



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

- **Product identifier**
- **Trade name: 4-[5-[Bis(2-chloroethyl)amino]-1-methylbenzimidazol-2-yl] butanoic acid, hydrochloride; Bendamustin hydrochloride**
- **Article number:** 89880163
- **CAS Number:**
3543-75-7
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Active pharmaceutical ingredients
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Heraeus Precious Metals GmbH & Co. KG
Chemicals Division - Pharmaceutical Ingredients
Heraeusstr. 12-14, D-63450 Hanau
Germany/ Deutschland
- **Further information obtainable from:**
Herr Dr. Friedrich Wissmann
Phone: +49 6181 35-4303
mobile: +49 151 12543294
Fax: +49 6181 35-4302
E-Mail: friedrich.wissmann@heraeus.de
- **Emergency telephone number:** Tel: +49 151 12543294

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Acute Tox. 2 H300 Fatal if swallowed.
Muta. 1B H340 May cause genetic defects.
Carc. 1A H350 May cause cancer.
Repr. 1B H360D May damage the unborn child.
Eye Irrit. 2 H319 Causes serious eye irritation.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
T; Toxic
R45-46-61-25: May cause cancer. May cause heritable genetic damage. May cause harm to the unborn child.
Toxic if swallowed.
.....
Xi; Irritant
R36: Irritating to eyes.
- **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**
Fatal if swallowed.
Causes serious eye irritation.

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May cause genetic defects.

May cause cancer.

May damage the unborn child.

Restricted to professional users.

· **Precautionary statements**

Obtain special instructions before use.

Use personal protective equipment as required.

Do not breathe dust.

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

Store locked up.

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

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Substances**

· **CAS No. Description**

3543-75-7 4-[5-[Bis(2-chloroethyl)amino]-1-methylbenzimidazol-2-yl]
butanoic acid, hydrochloride; Bendamustin hydrochloride

4 First aid measures

· **Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.

In case of accident or if you feel unwell, seek medical advice immediately.

· **After inhalation:**

Supply fresh air.

Call a doctor immediately.

· **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 with water.

Call a doctor immediately.

· **Information for doctor:** Area of application: cytostatic drug

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

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

No further relevant information available.

5 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **Special hazards arising from the substance or mixture**

In case of fire, the following can be released:

Hydrogen chloride (HCl)

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Nitrogen oxides (NO_x)
Carbon monoxide and carbon dioxide
· **Advice for firefighters**
· **Protective equipment:**
Wear fully protective suit.
Wear self-contained respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
The usual precautionary measures are to be adhered to when handling chemicals.
- **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Send for recovery or disposal in suitable receptacles.
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Work only in fume cupboard.
Prevent formation of dust.
Wear protective equipment. Keep unprotected persons away.
Only accessible to qualified persons.
Open and handle receptacle with care.
The usual precautionary measures are to be adhered to when handling chemicals.
- **Information about fire - and explosion protection:**
Material is combustible.
Keep ignition sources away - Do not smoke.
In case of fire, the following can be released:
see chapter 5
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store only in the original receptacle.
Store in dry conditions.
- **Information about storage in one common storage facility:**
Do not store with materials which release oxygen.
Store away from flammable substances.
Store away from foodstuffs.
- **Further information about storage conditions:**
Protect from exposure to the light.

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- Store under lock and key and with access restricted to technical experts or their assistants only.
- **Recommended storage temperature:** < 25 °C
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:**
Ensure good ventilation/exhaustion at the workplace.
Work only in fume cupboard.
Waste air is to be released into the atmosphere only via suitable separators.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
We recommend the reference point of 1 µg/m³ for cytostatic drug.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Wear protective equipment. Keep unprotected persons away.
Do not eat, drink, smoke or sniff while working.
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:**
If dust or aerosol is present use respiratory protection filter P3 (push on filter EN 143 or screwed filter EN 149).
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

- **Material of gloves**
Natural rubber, NR
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solid
Colour:	White

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· Odour:	Odourless
· Change in condition Boiling point/Boiling range:	Not applicable.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Undetermined.
· Ignition temperature:	
Decomposition temperature:	≈ 240 °C
· Danger of explosion:	Product does not present an explosion hazard.
· Density:	Not determined.
· Bulk density at 20°C:	≈ 1.0 kg/m ³
· Solubility in / Miscibility with water at 20°C:	12.5 g/l
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions** Reacts with strong oxidizing agents.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values relevant for classification:**

Oral	LD50	40 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** No data available.
- **on the eye:** Irritating effect.
- **Subacute to chronic toxicity:**
The substance effects in a genotoxic way. Therefore it may be carcinogenic, mutagenic or/and reproductive toxic. Cytostatic drugs are classified in category 1 or 2 concerning the carcinogenic potential under german regulation (TRGS 905). This means the substance is carcinogenic for human or animal.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
Muta. 1B, Carc. 1A, Repr. 1B

12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** No further relevant information available.

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- **Persistence and degradability** No data available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** No data available.
- **Additional ecological information:**
- **General notes:**
Do not allow to enter sewers/ surface or ground water.
Do not allow to penetrate the ground/soil.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations


- **Waste treatment methods**
- **Recommendation**
Waste requires supervision.
Inform disposer that delivery contains cytostatic drug.
Hand over to hazardous waste disposers.

- **European waste catalogue**

18 01 08	cytotoxic and cytostatic medicines
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- **Uncleaned packaging:**
- **Recommendation:** Packagings that may not be cleaned are to be disposed of in the same manner as the product.

14 Transport information

- **UN-Number**
- **ADR, IMDG, IATA** UN2811
- **UN proper shipping name**
- **ADR** 2811 TOXIC SOLID, ORGANIC, N.O.S. (4-[5-[Bis(2-chloroethyl)amino]-1-methylbenzimidazol-2-yl] butanoic acid, hydrochloride; Bendamustin hydrochloride)
- **IMDG, IATA** TOXIC SOLID, ORGANIC, N.O.S. (4-[5-[Bis(2-chloroethyl)amino]-1-methylbenzimidazol-2-yl] butanoic acid, hydrochloride; Bendamustin hydrochloride)
- **Transport hazard class(es)**
- **ADR**
- 
- **Class** 6.1 Toxic substances.

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· Label	6.1
· IMDG, IATA	
	
· Class	6.1 Toxic substances.
· Label	6.1
· Packing group	
· ADR, IMDG, IATA	II
· Special precautions for user	Warning: Toxic substances.
· Danger code (Kemler):	60
· EMS Number:	F-A,S-A
· Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Tunnel restriction code	D/E
· UN "Model Regulation":	UN2811, TOXIC SOLID, ORGANIC, N.O.S. (4-[5-[Bis(2-chloroethyl)amino]-1-methylbenzimidazol-2-yl] butanoic acid, hydrochloride; Bendamustin hydrochloride), 6.1, II

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Information about limitation of use:**
Employment restrictions concerning pregnant and lactating women must be observed.
Employment restrictions concerning juveniles must be observed.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing MSDS:** HH-US
- **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent