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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 : GC9081

Product name : D(+)-Lactose monohydrate, 99.5%, Ph. Eur. grade

CAS number : 64044-51-5
EINECS : 200-559-2
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.

1.3 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

2. Hazards identification

2.1 Classification of the substance or mixture

Classification under CLP according to (EC) 1272/2008

This product has no classification under CLP.

2.2 Label elements

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

This product has no label elements.

2.3 Other hazards

PBT

This substance is not identified as a PBT substance.

3.0 Composition/information on ingredients

3.1 Substances

Name	Identifier	%	Classification
D(+)-Lactose monohydrate, 99.5%, Ph. Eur. grade	CAS: 64044-51-5 EC: 200-559-2 REACH: Not applicable	99.5%	Not classified

4. First aid measures

4.1 Description of first aid measures

Skin contact	Wash immediately with plenty of soap and water.
Eye contact	Bathe the eye with running water for 15 minutes.
Ingestion	Wash out mouth with water.
Inhalation	Consult a doctor.

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4.2 Most important symptoms and effects, both acute and delayed

Skin contact	There may be mild irritation at the site of contact.
Eye contact	There may be irritation and redness.
Ingestion	There may be irritation of the throat.
Inhalation	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

No data available.

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

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

Wash the spillage site with large amounts of water.

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 the formation or spread of dust in the air.

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

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8.2 Exposure controls

Engineering measures	No data available.
Respiratory protection	Respiratory protective device with particle filter.
Hand protection	Protective gloves.
Eye protection	Ensure eye bath is to hand. Safety glasses.
Skin protection	Protective clothing.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state Colour No data available. Odour Melting point/Freezing point No data available. Boiling point/initial boiling point/boiling range No data available. No data available. Flammability Lower/Upper explosion limit No data available. Flash Point No data available. Auto-ignition temperature No data available. No data available. Decomposition temperature рΗ No data available. Kinematic viscosity No data available No data available. Solubility Partition coefficient n-octanol/water No data available. Vapour pressure No data available. Density/relative density 0.580 Relative vapour pressure No data available.

9.2 Other information

No data available.

Particle characteristics

10. Stability and reactivity

10.1 Reactivity

Stable under recommended transport or storage conditions.

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.

No data available.

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

No data available.

c) Serious eye damage/irritation

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No data available.

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

No data available.

i) STOT-repeated exposure

No data available.

j) Aspiration hazard

No data available.

Symptoms / routes of exposure

Skin contact	There may be mild irritation at the site of contact.
Eye contact	There may be irritation and redness.
Ingestion	There may be irritation of the throat.
Inhalation	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

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



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13.1 Waste treatment methods

Disposal operations

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

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

Transport information 14.

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

No data available.

authorisation:

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 No data available.

2019/1021:

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

Abbreviations Full Texts

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

Classification, Labelling and Packaging Regulations CLP 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

IΡ Intraperitoneal IV Intravascular LD50 Lethal Dose 50%

LOEC Lowest Observable Effective Concentration

LTEL Long Term Exposure Limit

NOFC No Observable Effective Concentration

Organisation for Economic Cooperations and Development OECD

PRT Persistent Bioaccumulative Toxic PPE Personal Protective Equipment

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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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