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According to REACH Regulations (EC) 1907/2006 and (EU) 2020/878

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product code : GP8618

Product name : Zoledronate disodium salt tetrahydrate

CAS number : 165800-07-7
Physical form : solid, substance

REACH : A registration number is not available for this substance as the substance or its uses

are exempted from registration, the annual tonnage does not require a registration or

the registration is envisaged for a later registration deadline.

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

PC21: Laboratory chemicals.

Details of the supplier of the safety data sheet

Company name : Glentham Life Sciences Ltd Telephone : +44 (0) 1225 667 798

Unit 5 Leafield Way Fax : +44 (0) 2033 978 909
Corsham SN13 9SW Email : info@glentham.com
United Kingdom Web : www.glentham.com

1.4 Emergency telephone number

Emergency telephone: NHS Direct 111 (UK, 24 hours), 112 (EU, 24 Hours), +44 (0) 1225 667 798 (09.00 - 17.00 GMT)

number

1.3

2. Hazards identification

2.1 Classification of the substance or mixture

Classification under CLP according to (EC) 1272/2008

 H315
 Skin Irr. 2

 H319
 Eye Irr. 2A

 H335
 STOT SE 3

 H336
 STOT SE 3

2.2 Label elements

Label elements under CLP according to (EC) 1272/2008

Pictograms



GП30

Signal words Warning

Hazard statements

H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation
H336 May cause drowsiness or dizziness

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapors/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: wash with plenty of water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and

easy to do - continue rinsing.

P264 Do not breathe fume.

2.3 Other hazards

PBT

This substance is not identified as a PBT substance.

3.0 Composition/information on ingredients

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3.1 Substances

Name	Identifier	%	Classification
Zoledronate disodium salt tetrahydrate	CAS: 165800-07-7 EC: REACH: Not applicable		H315, Skin Irr. 2 H319, Eye Irr. 2A H335, STOT SE 3 H336, STOT SE 3

4. First aid measures

4.1 Description of first aid measures

Skin contact	Consult a doctor. Remove all contaminated clothes and footwear immediately unless stuck to skin. Wash immediately with plenty of soap and water.
Eye contact	Consult a doctor. Bathe the eye with running water for 15 minutes.
Ingestion	Consult a doctor. Wash out mouth with water.
Inhalation	Consult a doctor. Remove casualty from exposure ensuring one's own safety whilst doing so.

4.2 Most important symptoms and effects, both acute and delayed

Skin contact	There may be irritation and redness at the site of contact.
Eye contact	The eyes may water profusely. There may be irritation and redness.
Ingestion	There may be soreness and redness of the mouth and throat.
Inhalation	Exposure may cause coughing or wheezing. There may be irritation of the throat with a feeling of tightness in the chest.
Delayed / immediate effects	Immediate effects can be expected after short-term exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Immediate / special treatment

Eye bathing equipment should be available on the premises.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media for the surrounding fire should be used.

5.2 Special hazards arising from the substance or mixture

Exposure hazards

In combustion emits toxic fumes.

5.3 Advice for fire-fighters

Wear protective clothing to prevent contact with skin and eyes. Wear self-contained breathing apparatus.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions

Do not create dust. If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Refer to section 8 of SDS for personal protection details.

6.2 Environmental precautions

Do not discharge into drains or rivers.

6.3 Methods and material for containment and cleaning up

Clean-up procedures

Transfer to a closable, labelled salvage container for disposal by an appropriate method.

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6.4 Reference to other sections

Refer to section 8 of SDS.

7. Handling and storage

7.1 Precautions for safe handling

Handling requirements

Avoid direct contact with the substance. Avoid the formation or spread of dust in the air. Do not handle in a confined space. Ensure there is sufficient ventilation of the area.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Avoid contact with water or humidity. Keep container tightly closed. Store in cool, well ventilated area.

7.3 Specific end use(s)

No data available.

8. Exposure controls/personal protection

8.1 Control parameters

Workplace exposure limits

No workplace exposure limit control parameters set

8.2 Exposure controls

Engineering measures	Ensure there is sufficient ventilation of the area.
Respiratory protection	Respiratory protective device with particle filter. Self- contained breathing apparatus must be available in case of emergency.
Hand protection	Protective gloves.
Eye protection	Ensure eye bath is to hand. Safety glasses.
Skin protection	Protective clothing.

