

Trade name: Bleomycin medac**Product no.:** MED011056-06-7**Current version :** 2.0.0, issued: 17.05.2013**Replaced version:** 1.1.0, issued: 06.03.2012**Region:** GB**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name

Bleomycin medac**1.2 Relevant identified uses of the substance or mixture and uses advised against**Relevant identified uses of the substance or mixture
pharmaceutical products**1.3 Details of the supplier of the safety data sheet****Address**medac Gesellschaft für klinische Spezialpräparate mbH
Fehlandtstrasse 3
20354 Hamburg

Telephone no. +49-4103-8006-0

Fax no. +49-4103-8006-100

Information provided by / telephone

Wedel site: Tel: +49 (4103)-8006-0; Fax: +49 (4103)-8006-100

Advice on Safety Data Sheet

sdb_info@umco.de

1.4 Emergency telephone number

For medical advice (in German and English):

+49 (0)551 192 40 (Giftinformationszentrum Nord)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification in accordance with Regulation (EC) No 1272/2008 (CLP)**

Carc. 1B; H350

Repr. 1A; H360D

Resp. Sens. 1; H334

Skin Sens. 1; H317

STOT SE 1; H370i

STOT SE 1; H370o

Classification in accordance with Directive 67/548/EEC or 1999/45/EC

Carc.Cat.2; R45

Repr.Cat.2; R61

T; R39/23/25

R42/43

2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008 (CLP Regulation)****Hazard pictograms**

GHS08

Signal word

Danger

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

bleomycin (INN)

Hazard statements

H350

May cause cancer

H360D

May damage the unborn child.

H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317

May cause an allergic skin reaction.

H370i

Causes damage to organs if inhaled.

H370o

Causes damage to organs if swallowed.

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Precautionary statements

P260 Do not breathe spray.
 P281 Use personal protective equipment as required.
 P285 In case of inadequate ventilation wear respiratory protection.
 P201 Obtain special instructions before use.
 P304+P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
 P307+P311 IF exposed: Call a POISON CENTER or doctor/physician.
 P501 Dispose of contents / container in accordance with local / regional / national / international regulations.

Supplemental label elements

"Restricted to professional users"

Labelling information

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.

2.3 Other hazards

No data available.

SECTION 3: Composition/information on ingredients**3.1 Substances**

Not applicable. The product is not a substance.

3.2 Mixtures**Hazardous ingredients**

No	Substance name	Classification	Classification (EC)	Additional information	
	CAS / EC / Index / REACH no	67/548/EEC	1272/2008 (CLP)	Concentration	%-b.w.
1	bleomycin (INN)				
	11056-06-7 232-925-2 - -	Carc.Cat.2; R45 Repr.Cat.2; R61 T; R39/23/25 R42/43	Carc. 1B; H350 Repr. 1B; H360D Resp. Sens. 1; H334 Skin Sens. 1; H317 STOT SE 1; H370i STOT SE 1; H370o	< 100.00	%-b.w.

Full Text for all R-phrases , H-phrases and EUH-phrases: pls. see section 16

SECTION 4: First aid measures**4.1 Description of first aid measures****General information**

In case of persisting adverse effects, consult a physician. Remove contaminated, soaked clothing immediately and dispose of safely.

After inhalation

Summon a doctor immediately. Administer a corticosteroid therapy in large doses. Careful monitoring of pulmonary function.

After skin contact

Wash off immediately with soap and water.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Seek medical assistance.

After ingestion

Summon a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Fire-fighting measures**5.1 Extinguishing media****Suitable extinguishing media**

Alcohol resistant foam, CO2, powders, water spray

Unsuitable extinguishing media

Full water jet

5.2 Special hazards arising from the substance or mixture

Combustion products of this material have to be classed invariably as respiratory poison.

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5.3 Advice for firefighters

Use self-contained breathing apparatus. Fire residues and contaminated firefighting water must be disposed off in accordance with the local regulations. Wear full protective suit.

SECTION 6: Additional safety measures**6.1 Personal precautions, protective equipment and emergency procedures****For non-emergency personnel**

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 with side protection shield
- 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

For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions

Do not allow to enter drains or waterways.

6.3 Methods and material for containment and cleaning up

Refrain from a chemical inactivation as no standard method exists for inactivation. In many cases strong acids or lyes are necessary; optionally oxidants such as hypochlorite solution can also be used. Inactivating agents must be added in abundance and left for a longer period of time to take effect. One would be constrained to render innocuous a CMR substance using "hazardous substances" which are substances of concern. The use of heat to inactivate in case of spills is all but impossible because of the high temperatures. Likewise it is possible that the described methods release other, toxic artefacts. Remove immediately and appropriately soiling. A further spreading of spillage on the floor with footwear has to be avoided. Keep ready a decontamination kit. Take-up of liquid drugs spill.

Cover contaminated area carefully using disposable cloth 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. A dispersal must be avoided.

Take-up of glass breakage:

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

Clean thoroughly contaminated areas.

Decontamination procedure for handling exposed persons:

- Remove contaminated clothes immediately.
- As for prevention, shower thoroughly.
- After direct contact with skin, seek medical advice.
- In case of eye contact, rinse with isotonic saline solution and seek medical advice.
- Prepare a full accident report / make a record in the accident book.

