

Trade name: Lomustine medac (lomustine)

Status: 21.05.2008

Version: 3.0.0 / GB

Date of printing: 21.05.2008

1.) Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Trade name

Lomustine medac (lomustine)

Use of the substance/preparation

pharmaceutical products

Company/undertaking identification

Address

medac Gesellschaft für klinische Spezialpräparate mbH
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Emergency telephone

+49(0)551 / 19240 {Giftinformationszentrum Nord (GIZ-Nord)} (Service in english)

Advice on Safety Data Sheet

sdb_info@umco.de

2.) Hazards identification

Classification

Carc.Cat.2; R45	May cause cancer.
Repr.Cat.3; R63	Possible risk of harm to the unborn child.
Muta.Cat.2; R46	May cause hereditary genetic damage.
Xn; R20/21/22	Harmful by inhalation, in contact with skin and if swallowed.
Xi; R36/37/38	Irritating to eyes, respiratory system and skin.

Hazard symbols

T Toxic

R phrases

45	May cause cancer.
46	May cause hereditary genetic damage.
20/21/22.1	Also harmful by inhalation, in contact with skin and if swallowed.
36/37/38	Irritating to eyes, respiratory system and skin.
63	Possible risk of harm to the unborn child.

3.) Composition / information on ingredients

Hazardous ingredients

lomustine

EC no.	235-859-2	Index no.	-	CAS no.	13010-47-4
Concentration	> 10	<	30	%-b.w.	
Classification	Carc.Cat.2; R45	Repr.Cat.3; R63	Muta.Cat.2; R46	T; R23/24/25	Xi; R36/37/38
Hazard symbols	T	R phrases	45-46-23/24/25-36/37/38-63		

4.) First aid measures

General information

In case of persisting adverse effects, consult a physician.

After inhalation

Remove the casualty into fresh air and keep him calm. In case of respiratory arrest induce breathing with a respiratory device. Seek medical advice. Ensure supply of fresh air.

After skin contact

When in contact with the skin, clean with soap and water. Remove contaminated clothing immediately, even underwear and shoes.

After eye contact

In case of contact with eyes rinse thoroughly with copious amounts of water and seek medical advice.

After ingestion

Rinse out mouth and give plenty of water to drink. Induce vomiting if patient is conscious, seek medical advice.

5.) Fire-fighting measures

Suitable extinguishing media

Water spray jet; Dry chemical extinguisher; Foam

Trade name: Lomustine medac (lomustine)

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Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases

Fire gas of organic material has to be classed invariably as respiratory poison.

Special protective equipment for fire-fighters

Fire-fighting operations, rescue and clearing work under effect of combustion and smoulder gases just may be done with breathing apparatus.

6.) Accidental release measures

Personal precautions

Remove persons to safety. Use personal protective clothing. Cordon and mark contaminated area. Cordon and mark contaminated area. Personal protection equipment for removal of unintentional contamination or in the event of rupture :

- Overshoes
- liquid-proof protective long-sleeved coat with close-fitting sleeve-band
- protective goggles
- protective gloves
- Protective face mask min. P2 according to the provisions of the professional organisation "Rules for use of breathing apparatuses"
- cut cellulose in sufficient quantity
- receptacle and waste container, shovel

Environmental precautions

Do not allow to enter drains or waterways.

Methods for cleaning up/taking up

Kittake-up of liquid drugs spill:

cover contaminated area carefully using disposable cloths or cellulose, so that the liquid is completely absorbed.

take-up of dry solid matters:

cover with several layers of cellulose contaminated area carefully over its whole surface, so that the cellulose can be wetted cautiously from above.

; Take-up of glass breakage:

Use of suitable means and use of an additional pair of protective gloves.

Clean thoroughly contaminated areas.

Additional informations (chapter 6)

Information regarding Waste Disposal, see chapter 13.

7.) Handling and storage

Handling

Advice on safe handling

Work only in fume cupboards. Avoid the formation and deposition of dust. Open and handle container with care. Only qualified and trained persons are authorised to handle; Production of the drug prepared for application using the Laminar Air Flow (safety bench category 2).

Storage

Further information on storage conditions

Keep container tightly closed. Keep in a cool place. Store in a dry place.

Recommended storage temperature

Value 2 - 8 °C

Storage stability

Value 3 a

Specific use(s)

production of the drug prepared for application using the Laminar Air Flow (safety bench category 2).

8.) Exposure controls / personal protection

Exposure limit values

N O N E

Exposure controls

Occupational exposure controls

Handling of toxic, carcinogenic, mutagenic or reproduction toxic drugs must always take place in separated, clearly marked working areas in compliance with TRGS 525.

Personal protective equipment

Respiratory protection

If ventilation insufficient, use a respiratory protection apparatus.

