

Chris Thornton

De: Inorganic Phosphates REACH Consortium [ip@reachcentrum.eu]
Envoyé: jeudi 3 juin 2010 21:39
À: thornton
Objet: REACH SIEF merger and dossier preparation - MDCP - calcium phosphate reaction mass

To all members of the REACH SIEFs for calcium phosphates MDCP (EC 233-283-6) and MCP-DCP reaction mass

3rd June 2010

Substances concerned

MDCP calcium phosphate: EC 233-283-6, CAS 10103-46-5

Reaction mass of MCP calcium bis(dihydrogenorthophosphate) (CAS 7758-23-8 / EC : 231-837-1) and DCP calcium hydrogenorthophosphate (CAS 7757-93-9 / EC : 231-826-1)

Copy for information to SIEFs for MCP (Mono Calcium Phosphate) and DCP (Di Calcium Phosphate)

After discussions between the Roullier Group (FIEF facilitator for the two above mentioned substances), the Inorganic Phosphates (IP) Consortium and the FARM Consortium, it is proposed that the two above substances be considered the same under REACH and that the Lead Registrant (2010 Registration Deadline) shall be Roullier, with dossier management and SIEF relations delegated to the IP Consortium Secretariat, ReachCentrum.

This dossier will be prepared principally by read across from the dossiers currently being developed (for 2010 submission) for IP21 MCP and IP22 DCP (both by the IP Consortium, both with Lead Company Chemische Fabrik Budenheim).

Testing to complete the dossier (physico-chemistry and toxicology) is currently performed at Harlan Laboratories.

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 by end June, 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 late 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.

Sameness Proposal for MDCP (EC 233-283-6) and MCP-DCP reaction mass

REACH Registration substance sameness proposal	
IP substance number IP60 (IP21-IP22 reaction mass)	Date: 3-6-2010
Type of substance	Composition
	Origin
Reference EC number (s)	233-283-6
Other EC numbers considered to be the same substance	None
EC name	Calcium phosphate
Synonyms	MDCP (Mono Di Calcium Phosphate) MCP - DCP Reaction Mass
CAS number (s)	10103-46-5
SMILES	
EU food legislation number / INS n°	Not applicable
Molecular formula (or formulae)	CaHPO4 ; Ca(H2PO4)2
Structure image or diagram (indicative)	removed by email sender
Molecular weight (or range)	420-430
Granulometry range	>1.4mm : 5% max >0.2 mm: 5% max 0 % of particles have a diameter of <100 µm
pH range for aqueous solution	3 to 5

Impurities			
The Registration Dossier prepared will address a "pure" mixture of MCP and DCP conform to the ranges indicated below.			
Each registrant will have to specify separately the conformity of their substance to these content ranges, and 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	Range of MCP content	40-75%	Expressed as % dry weight , that is excluding water
	Range of DCP content	10-40%	
The substance may contain the following main impurities, derived from the production process:			
Impurities in the substance	Tricalcium phosphate (Hydroxylapatite) EC# 215-145-7	< 10%	
	Phosphoric acid EC# 231-633-2	< 5 %	

	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	Classification pending eye irritation studies of MCP and DCP underway
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Lead Registrant	Roullier Group
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Dossier Management and SIEF relations	IP (Inorganic Phosphates) Consortium Secretariat = ReachCentrum Contact: ip@reachcentrum.eu
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<http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/ip-reach-consortium.aspx>

Technical work	Harlan Laboratories, UK
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