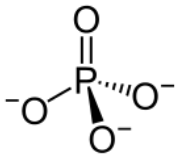

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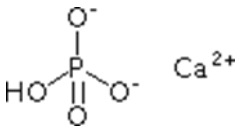
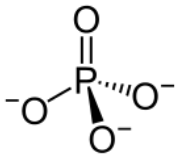
Version
v.4
13/06/2023

SUBSTANCE IDENTIFICATION PROFILE (SIP)

No	1.1. Chemical Name	1.2. EC Number	1.3. CAS Number	1.4. Composition Type
IP22	Calcium hydrogenorthophosphate	231-826-1	7757-93-9	mono-constituent substance

This Substance Identification Profile (SIP) is developed to represent the Identification parameters of the substance described in line with the Substance Identification requirements of REACH Annex VI and relevant guidance for the purpose of identifying the registered substance and the provision of a 'boundary composition' for IUCLID 6 dossier updates.

Reference	SI Parameter	Value / Not necessary / Not for SIP	Remark / Justification
2.1.A	**Name or other Identifiers of the substance**		
	CAS (hydrates)	7789-77-7	
	synonyms	dIcalcium Phosphate (MCP), Dicalcium Orthophosphate, Dibasic calcium phosphate, Brushite	
	SMILES	OP(=O)([O-])[O-].[Ca+2]	
	Molecular formula	CaHPO4 or Ca.H3O4P	
	Structural image / diagram (indicative)		
	EU food legislation number / INS n°	E341ii	
	State / form	Solid: Partiulate / Powder	
	Granulometry range	Up to 100% of particles have a diameter of <100 µm	The substance is considered to be inhalable. Nano forms (in accordance with COMMISSION REGULATION (EU) 2018/1881 of 3 December 2018 on the definition of nanomaterial) have not been identified.
	pH range for aqueous solutions	The pH of the solution observed in the water solubility study was pH 6.5. pH of 10 % suspension acc. to DIN EN ISO 797-9: 5.0 - 8.0	



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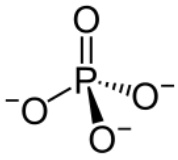
2.1.B	**Substances (with core identifiers) also falling under this substance (with justification)**		
	Name or other Identifiers of the substance	Not applicable	
2.3	**Chemical Composition of the substance**		
2.3.1	**Main Constituent**		
	Name	calcium hydrogenorthophosphate	
	Typical concentration (%w/w)	80%	
	Concentration range (%w/w)	>70 - 100%	
2.3.2	**Typical Impurity / Impurities (above 1% or lower if contributing to the hazard or PBT profile) - create repeat blocks if necessary**		
2.3.2.1	Name -Impurity (1)	Calcium bis(dihydrogenorthophosphate)	
	CAS Number -Impurity (1)	7758-23-8	
	EC Number -Impurity (1)	231-837-1	
	Molecular Formula -Impurity (1)	Ca2(H2PO4)2	
	Typical concentration (%w/w) -Impurity (1)	<10%	
	Concentration range (%w/w) -Impurity (1)	>0 <10%	
	Relevant for classification and labelling?	N	
2.3.2.2	Name -Impurity (2)	Calcium sulphate	
	CAS Number -Impurity (2)	7778-18-9	
	EC Number -Impurity (2)	231-900-3	
	Molecular Formula -Impurity (2)	CaH2O4S	
	Typical concentration (%w/w) -Impurity (2)	<10%	
	Concentration range (%w/w) -Impurity (2)	>0 <10%	
	Relevant for classification and labelling?	N	
2.3.2.3	Name -Impurity (3)	Tricalcium bis(orthophosphate)	
	CAS Number -Impurity (3)	7758-87-4	
	EC Number -Impurity (3)	231-840-8	
	Molecular Formula -Impurity (3)	Ca3(PO4)2	



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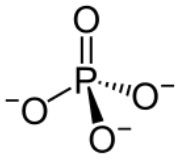
	Typical concentration (%w/w) -Impurity (3)	<5%	
	Concentration range (%w/w) -Impurity (3)	>0 <5%	
	Relevant for classification and labelling?	N	
2.3.2.4	Name -Impurity (4)	mineral phosphate rock	
	CAS Number -Impurity (4)	1306-05-4	
	EC Number -Impurity (4)	215-144-1	
	Molecular Formula -Impurity (4)	N/A	
	Typical concentration (%w/w) -Impurity (4)	<5%	
	Concentration range (%w/w) -Impurity (4)	>0 <5%	
	Relevant for classification and labelling?	N	
2.3.2.5	Name -Impurity (5)	Iron salts - IDENTITY NOT DEFINED	
	CAS Number -Impurity (5)		
	EC Number -Impurity (5)		
	Molecular Formula -Impurity (5)		
	Typical concentration (%w/w) -Impurity (5)	<5%	
	Concentration range (%w/w) -Impurity (5)	>0 >5%	
	Relevant for classification and labelling?	N	
2.3.2.6	Name -Impurity (6)	Magnesium salts - IDENTITY NOT DEFINED	
	CAS Number -Impurity (6)		
	EC Number -Impurity (6)		
	Molecular Formula -Impurity (6)		
	Typical concentration (%w/w) -Impurity (6)	<5%	
	Concentration range (%w/w) -Impurity (6)	>0 >5%	
	Relevant for classification and labelling?	N	
2.3.2.7	Name -Impurity (7)	Pentacalcium hydroxide	



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		tris(orthophosphate)	
	CAS Number -Impurity (7)	12167-74-7	
	EC Number -Impurity (7)	235-330-6	
	Molecular Formula -Impurity (7)	Ca5HO13P3	
	Typical concentration (%w/w) -Impurity (7)	ca. 18 %	
	Concentration range (%w/w) -Impurity (7)	0-20 %	
	Relevant for classification and labelling?	N	
2.3.2.8	Name -Impurity (8)	Silicon dioxide	
	CAS Number -Impurity (8)	7631-86-9	
	EC Number -Impurity (8)	231-545-4	
	Molecular Formula -Impurity (8)	O2Si	
	Typical concentration (%w/w) -Impurity (8)	< 1 %	
	Concentration range (%w/w) -Impurity (8)	0-1 %	
	Relevant for classification and labelling?	N	
2.3.3	**Additives - create block similar to impurities if relevant**		
Not relevant			
2.4	**Classification and labelling**		
Not classified			
2.5	**Justification for deviation from substance identity rules**		
In accordance with ECHA Guidance for identification and naming of substances under REACH and CLP, version 1.4, when the concentration of the main constituent is <70% the following requirement(s) are met: 1. The substance has been shown to have similar physico-chemical properties and the same hazard profile as other mono-constituent substances with the same identity that fulfil the 80% rule. and/or 2. The range of concentrations for the main constituent and the impurities overlap the 80% criterion and the main constituent is only occasionally ≤ 80%.			