Respiratory filter (part): min. P2

Hand protection

Disposable gloves with long gauntlet and, if possible, revolving sleeve made of natural Latex, PVC or synthetics with tight closing band around the gauntlet (i.e. Biogel@Standard; Biogel@Skinsense™ or Biogel@Indicator)

- unpowdered, poor protein content, close-fitting, firm surface
- quality requirements according to DIN EN 374

Trade name: Lomustine medac (lomustine)

Status: 21.05.2008

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- finger area designed with double wall thickness
 - advantageous: dyed gloves recommendation
 - Wearing of two pairs of gloves (i.e. Biogel®Indicator™)
- | | | | |
|--------------------|---|-----|----|
| Material thickness | > | 0,2 | mm |
|--------------------|---|-----|----|

Eye protection

Safety glasses with side protection shield (EN 166)

Skin protection

Liquid-proof protective long-sleeved coat with close-fitting sleeve-band obligatory.

General protective and hygiene measures

Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately. Wash thoroughly after work. It is essential for pregnant women to avoid inhaling the product and not to let it come in contact with the skin. Keep separated from food-stuffs and feed-stocks. Wash hands before breaks and after work. An antechamber equipped with separated storage facilities must exist for changing (protective clothes and normal clothes) before the working space (lock).

9.) Physical and chemical properties

General information

Form	Capsule
Odour	odourless

10.) Stability and reactivity

Materials to avoid

[P_ID:8016128!]; Reactions with strong alkalis. Reactions with strong oxidising agents.

Hazardous decomposition products

Carbon monoxide and carbon dioxide; Nitrous oxides (NOx); Hydrogen chloride (HCl)

Thermal decomposition

Remarks	No decomposition if used as prescribed.
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11.) Toxicological information

Acute toxicity

Acute oral toxicity

LD50	70	mg/kg
Species	rat	
Reference substance	Lomustine	
LD50	38	mg/kg
Species	mouse	
Reference substance	Lomustine	

Acute toxicity / further data

LD50	50,350	mg/kg
Species	rat	
Route of exposure	intraperitoneal	
Reference substance	Lomustine	
LD50	53	mg/kg
Species	mouse	
Route of exposure	intraperitoneal	
Reference substance	Lomustine	
LD50	8204	mg/kg
Species	rat	
Route of exposure	s.c.	
Reference substance	Lomustine	
LD50	54	mg/kg
Species	mouse	
Route of exposure	s.c.	
Reference substance	Lomustine	

Effects after repeated or prolonged exposition (subacute, subchronic, chronic)

Mutagenicity

Reference substance	Lomustine
Remarks	Product contains over 0.1% of a substance classified as mut. cat. 2 that is also classified as mut. cat. 2 according to the directive 1999/45/CE.

Reproduction toxicity

Reference substance	Lomustine
Remarks	Product contains over 1% of a substance classified as rep. cat. 3 that is also classified as rep. cat. 3 according to the directive 1999/45/CE.

Carcinogenicity

Value	Product contains over 0.1% of a substance classified as carc. Cat. 2 that is also classified as carc. cat. 2 according to the directive 1999/45/CE.
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Experience in practice

- Irritates respiratory tract.
- Irritates the eyes and the skin.
- Irritates the mucous membrane.

Other information (chapter 11.)

- The product is a substance of Muta. Cat. 2.
- The product is a substance of Repr. Cat. 3.

12.) Ecological information

Other adverse effects

- Ecological data are not available.
- Do not discharge product unmonitored into the environment.

13.) Disposal considerations

Product

Cytostatic remainders as well as with cytostatics contaminated materials can form both with preparation and with application.

During formulation various quantities of following materials are produced:

- residues of concentrated solutions of cytostatic agent (injections)
- residues of diluted solutions (infusions, instillations)
- empty material (original receptacles, syringes)
- auxiliary means for formulation/preparation (cannula, swabs, pads, gloves etc.)

Following waste materials are produced when used:

- empty material (syringes, infusion receptacles)
- cytostatic residues from injections, that have not been completely consumed
- injection residues in hoses, infusion sets, unemptied bags/bottles of infusion

Note:

Collect waste material separately in suitable waste containers where produced (on cytostatic workbench in pharmacy, during preparation of administration, in the treatment room) and prepare for in-house transport.

The legal provisions relating to waste of the respective state must be adhered to.

German Federal States follow the so-called "Guidelines ruling the correct disposal of waste from health service facilities" issued by the Working Group of the Federal States on Waste (LAGA).

Following cytostatic waste materials must be disposed of as hazardous waste ("special waste"):

- original receptacles that are not completely emptied such as cytostatics resulting from discontinued therapy or unintended use
- decayed CMR drugs in original packing
- residues of dry substances and broken tablets
- syringe barrel and infusion bottles / bags with visible filling level/residual contents (> 20 ml)
- Infusions systems and other cytostatics contaminated material (> 20 ml)
- material that has been evidently contaminated through spillage of large quantities of liquids or solids during preparation or use of the aforementioned drugs (i.e. pads, strongly contaminated individual protective equipment).

Such waste needs to be collected in pedal bins or waste containers with an opening mechanism in order to avoid any direct contact of hands/gloves with the waste.

