

according to Regulation UK SI 2019/758 and UK SI 2020/1577 as amended

Revision Date 29-Sep-2023 Revision Number 5

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1. Product identifier

Product Description: <u>Hydroxylapatite</u>

Cat No.: 371260000; 371260010; 371260250; 371261000

Synonyms Calcium phosphate hydroxide; Durapatite; Calcium phosphate tribasic

 CAS No
 1306-06-5

 EC No
 215-145-7

 Molecular Formula
 H Ca5 O13 P3

 REACH registration number
 01-2119490075-38

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Laboratory chemicals.
Uses advised against No Information available

#### 1.3. Details of the supplier of the safety data sheet

Company

UK entity/business name

Fisher Scientific UK Bishop Meadow Road,

Loughborough, Leicestershire LE11 5RG, United Kingdom

**EU entity/business name** Thermo Fisher Scientific

Janssen Pharmaceuticalaan 3a, 2440 Geel, Belgium

E-mail address begel.sdsdesk@thermofisher.com

1.4. Emergency telephone number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

## **SECTION 2: HAZARDS IDENTIFICATION**

#### 2.1. Classification of the substance or mixture

#### CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567

## **Physical hazards**

Based on available data, the classification criteria are not met

#### **Health hazards**

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Based on available data, the classification criteria are not met

#### **Environmental hazards**

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

#### 2.2. Label elements

None required

#### 2.3. Other hazards

This product does not contain any known or suspected endocrine disruptors

## **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

#### 3.1. Substances

Component	CAS No	EC No	Weight %	CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
Hydroxylapatite (Ca5(OH)(PO4)3)	1306-06-5	EEC No. 215-145-7	100	-

REACH registration number	01-2119490075-38

Full text of Hazard Statements: see section 16

## **SECTION 4: FIRST AID MEASURES**

#### 4.1. Description of first aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Wash off immediately with soap and plenty of water while removing all contaminated

clothes and shoes. Get medical attention.

**Ingestion** Clean mouth with water. Get medical attention.

**Inhalation** Remove from exposure, lie down. Remove to fresh air. Get medical attention.

**Self-Protection of the First Aider** No special precautions required.

## 4.2. Most important symptoms and effects, both acute and delayed

No information available.

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#### 4.3. Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

## **SECTION 5: FIREFIGHTING MEASURES**

#### 5.1. Extinguishing media

#### Suitable Extinguishing Media

Water spray. Carbon dioxide (CO<sub>2</sub>). Dry chemical. Chemical foam.

## Extinguishing media which must not be used for safety reasons

No information available.

#### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

#### **Hazardous Combustion Products**

None known.

#### 5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

#### 6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation.

#### 6.2. Environmental precautions

See Section 12 for additional Ecological Information.

#### 6.3. Methods and material for containment and cleaning up

Avoid dust formation. Sweep up and shovel into suitable containers for disposal. Do not let this chemical enter the environment.

#### 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

## **SECTION 7: HANDLING AND STORAGE**

#### 7.1. Precautions for safe handling

Avoid contact with skin and eyes. Do not breathe dust. Do not ingest. If swallowed then seek immediate medical assistance.

#### **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

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#### 7.2. Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place. Keep container tightly closed.

Technical Rules for Hazardous Substances (TRGS) 510 Class 11

Storage Class (LGK) (Germany)

#### 7.3. Specific end use(s)

Use in laboratories

## **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### 8.1. Control parameters

#### **Exposure limits**

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

#### **Biological limit values**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

#### Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)

No information available

#### **Predicted No Effect Concentration (PNEC)**

No information available.

#### 8.2. Exposure controls

## **Engineering Measures**

None under normal use conditions.

#### Personal protective equipment

**Eye Protection** Wear safety glasses with side shields (or goggles) (European standard - EN 166)

Hand Protection Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Nitrile rubber Neoprene	See manufacturers recommendations	-	EN 374	(minimum requirement)
Natural rubber PVC				

**Skin and body protection**Wear appropriate protective gloves and clothing to prevent skin exposure.

Inspect gloves before use.

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Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

**Respiratory Protection** No protective equipment is needed under normal use conditions.

Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits Large scale/emergency use

are exceeded or if irritation or other symptoms are experienced

Solid

Recommended Filter type: Particle filter

Small scale/Laboratory use Maintain adequate ventilation

**Environmental exposure controls** No information available.

#### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

#### 9.1. Information on basic physical and chemical properties

Powder Solid **Physical State** 

**Appearance** White Odorless Odor

**Odor Threshold** No data available Melting Point/Range 1700 °C / 3092 °F **Softening Point** No data available **Boiling Point/Range** No information available

Flammability (liquid) Not applicable

Flammability (solid,gas) No information available

No data available **Explosion Limits** 

No information available Flash Point Method - No information available

**Autoignition Temperature** Not applicable

No data available **Decomposition Temperature** 

No information available рΗ

Not applicable Solid **Viscosity** 

Water Solubility nealiaible

Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

**Vapor Pressure** No data available **Density / Specific Gravity** No data available **Bulk Density** No data available **Vapor Density** Not applicable

Solid

Particle characteristics No data available

## 9.2. Other information

Molecular Formula H Ca5 O13 P3 **Molecular Weight** 502.31

**Evaporation Rate** Not applicable - Solid

## **SECTION 10: STABILITY AND REACTIVITY**

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10.1. Reactivity

None known, based on information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions No information available.

