reply to this email, or no comment from you, is considered as acceptance of this proposal to merge* these two SIEFs, acceptance of the proposed SIEF Agreement, and acceptance of the proposed Lead Company.

SIEF Agreement

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 IP SIEF Agreement for your approval** (at present, one "model" text for all IP substances, 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.

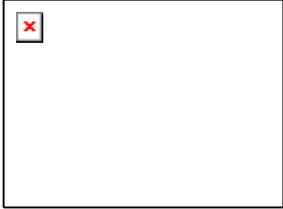
Signature of the SIEF Agreement will be done using the specific electronic signature tool which ReachCentrum will open in early June 2010.

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 : we nonetheless recommend that you should consider joining the Consortium if you wish to be directly involved with following the dossier registration preparation work. Details of conditions are at the above website.

*** NOTE: merging of SIEFs**

One Joint Submission Object only will be created (hydroxylapatite EC 215-145-7). For companies having pre-registered Bone Ash only (and not hydroxylapatite), they will simply register by joining this Joint Submission (hydroxylapatite), using the pre-registration number obtained for Bone Ash, and including a comment in the free text in IUCLID that the two SIEFs have been merged. More precise indications (and model text to insert) will be issued along with other guidance regarding how to prepare your registration (notes on spectra, use of tokens, etc) after your online signature of the SIEF Agreement.

Sameness Proposal for IP24: Hydroxylapatite = pentacalcium hydroxide tris(orthophosphate) = Bone Ash

Inorganic Phosphates (IP) REACH Registration substance sameness proposal	
IP substance number 24	Date: 23/06/09
Type of substance	Composition
	Origin
Reference EC number (s)	mono-constituent inorganic
Other EC numbers considered to be the same substance	215-145-7
EC name	235-330-6 270-423-5
Synonyms	hydroxylapatite / pentacalcium hydroxide tris(orthophosphate) / Bone ash
CAS number (s)	Hydroxy Apatite Calcium Hydroxide Phosphate Pentacalcium Hydroxy Monophosphate Tricalcium Phosphate (frequently used commercial name)
SMILES	1306-06-5 (hydroxylapatite) 12167-74-7 (Calcium Hydroxide Phosphate)
EU food legislation number / INS n°	[OH-].[O-]P(=O)([O-])[O-].[O-]P(=O)([O-])[O-].[O-]P(=O)([O-])[O-].[Ca+2]. .[Ca+2].[Ca+2].[Ca+2]
Molecular formula (or formulae)	E341iii (same as IP23)
Structure image or diagram (indicative)	Ca ₅ (PO ₄) ₃ OH or 10 CaO ₃ (P ₂ O ₅)H ₂ O or Ca ₅ HO ₁₃ P ₃ (hydroxylapatite)
Molecular weight (or range)	
Granulometry range	502
pH range for aqueous solution	More than 10 % of particles have a diameter of <100 µm

Impurities
The Registration Dossier prepared will address the pure substance. Each registrant will have to specify separately the impurities in their own product, in the company-specific (confidential) part of the joint registration dossier.
The Registration Dossier, and in particular the Classification and Labelling proposals and hazard

assessment will assume that substance as placed on the market conforms to the following:			
Purity	Typical purity of substance	> 90 %	Expressed as % dry weight , that is excluding water
	Lower content	> 70 %	
	Higher content	100 %	
The substance may contain the following main impurities, derived from the production process:			
Impurities in the substance	Calcium hydrogenorthophosphate - # EINECS : 231-826-1	< 25%	
	Calcium carbonate - # EINECS : 207-439-9	< 10 %	
	All other impurities > 5% are other inorganic phosphates or other related inorganic substances, similar to the Registered substance, and which do not significantly affect its toxicological and ecotoxicological properties		
	All hazardous impurities are < 0.1%		

Proposed tonnage band	
The IP Consortium is currently planning to prepare registration for this substance conform to the REACH deadline for the following tonnage band	>1,000 tonnes/year

Proposed GHS Classification	Not Classified
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Lead Registrant	Budenheim Chemische Fabrik
Dossier Management and SIEF relations	IP (Inorganic Phosphates) Consortium Secretariat = ReachCentrum Contact: ip@reachcentrum.eu
	http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/ip-reach-consortium.aspx
Technical work	Harlan Laboratories, UK