According to the legal provisions relating to hazardous goods and waste, such waste needs to be placed in appropriate, airtight and sound containers for disposal at a special facility displaying the following information: "AS 18 0108* – Cytotoxic and cytostatic waste" and the proper UN No. (pls. see below) according to the Transport of Dangerous Goods Regulations.

The ADR label No 6.1 (Symbol „skull and crossbones“) shall be always affixed to the disposal containers. According to the regulation on hazardous substances Gefahrstoffverordnung (GefStoffV) disposal containers containing cytostatics labelled with the ADR label No 6.1 need no additional labelling (hazard symbol T, skull and crossbones on an orange background).

Cytostatic waste disposed of under the waste name "AS 18 0108* – Cytotoxic and cytostatic waste" shall be provided with one of the following UN No.:

- UN 2810 "TOXIC LIQUID, ORGANIC, N.O.S.": Suitable for liquid cytostatics residues. In case of low liquid quantities, the packaging must only comply with the requirements of the Packaging group III.
- UN 2811 „TOXIC SOLID ORGANIC, N.O.S.“: Suitable for solid cytostatic residues (i.e. broken tablets) and strongly contaminated materials.
- UN 3243 „SOLIDS CONTAINING TOXIC LIQUID, N.O.S.“: Can be used as an alternative to UN 2810 and UN 2811.

Usually following low-contaminated waste does not fall under the scope of the aforementioned group of hazardous waste:

- gauntlets
- gloves
- face masks
- single-use lab coats
- swabs
- wipes

Trade name: Lomustine medac (lomustine)

Status: 21.05.2008

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- empty cytostatics containers after intended use (ampoules, syringes, infusion accessories, infusion receptacles)
- air filters from safety workbenches

Low contaminated cytostatic waste shall be collected in airtight, plastic bags before final disposal immediately at the point of origin. They are disposed of using the official code and name "AS 18 01 04 – Wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)". They may be disposed of together with hospital waste (former B waste). Sharp or pointed objects such as cannula, transfer cannula, spikes and cullets shall be collected at the point of waste origin, in puncture resistant and safely closed containers (i.e. sharps bin). When disposing of waste that is containing cytostatics, the provisions of the respective local waste regulation must be adhered to (i.e. does exist a duty to offer to an official buyer).

14.) Transport information

Other information (chapter 14.)

The product is not defined under national/international road, rail, sea and air dangerous good transport regulations as a hazardous material.

Containerise toxic drugs in unbreakable, liquid-proof and tight closing containers

Marking of transport containers:

Name and address of patient or surgery or hospital ward

if necessary label: „Caution CMR-substance“

if necessary label: „refrigerated ware“

if necessary label: „Caution breakable glass“, and instructions for the event of breakage

Heat-sealing of primary containers recommended.

15.) Regulatory information

Labelling in accordance with EC directives

The product is classified and labelled in accordance with EC Directive 1999/45/EC.

The product is not subject to the chemicals act. However it has been classified according to the rules of the chemicals act, so that the precautionary measures comply with the procedures generally foreseen for chemicals handling and to make them comparable.

Hazard symbols

T Toxic

Hazardous component(s) to be indicated on label, contains:

lomustine

R phrases

45	May cause cancer.
46	May cause hereditary genetic damage.
20/21/22.1	Also harmful by inhalation, in contact with skin and if swallowed.
36/37/38	Irritating to eyes, respiratory system and skin.
63	Possible risk of harm to the unborn child.

S phrases

53	Avoid exposure --- obtain special instructions before use.
1/2	Keep locked up and out of the reach of children.
36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Special labelling for certain preparations

"Restricted to professional users"

Restriction of occupation

Observe employment restrictions for young people.

Observe employment restrictions for child bearing mothers and nursing mothers.

Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances

Laufende Nr. Anhang I 2

16.) Other information

Further information

Processing notes Please read packing specification of the drug for additional drug related information.

The data of this safety data sheet reflect the actual state of knowledge. The safety data sheet describes the product in view of its handling and safety relevant requirements of the pharmaceutical ingredient as bulk ware (chemical).

The information is based on our current knowledge however it does not represent a guarantee of product properties nor does it create any legal obligation.

Sources of key data used to compile the data sheet:

EC Directive 67/548/EC resp. 99/45/EC as amended in each case.

Regulation (EC) No 1907/2006 (REACH) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC as amended in each case.

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

Trade name: Lomustine medac (lomustine)

Status: 21.05.2008

Version: 3.0.0 / GB

Date of printing: 21.05.2008

Relevant R-phrases (chapter 3):

23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
36/37/38	Irritating to eyes, respiratory system and skin.
45	May cause cancer.
46	May cause hereditary genetic damage.
63	Possible risk of harm to the unborn child.

Department issuing safety data sheet

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Ready-made medical preparations are not ruled by the chemical's act, so that the submission of a safety data sheet is not obligatory. Medac, however, opts for this form because the safety data sheet constitutes a reliable source of information regarding the handling of hazardous substances and preparations, and because many occupational safety measures are basing on the safety data sheet structure.