9. Physical and chemical properties

Physical state

9.1 Information on basic physical and chemical properties

White Colour No data available. Odour Melting point/Freezing point No data available. Boiling point/initial boiling point/boiling range No data available. Flammability No data available. No data available. Lower/Upper explosion limit Flash Point No data available. No data available. Auto-ignition temperature No data available. Decomposition temperature No data available. Kinematic viscosity No data available. Solubility No data available. Partition coefficient n-octanol/water No data available. Vapour pressure No data available. No data available Density/relative density Relative vapour pressure No data available. Particle characteristics No data available.

9.2 Other information

No data available.

10. Stability and reactivity

10.1 Reactivity

Stable under recommended transport or storage conditions.

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10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions

Decomposition may occur on exposure to conditions or materials listed below. Hazardous reactions will not occur under normal transport or storage conditions.

10.4 Conditions to avoid

Heat

10.5 Incompatible materials

Materials to avoid

Strong acids. Strong oxidising agents.

11. Toxicological information

11.1 Information on toxicological effects

a) Acute toxicity

No data available.

b) Skin corrosion/irritation

Skin corrosion/irritation (Category 2)

c) Serious eye damage/irritation

Serious eye damage/eye irritation (Category 2A)

d) Respiratory or skin sensitisation

No data available.

e) Germ cell mutagenicity

No data available.

f) Carcinogenicity

No data available.

g) Reproductive toxicity

No data available.

h) STOT-single exposure

Specific target organ toxicity, single exposure; Respiratory tract irritation (Category 3)

i) STOT-repeated exposure

No data available.

j) Aspiration hazard

No data available.

Symptoms / routes of exposure

Skin contact	There may be irritation and redness at the site of contact.
Eye contact	The eyes may water profusely. There may be irritation and redness.
Ingestion	There may be soreness and redness of the mouth and throat.
Inhalation	Exposure may cause coughing or wheezing. There may be irritation of the throat with a feeling of tightness in the chest.
Delayed / immediate effects	Immediate effects can be expected after short-term exposure.
Other information	No data available.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

This product does not contain known or suspected endocrine disruptors according to REACH or relevant EU Regulations.

11.2.2 Other information

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No additional information

12. Ecological information

12.1 Toxicity

No data available.

12.2 Persistence and degradability

Biodegradable.

12.3 Bioaccumulative potential

No bioaccumulation potential.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

This substance is not identified as a PBT substance.

12.6 Endocrine disrupting properties

This substance is not identified as having endocrine disrupting properties

12.7 Other adverse effects

No data available.

13. Disposal considerations

13.1 Waste treatment methods

Disposal operations

Transfer to a suitable container and arrange for collection by specialised disposal company.

NΒ

The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

14. Transport information

This product does not require a classification for transport.

15. Regulatory information

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

This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/878.

Authorisations/Restrictions

Regulation (EC) 1907/2006, REACH, Annex XIV list of substances subject to authorisation:

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Regulation (EC) 1907/2006, REACH, Annex XVII restrictions on the manufacture, placing No data available. on the market and use of certain dangerous substances:

Regulation (EC) 1005/2009 on substances that deplete the ozone layer:

No data available.

Regulation (EC) 850/2004 on persistent organic pollutants, amended by (EU) No

2019/1021:

No data available.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

16. Other information

H-Statement Full Texts

H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation
H336 May cause drowsiness or dizziness

Abbreviations Full Texts

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ADN European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road

ALARP As low as is reasonably practicable

CAS Chemical Abstracts Service

CLP Classification, Labelling and Packaging Regulations

COSHH Control of Substances Hazardous to Health

EC Number European Community Number EC50 Effective Concentration 50%

EILINCS European List of Notified Chemical Substances

EINECS European Inventory of Existing Commercial Chemical Substances

GHS Globally Harmonised System
HSE Health & Safety Executive UK
IATA International Air Transport Association

IM Intramuscular

IMDG The International Maritime Dangerous Goods Code

IP Intraperitoneal IV Intravascular LD50 Lethal Dose 50%

LOEC Lowest Observable Effective Concentration

LTEL Long Term Exposure Limit

NOEC No Observable Effective Concentration

OECD Organisation for Economic Cooperations and Development

PBT Persistent Bioaccumulative Toxic
PPE Personal Protective Equipment

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

RID Regulations Concerning the International Carriage of Dangerous Goods by Rail

SC Subcutaneous
SDS Safety Data Sheet
STEL Short Term Exposure Limit
STOT Specific Target Organ Toxicity
VOC Volatile Organic Compounds

vPvB Very Persistent and Very Bioaccumulative

WEL Workplace Exposure Limits

This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/878.

Disclaimer: Glentham Life Sciences shall not be held liable for any damage resulting from handling or from contact with the above product. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This document does not guarantee the properties or quality of the product.

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