10.4. Conditions to avoid

Avoid dust formation. Incompatible products.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

None known.

## **SECTION 11: TOXICOLOGICAL INFORMATION**

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### **Product Information**

(a) acute toxicity;

Oral Based on available data, the classification criteria are not met

DermalNo data availableInhalationNo data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydroxylapatite (Ca5(OH)(PO4)3)	LD50 > 25350 mg/kg (Rat)	-	-

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

Respiratory No data available Skin No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; No data available

(h) STOT-single exposure; No data available

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(i) STOT-repeated exposure; No data available

**Target Organs** No information available.

(j) aspiration hazard; Not applicable

Solid

Symptoms / effects,both acute and No information available.

delayed

11.2. Information on other hazards

Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any

known or suspected endocrine disruptors.

## **SECTION 12: ECOLOGICAL INFORMATION**

12.1. Toxicity

**Ecotoxicity effects** Do not empty into drains.

12.2. Persistence and degradability

12.3. Bioaccumulative potential No information available

**12.4. Mobility in soil**No information available

12.5. Results of PBT and vPvB

assessment

No data available for assessment.

12.6. Endocrine disrupting

properties

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects

Persistent Organic Pollutant Ozone Depletion Potential This product does not contain any known or suspected substance This product does not contain any known or suspected substance

## **SECTION 13: DISPOSAL CONSIDERATIONS**

13.1. Waste treatment methods

Waste from Residues/Unused

**Products** 

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Consult local, regional, and national hazardous waste regulations to

ensure complete and accurate classification.

Contaminated Packaging Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use

empty containers.

European Waste Catalogue (EWC) According to the European Waste Catalog, Waste Codes are not product specific, but

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application specific.

Other Information Waste codes should be assigned by the user based on the application for which the product

was used.

## **SECTION 14: TRANSPORT INFORMATION**

IMDG/IMO Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

ADR Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

<u>IATA</u> Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

**14.5. Environmental hazards**No hazards identified

14.6. Special precautions for user No special precautions required.

14.7. Maritime transport in bulk

according to IMO instruments

## **SECTION 15: REGULATORY INFORMATION**

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Not applicable, packaged goods

#### **International Inventories**

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	EINECS	ELINCS	NLP	IECSC	TCSI	KECL	ENCS	ISHL
Hydroxylapatite (Ca5(OH)(PO4)3)	1306-06-5	215-145-7	ı	ı	X	Χ	KE-20608	X	X

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
Hydroxylapatite (Ca5(OH)(PO4)3)	1306-06-5	X	ACTIVE	X	-	X	X	X

**Legend:** X - Listed '-' - Not Listed **KECL** - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

Authorisation/Restrictions according to EU REACH Not applicable

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Component	CAS No	REACH (1907/2006) -	REACH (1907/2006) -	REACH Regulation (EC
_		Annex XIV - Substances	Annex XVII - Restrictions	1907/2006) article 59 -
		Subject to Authorization	on Certain Dangerous	Candidate List of
			Substances	Substances of Very High
				Concern (SVHC)
Hydroxylapatite (Ca5(OH)(PO4)3)	1306-06-5	-	-	=

#### Seveso III Directive (2012/18/EC)

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements
Hydroxylapatite (Ca5(OH)(PO4)3)	1306-06-5	Not applicable	Not applicable

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)? Not applicable

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work .

#### **National Regulations**

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

**WGK Classification** Water endangering class = 2 (self classification)

#### 15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

#### **SECTION 16: OTHER INFORMATION**

## Full text of H-Statements referred to under sections 2 and 3

## Legend

CAS - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b)
Inventory

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical **DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances/EU List of Notified Chemical Substances

Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances
IECSC - Chinese Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
NZIoC - New Zealand Inventory of Chemicals

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WEL - Workplace Exposure Limit

**ACGIH** - American Conference of Governmental Industrial Hygienists

**DNEL** - Derived No Effect Level

**RPE** - Respiratory Protective Equipment **LC50** - Lethal Concentration 50%

**NOEC** - No Observed Effect Concentration **PBT** - Persistent, Bioaccumulative, Toxic

**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

**Training Advice** 

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Revision Date 29-Sep-2023 Revision Summary Not applicable. TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%
POW - Partition coefficient Octanol:Water
vPvB - very Persistent, very Bioaccumulative

**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from Ships

ATE - Acute Toxicity Estimate
VOC - (Volatile Organic Compound)

# This safety data sheet complies with Regulation UK SI 2019/758 and UK SI 2020/1577 as amended.

## Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

## **End of Safety Data Sheet**