

Safety Data Sheet

Release 1.0
Revision 02/05/2021
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1 Identification of the substance

1.1 Product identifier

Identification of the substance Bendamustine hydrochloride

Additional identification 5-[Bis(2-chloroethyl)-amino]-1-methyl-1H-benzimidazole-2-butanoic acid HCl; Cytostasan; Ribomustin

Catalogue Number FB18163

REACH No. A registration number is not available for this substance as the substance or its uses are exempted from registration or the annual tonnage does not require a registration.

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

Identified uses other biochemicals

Restriction on use not for food or drug use, for laboratory use only

1.3 Details of the supplier of the safety data sheet

Company Carbosynth Ltd
8&9 Old Station Business Park
COMPTON RG20 6NE
Phone +44 1635 578444
Mail customerservice@biosynth-carbosynth.com

1.4 Emergency telephone number

Phone 24hr/7days: +44 118 338 8269

2 Hazards identification

2.1 Classification of the substance or mixture

Physical Hazards

not classified

Health Hazards

not classified

acute toxicity (Category 3)

Germ cell mutagenicity 2

Carcinogenicity (Category 2), H351

Reproductive toxicity (Category 1B), H360

Specific target organ toxicity, single exposure (Category 2), H371

Environmental Hazards

not classified

2.2 Label elements

Regulatory List

EC1272/08 Regulation (EC) 1272/2008 (GHS/CLP)

Symbol

GHS06 skull and crossbones

Pictogram



GHS08 health hazard

Pictogram



Signal Word

Danger Danger

Hazard Statement

H301 Toxic if swallowed.
H341 Suspected of causing genetic defects.
H351 Suspected of causing cancer.
H360 May damage fertility or the unborn child.
H371 May cause damage to organs.

Precautionary Statement

P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P501 Dispose of contents / container in accordance with local / regional / national / international regulations.

2.3 Other hazards

Caution! To the best of our knowledge the toxicological properties of this material have not been thoroughly investigated.

3 Composition/information on ingredients**Substance related information**

<i>Substance name</i>	Bendamustine hydrochloride
<i>Synonyms</i>	5-[Bis(2-chloroethyl)-amino]-1-methyl-1H-benzimidazole-2-butanoic acid HCl; Cytostasan; Ribomustin
<i>Cas No.</i>	[3543-75-7]
<i>Formula</i>	C ₁₆ H ₂₂ Cl ₃ N ₃ O ₂

4 First aid measures**4.1 Description of first aid measures****First Aid: Eye**

Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Consult an ophthalmologist.

First Aid: Skin

Wash immediately with plenty of water and soap for at least 15 minutes. Remove contaminated clothing and shoes. Wash contaminated clothes before reuse. Call a physician.

First Aid: Ingestion

Wash out mouth with water provided person is conscious. Call a physician.

4.2 Most important symptoms and effects, both acute and delayed**Hints for Physician: Symptoms**

See Section 11 for additional information on health hazards

4.3 Indication of any immediate medical attention and special treatment needed**First Aid: Inhalation**

Remove casualty to fresh air and keep warm and at rest. If breathing is irregular or stopped, administer artificial respiration. Call a physician.

Hints for Physician: Treatment

Treat symptomatically.

5 Firefighting measures**5.1 Extinguishing Media****Suitable**

foam, dry extinguishing powder, carbon dioxide (CO₂), water spray jet

5.2 Special hazards arising from the substance or mixture

Wear a self-contained breathing apparatus and chemical protective clothing.

Hazards During Fire-Fighting

toxic fumes

5.3 Fire-Fighting/Further Advice

Do not inhale explosion and combustion gases. Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Move undamaged containers from immediate hazard area if it can be done safely.

6 Accidental release measures**6.1 Personal Precautions, protective equipment and emergency procedures**

Wear breathing apparatus if exposed to vapours/dusts/aerosols. Provide adequate ventilation.

6.2 Environmental Precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Ensure all waste water is collected and treated via a waste water treatment plant.

6.3 Methods and material for containment and cleaning up

not available

6.4 Further Accidental Release Measures

Collect in closed and suitable containers for disposal. Clear contaminated areas thoroughly. Ventilate affected area.

