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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 : GP6515

Product name : Bendamustine hydrochloride

CAS number : 3543-75-7
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.

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

H301 Acute Tox. 3 H341 Muta. 2 H351 Carc. 2 H361 Repr. 2

2.2 Label elements

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

Pictograms





GHS06 GHS08

Signal words Danger

Hazard statements

H301 Toxic if swallowed

H341 Suspected of causing genetic defects H351 Suspected of causing cancer

H361 Suspected of damaging fertility or the unborn child

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/...

P308+P313 IF exposed or concerned: Get medical advice/attention.

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

3.1 Substances

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Name	Identifier	%	Classification
Bendamustine hydrochloride	CAS: 3543-75-7 EC: REACH: Not applicable	99.0%	H301, Acute Tox. 3 H341, Muta. 2 H351, Carc. 2 H361, Repr. 2

4. First aid measures

4.1 Description of first aid measures

Skin contact	Consult a doctor. Drench the affected skin with running water for 10 minutes or longer if substance is still on skin. Remove all contaminated clothes and footwear immediately unless stuck to skin. Transfer to hospital if there are burns or symptoms of poisoning.
Eye contact	Consult a doctor. Transfer to hospital for specialist examination. Bathe the eye with running water for 15 minutes.
Ingestion	Consult a doctor. Do not induce vomiting. If conscious, give half a litre of water to drink immediately. If unconscious and breathing is OK, place in the recovery position. If unconscious, check for breathing and apply artificial respiration if necessary. Transfer to hospital as soon as possible. Wash out mouth with water.
Inhalation	If breathing becomes bubbly, have the casualty sit and provide oxygen if available. If conscious, ensure the casualty sits or lies down. If unconscious and breathing is OK, place in the recovery position. If unconscious, check for breathing and apply artificial respiration if necessary. Remove casualty from exposure ensuring one's own safety whilst doing so. Transfer to hospital as soon as possible. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

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Skin contact	Absorption through the skin may be fatal. Irritation or pain may occur at the site of contact. There may be irritation and redness at the site of contact. There may be redness or whiteness of the skin in the area of exposure.
Eye contact	The eyes may water profusely. There may be irritation and redness. There may be severe pain.
Ingestion	Convulsions may occur. Nausea and stomach pain may occur. There may be loss of consciousness. There may be soreness and redness of the mouth and throat. There may be vomiting.
Inhalation	Absorption through the lungs can occur causing symptoms similar to those of ingestion. Convulsions may occur. Nausea and stomach pain may occur. There may be irritation of the throat with a feeling of tightness in the chest. There may be loss of consciousness. There may be shortness of breath with a burning sensation in the throat. There may be vomiting.
Delayed / immediate effects	Convulsions may occur. Immediate effects can be expected after short-term exposure. Nausea and stomach pain may occur. There may be loss of consciousness.

4.3 Indication of any immediate medical attention and special treatment needed

Immediate / special treatment

 $Do \ not \ induce \ vomiting. \ Immediate \ medical \ attention \ is \ required. \ Show \ this \ safety \ data \ sheet \ to \ the \ doctor \ in \ attendance.$

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

5.2 Special hazards arising from the substance or mixture

Exposure hazards

In combustion emits toxic fumes. Toxic.

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



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6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions

Do not attempt to take action without suitable protective clothing - see section 8 of SDS. 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. Notify the police and fire brigade immediately. 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

Clean-up should be dealt with only by qualified personnel familiar with the specific substance. Transfer to a closable, labelled salvage container for disposal by an appropriate method. Absorb into dry earth or sand.

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 exhaust ventilation of the area. 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 exhaust ventilation of the area. Ensure there is sufficient ventilation of the area.
Respiratory protection	Particle filter class P1 (EN143). Respiratory protective device with particle filter. Self- contained breathing apparatus must be available in case of emergency.
Hand protection	Impermeable gloves. Protective gloves.
Eye protection	Ensure eye bath is to hand. Safety glasses with side-shields. Safety glasses.
Skin protection	Protective clothing.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Solid
White
No data available.
148-151 °C
No data available.

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GP6515 v2.0



Safety Data Sheet

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Kinematic viscosity

Solubility

Partition coefficient n-octanol/water

Vapour pressure
Density/relative density
Relative vapour pressure
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.

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

No data available.

c) Serious eye damage/irritation

No data available.

d) Respiratory or skin sensitisation

No data available.

e) Germ cell mutagenicity

Germ cell mutagenicity (Category 2)

f) Carcinogenicity

No data available.

g) Reproductive toxicity

Reproductive toxicity (Category 2)

h) STOT-single exposure

No data available.

i) STOT-repeated exposure

No data available.

j) Aspiration hazard

No data available.

11.2 Symptoms / routes of exposure

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Skin contact	Absorption through the skin may be fatal. Irritation or pain may occur at the site of contact. There may be irritation and redness at the site of contact. There may be redness or whiteness of the skin in the area of exposure.
Eye contact	The eyes may water profusely. There may be irritation and redness. There may be severe pain.
Ingestion	Convulsions may occur. Nausea and stomach pain may occur. There may be loss of consciousness. There may be soreness and redness of the mouth and throat. There may be vomiting.
Inhalation	Absorption through the lungs can occur causing symptoms similar to those of ingestion. Convulsions may occur. Nausea and stomach pain may occur. There may be irritation of the throat with a feeling of tightness in the chest. There may be loss of consciousness. There may be shortness of breath with a burning sensation in the throat. There may be vomiting.
Delayed / immediate effects	Convulsions may occur. Immediate effects can be expected after short-term exposure. Nausea and stomach pain may occur. There may be loss of consciousness.
Other information	No data available.

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

Readily absorbed into soil.

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.

NB

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

14. Transport information

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
UN2811	UN2811	UN2811	UN2811	UN2811
14.2. UN proper shipping name				
TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.	TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.

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	Transport	document	description
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UN2811 TOXIC SOLID, ORGANIC,

N.O.S. (BENDAMUSTINE HYDROCHLORIDE), 6.1, III

UN2811 TOXIC SOLID, ORGANIC, N.O.S.

(BENDAMUSTINE HYDROCHLORIDE). 6.1, III

UN2811 Toxic solid, organic, n.o.s. (Bendamustine hydrochloride), 6.1, III **UN2811 TOXIC** SOLID, ORGANIC, N.O.S.

(BENDAMUSTINE HYDROCHLORIDE), 6.1, III

UN2811 TOXIC SOLID, ORGANIC, N.O.S.

(BENDAMUSTINE HYDROCHLORIDE).

6.1, III

14.3. Transport hazard class(es)

6.1

6.1



6.1





6.1

14.4. Packing group

Ш

Ш

6.1

14.5. Environmental hazards

No No No

Ш

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) 2020/787.

Authorisations/Restrictions

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

No data available.

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

H301 Toxic if swallowed

H341 Suspected of causing genetic defects H351 Suspected of causing cancer

H361 Suspected of damaging fertility or the unborn child

Abbreviations Full Texts

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

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





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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
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) 2020/787.

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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