SAFETY DATA SHEET



1. Identification

Product identifier Bendamustine Related Compound B

Other means of identification

Catalog number 1065243

Synonyms BM1-HP3 hydrochloride

Chemical name 4-(1-Methyl-5-morpholino-1H -benzimidazol-2-yl)butanoic acid hydrochloride

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway

Rockville MD

20852-1790 United States

Telephone RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.
Health hazards Not classified.
Environmental hazards Not classified.
OSHA defined hazards Not classified.

Label elements

Hazard symbol None.
Signal word None.

Hazard statement Not available.

Precautionary statement

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Not available.

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Pharmaceutical related compound of unknown potency.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Bendamustine Related Compound	BM1-HP3 hydrochloride	No Data	100
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4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Rinse skin with water/shower. Get medical attention if irritation develops and persists. Skin contact

Rinse with water. Get medical attention if irritation develops and persists. Eye contact

Ingestion Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important

symptoms/effects, acute and

delayed

Pharmaceutical related compound of unknown potency. It is not known if occupational exposure

may cause physiological effects.

Indication of immediate medical attention and special

treatment needed

General information

Provide general supportive measures and treat symptomatically.

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire fighting

equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage. including any incompatibilities Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

Biological limit values

No exposure limits noted for ingredient(s).

Appropriate engineering controls

No biological exposure limits noted for the ingredient(s).

Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). No open handling.

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Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary.

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Hand protection Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved

or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Consider double gloves.

Other Base the choice of skin protection on the job activity, potential for skin contact and solvents and

reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Train employees in proper gowning and degowning practices. Wear disposable lab

coat, disposable sleeve covers and two pair of gloves as appropriate for the task.

Respiratory protection Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head

cover for spill cleanup.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards.

Procedures for any other uses or quantities should be determined after an appropriate

assessment. Pharmacological effects may be seen with occupational exposure.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.
Form Solid.
Color White.

Odor Not available.
Odor threshold Not available.
pH Not available.
Melting point/freezing point Not available.
Initial boiling point and boiling Not available.

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

Explosive limit - lower (%) Not available.
Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Molecular formula C16H21N3O3·xHCI

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

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Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid

Contact with incompatible materials.

Incompatible materials

Strong oxidizing agents. Reducing agents.

Hazardous decomposition

Strong oxidizing agents. Reducing agents

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx, CI-.

11. Toxicological information

Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.IngestionKnowledge about health hazard is incomplete.

Symptoms related to the physical, chemical, and

toxicological characteristics

Not available.

Information on toxicological effects

Acute toxicity

Knowledge about health hazard is incomplete.

irritation

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Knowledge about health hazard is incomplete.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicityKnowledge about health hazard is incomplete. **Specific target organ toxicity -**Knowledge about health hazard is incomplete.

Specific target organ toxicity - single exposure

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Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met. Knowledge about health hazard is

incomplete.

Further information Pharmaceutical related compound of unknown potency. It is not known if occupational exposure

may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to

Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

General information It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard

Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

No

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

(SDWA)

Not regulated.

US state regulationsCalifornia Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material

is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No

Country(s) or region Inventory name On inventory (yes/no)*

Korea Existing Chemicals List (ECL) New Zealand New Zealand Inventory No

Philippines Philippine Inventory of Chemicals and Chemical Substances No

(PICCS)

Taiwan Taiwan Chemical Substance Inventory (TCSI) No United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

03-12-2019 Issue date 06-27-2019 **Revision date**

Version # 03

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