7 Handling and storage**7.1 Precautions for safe handling****Handling advice**

Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation. Avoid prolonged or repeated exposure. Remove contaminated clothing and wash before reuse. Wash thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities**Storage temperature**

store at <-15°C

Storage condition

keep dry, keep under inert gas: Nitrogen, protect from light

Storage Requirements

Keep container tightly closed when not in use, since hygroscopic. Warm to Room Temperature before use. Keep away from incompatible substances. Keep container tightly closed when not in use. Store in a cool, dry, well-ventilated area away from incompatible substances.

7.3 Specific end use(s)

8 Exposure controles/personal protection**8.1 Exposure limit values**

Does not contain any substances with occupational exposure limits.

8.2 Exposure controles**Industrial Hygiene**

Mechanical exhaust required. Safety shower and eye shower.

8.3 Personal Protective Equipment**Respiratory Protection**

Wear NIOSH/MSHA or European Standard EN 149 approved respirator.

Hand Protection

Wear compatible chemical-resistant gloves to prevent skin exposure.

Eye Protection

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA.

Body Protection

Wear compatible chemical-resistant gloves and clothing to prevent skin exposure.

Advice on Safe Handling

Wash contaminated clothing before reuse. Wear appropriate protective clothing to prevent exposure.

9 Physical and chemical properties**9.1 Information on basic Physical and chemical color properties***Color*

white

Form

powder

9.2 Other information

Molar Mass
394.72 g/mol

10 Stability and reactivity**10.1 Reactivity**

No Data Available

10.2 Chemical stability

No Data Available

10.3 Possibility of hazardous reaction

No Data Available

10.4 Conditions to Avoid (SDS)

light, air

10.5 Incompatible materials

strong oxidizers

10.6 Hazardous decomposition products

nitrogen oxides (NOx), carbon dioxide (CO₂), hydrogen chloride (HCl), carbon monoxide

11 Toxicological information**11.1 Information on toxicological effects****Assessment Carcinogenicity**

Cancer suspect agent

Assessment Toxicity to Reproduction

May cause reproductive effects based upon animal studies.

Other Relevant Toxicity Information

Only selected Registry of toxic effects of chemical substances (RTECS) data is presented here. For the complete information, consult current entry in RTECS.

12 Ecological Information**12.1 Toxicity**

Acute toxicity versus Fishing	Test Type	Species	Method	Exposure Time	Value in standard unit mg/l
	No data available	No data available	No data available	No data available	No data available
Acute toxicity in aquatic plants	Test Type	Species	Method	Exposure Time	Value in standard unit mg/l
	No data available	No data available	No data available	No data available	No data available
Acute toxicity versus Daphnia and others aquatic invertebrates	Test Type	Species	Method	Exposure Time	Value in standard unit mg/l
	No data available	No data available	No data available	No data available	No data available

12.2 Persistence and degradability

Remarks : no data available

12.3 Bioaccumulative potential

Remarks : no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

no data available

12.6 Other adverse effects

no data available

13 Disposal considerations

Advice on Disposal and Packaging*Advice on Disposal*

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and Exhaust air. Dispose of waste according to laws applicable.

Advice on Packaging

not available

14 Transport information

	Road Transport(ADR/GGVS)	Air Transport(IATA)
14.1 UN number	2811	2811
14.2 UN proper shipping name	Toxic solid, organic, n.o.s. (Bendamustine hydrochloride)	Toxic solid, organic, n.o.s. (Bendamustine hydrochloride)
14.3 Transport hazard class(es)	6.1	6.1
14.4 Packing group	III	III
14.5 Environmental hazard class(es)	Not Dangerous Goods	Not Dangerous Goods
14.6 Special precautions for user	Passage through tunnels of category E is forbidden.	Not applicable
14.7 Transport in bulk according to Annex 11 of MARPOL and the IBC code	Not applicable	Not applicable

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

Component	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Bendamustine hydrochloride	-----	-----	-----

Regulatory List
EINECS, TCSI

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 Additional information

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