



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 02.07.2021

Version number 2 (replaces version 1)

Revision: 02.07.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

· **Product name:** Bendamustine Hydrochloride

· **Part number:** MM0154.00

· **CAS Number:**

3543-75-7

· **EC number:**

631-540-0

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

No further relevant information available.

· **Application of the substance / the mixture** Reference material for laboratory use only

· 1.3 Details of the supplier of the safety data sheet

· **Manufacturer/Supplier:**

LGC Limited

Queens Road

Teddington

Middlesex TW11 0LY

UNITED KINGDOM

Tel : +44 (0) 20 8943 7000

Fax : +44 (0) 20 8943 2767

eMail : gb@lgcstandards.com

Web : www.lgcstandards.com

· **Further information obtainable from:**

Product safety department

eMail : sds-request@lgcgroup.com

· **1.4 Emergency telephone number:**

For Hazardous Materials or Dangerous Goods Incident

Spill, Leak, Fire Exposure, or Accident

Call CHEMTREC:

USA & Canada 1-800-424-9300

Rest of the world +1 703-741-5970

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

· **Classification according to Regulation (EC) No 1272/2008**



skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed.



health hazard

Muta. 2 H341 Suspected of causing genetic defects.

Carc. 2 H351 Suspected of causing cancer.

Repr. 1B H360FD May damage fertility. May damage the unborn child.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

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· 2.2 Label elements**· Labelling according to Regulation (EC) No 1272/2008**

The substance is classified and labelled according to the CLP regulation.

· Hazard pictograms

GHS06 GHS08

· Signal word Danger**· Hazard statements**

H301 Toxic if swallowed.

H341 Suspected of causing genetic defects.

H351 Suspected of causing cancer.

H360FD May damage fertility. May damage the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

· Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

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

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P321 Specific treatment (see on this label).

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Additional information:

Restricted to professional users.

· 2.3 Other hazards**· Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· 3.1 Substances**· CAS No. Description**

3543-75-7 Bendamustine Hydrochloride

· Identification number(s) None**· EC number: 631-540-0****· RTECS: DE1590000**

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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SECTION 4: First aid measures

· 4.1 Description of first aid measures

· General information:

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.

In case of irregular breathing or respiratory arrest provide artificial respiration.

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

· After swallowing:

Rinse mouth. Do not induce vomiting.

Call for a doctor immediately.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

· **Suitable extinguishing agents:** Use fire extinguishing methods suitable for surrounding conditions.

· 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

· 5.3 Advice for firefighters

· **Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures** Avoid formation of dust.

· **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Dispose of contaminated material as waste according to item 13.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Remove dust thoroughly.

Store in cool, dry place in tightly closed receptacles.

· **Information about fire - and explosion protection:** No special measures required.

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- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
*Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
Store only in the original receptacle unless other advice is given on the CoA.
Keep container in a well-ventilated place. Keep away from sources of ignition and heat.*
- **Information about storage in one common storage facility:** *Store away from foodstuffs.*
- **Further information about storage conditions:** *None.*
- **7.3 Specific end use(s)** *No further relevant information available.*

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** *Not required.*
- **Additional information:** *Lists used were valid at the time of SDS preparation.*
- **8.2 Exposure controls**
- **Appropriate engineering controls** *No further data; see item 7.*
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
*Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Store protective clothing separately.*
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Hand protection**
*The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374*



Protective gloves

- **Material of gloves** *Nitrile rubber, NBR*
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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· **Eyeface protection**

Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Solid
· Colour:	White
· Odour:	Odourless
· Odour threshold:	Not determined.
· Melting point/freezing point:	165-166 °C
· Boiling point or initial boiling point and boiling range	Not determined.
· Flammability	Not determined.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· Auto-ignition temperature:	Not determined.
· Decomposition temperature:	Not determined.
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Not determined.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.

· 9.2 Other information

· Appearance:	
· Form:	Solid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Not determined
· Explosive properties:	Not determined.

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- **Change in condition**
- **Evaporation rate** Not applicable.
- **Information with regard to physical hazard classes**
- **Explosives** Not applicable
- **Flammable gases** Not applicable
- **Aerosols** Not applicable
- **Oxidising gases** Not applicable
- **Gases under pressure** Not applicable
- **Flammable liquids** Not applicable
- **Flammable solids** Not applicable
- **Self-reactive substances and mixtures** Not applicable
- **Pyrophoric liquids** Not applicable
- **Pyrophoric solids** Not applicable
- **Self-heating substances and mixtures** Not applicable
- **Substances and mixtures, which emit flammable gases in contact with water** Not applicable
- **Oxidising liquids** Not applicable
- **Oxidising solids** Not applicable
- **Organic peroxides** Not applicable
- **Corrosive to metals** Not applicable
- **Desensitised explosives** Not applicable

SECTION 10: Stability and reactivity

- **10.1 Reactivity**
Stable under normal conditions.
No further relevant information available.
- **10.2 Chemical stability** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:**
Formation of toxic gases is possible during heating or in case of fire.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** Heat.
- **10.5 Incompatible materials:** Strong oxidizing agents.
- **10.6 Hazardous decomposition products:**
Formation of toxic gases is possible during heating or in case of fire.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Toxic if swallowed.

LD/LC50 values relevant for classification:

Oral	LD50	200 mg/kg (rat)
	(LD50)	250 mg/kg (mouse)

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LD 50 (Intraperitoneal)	71 mg/kg (mouse)
LD 50 (Intravenous)	80 mg/kg (mouse)
	40 mg/kg (rat)

· Skin corrosion/irritation*Based on available data, the classification criteria are not met.**Based on available data, the classification criteria are not met.***· Serious eye damage/irritation** *Based on available data, the classification criteria are not met.***· Respiratory or skin sensitisation** *Based on available data, the classification criteria are not met.***· Germ cell mutagenicity** *Suspected of causing genetic defects.***· Carcinogenicity** *Suspected of causing cancer.***· Reproductive toxicity** *May damage fertility. May damage the unborn child.***· STOT-repeated exposure** *May cause damage to organs through prolonged or repeated exposure.***· Additional toxicological information:****· CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)***Muta. 2, Carc. 2, Repr. 1B***· 11.2 Information on other hazards****· Endocrine disrupting properties** *Substance is not listed.*

SECTION 12: Ecological information

· 12.1 Toxicity**· Aquatic toxicity:** *No further relevant information available.***· 12.2 Persistence and degradability** *No further relevant information available.***· 12.3 Bioaccumulative potential** *No further relevant information available.***· 12.4 Mobility in soil** *No further relevant information available.***· 12.5 Results of PBT and vPvB assessment****· PBT:** *Not applicable.***· vPvB:** *Not applicable.***· 12.6 Endocrine disrupting properties***The product does not contain substances with endocrine disrupting properties.***· 12.7 Other adverse effects****· Additional ecological information:****· General notes:***Water hazard class 3 (German Regulation) (Assessment by list): extremely hazardous for water**Do not allow product to reach ground water, water course or sewage system, even in small quantities.**Danger to drinking water if even extremely small quantities leak into the ground.*

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods**· Recommendation***Must not be disposed of together with household garbage. Do not allow product to reach sewage system.*

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- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with national regulations.

SECTION 14: Transport information

· 14.1 UN number or ID number · ADR, IMDG, IATA · ADR · IMDG, IATA	UN2811 2811 TOXIC SOLID, ORGANIC, N.O.S. (Bendamustine Hydrochloride) TOXIC SOLID, ORGANIC, N.O.S. (Bendamustine Hydrochloride)
· 14.3 Transport hazard class(es) · ADR, IMDG, IATA 	6.1 Toxic substances. 6.1
· 14.4 Packing group · ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category	Warning: Toxic substances. 60 F-A,S-A A
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ) · Transport category · Tunnel restriction code	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g 2 E
· UN "Model Regulation":	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (BENDAMUSTINE HYDROCHLORIDE), 6.1, III

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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **Seveso category H2 ACUTE TOXIC**
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. LGC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity – Category 3

Muta. 2: Germ cell mutagenicity – Category 2

Carc. 2: Carcinogenicity – Category 2

Repr. 1B: Reproductive toxicity – Category 1B

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

- **Sources**

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

- **Data compared to the previous version altered.** All sections have been updated.