Chemical inactivating method and combustion temperature of Bleomycin:

- Deactivation with 10% NaOCl for 24 h
- Thermal destruction with at least 1000°C

References:

Barth, J.(2007): Zytostatikaherstellung in der Apotheke, deutscher Apotheker Verlag

Allwood, M., Wright, P. (1997): The cytotoxics handbook, 3rd edition. Radcliffe Medical Press Ltd. 18 Marcham Road Abingdon Oxon OX14 1AA, UK

6.4 Reference to other sections

No data available.

SECTION 7: Handling and storage**7.1 Precautions for safe handling****Advice on safe handling**

Avoid the formation and deposition of dust. Open and handle container with care. Only qualified and trained persons are authorised to handle.

General protective and hygiene measures

An antechamber equipped with separated storage facilities must exist for changing (protective clothes and normal clothes) before the working space (lock). At work do not eat, drink, smoke or take drugs. Use barrier skin cream. Keep away from foodstuffs and beverages.

7.2 Conditions for safe storage, including any incompatibilities**Technical measures and storage conditions**

Keep container tightly closed and dry. Protect from light. Protect from direct sunlight.

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Advice on storage assembly

Do not store together with animal feedstocks.

7.3 Specific end use(s)

No data available.

SECTION 8: Exposure control/personal protection**8.1 Control parameters**

No parameters available for monitoring.

8.2 Exposure controls**Appropriate engineering controls**

Handling of cytostatics / virusstatics calls always for separated, clearly marked working spaces in compliance with TRGS 525 (technical provisions for hazardous substances).

Personal protective equipment**Respiratory protection**

If ventilation insufficient, use a respiratory protection apparatus.

Respiratory filter (part): P3

Eye / face protection

Safety glasses with side protection shield (EN 166)

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

- finger area designed with double wall thickness

- advantageous: dyed gloves recommendation

- Wearing of two pairs of gloves (i.e. Biogel@Indicator™); According to TRGS 525 cytostatics protective gloves must be changed every 30 minutes.

Material thickness > 0.02 mm

Other

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

Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties****Form/Colour**

crystalline powder; lyophilisate

white to slightly yellow

Odour

odourless

Odour threshold

No data available

pH value

Value appr. 4.7

Remarks solution in water

Boiling point / boiling range

No data available

Melting point / melting range

Value 202 - 209 °C

Remarks Decomposition

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Decomposition point / decomposition range

No data available

Flash point

No data available

Auto-ignition temperature

No data available

Oxidising properties

No data available

Explosive properties

No data available

Flammability (solid, gas)

No data available

Lower flammability or explosive limits

No data available

Upper flammability or explosive limits

No data available

Vapour pressure

No data available

Vapour density

No data available

Evaporation rate

No data available

Relative density

No data available

Density

No data available

Solubility in water

Remarks completely soluble

Solubility(ies)

No data available

Soluble in

Methanol

Partition coefficient: n-octanol/water

No data available

Viscosity

No data available

9.2 Other information**Other information**

No data available.

SECTION 10: Stability and reactivity**10.1 Reactivity**

No data available.

10.2 Chemical stability

No data available.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

In case of fire the following can be released: Nitrous oxides (NOx); Carbon monoxide; Sulphur dioxide

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SECTION 11: Toxicological information**11.1 Information on toxicological effects**

Acute oral toxicity	
Remarks	No data available.
Acute dermal toxicity	
Remarks	No data available.
Acute inhalational toxicity	
Remarks	No data available.
Skin corrosion/irritation	
No data available	
Serious eye damage/irritation	
No data available	
Respiratory or skin sensitisation	
Route of exposure	Skin
Remarks	Experience in practice
Evaluation	sensitizing
Germ cell mutagenicity	
No data available	
Reproduction toxicity	
Remarks	Product contains over 0.5% of a substance classified as rep. cat. 2 that is also classified as rep. cat. 2 according to the directive 1999/45/CE.
Carcinogenicity	
Remarks	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.
STOT-single exposure	
No data available	
STOT-repeated exposure	
No data available	
Aspiration hazard	
No data available	

SECTION 12: Ecological information**12.1 Toxicity**

Fish toxicity	
Remarks	No data available.
Daphnia toxicity	
Remarks	No data available.
Algae toxicity	
Remarks	No data available.
Bacteria toxicity	
Remarks	No data available.

12.2 Persistence and degradability

Biodegradability	
Remarks	The product is only slightly biodegradable.

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12.3 Bioaccumulative potential

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.

12.7 Other information

Other information
Do not discharge product unmonitored into the environment.

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SECTION 13: Disposal considerations**13.1 Waste treatment methods****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 Gefährstoffverordnung (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
- 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 culetts 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).

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SECTION 14: Transport information**14.1 Transport ADR/RID/ADN**

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

14.4 Other information

No data available.

14.5 Environmental hazards

Information on environmental hazards, if relevant, pls. see 14.1 - 14.3.

14.6 Special precautions for user

Containerise cytostatics only in unbreakable, liquid-proof and tightly closed containers. Marking of transport containers:

Name and address of patient or surgery or hospital ward

if necessary label: „Caution cytostatics“

if necessary label: „refrigerated ware“

if necessary label: „Caution breakable glass“, and instructions for the event of breakage; Heat-sealing of primary containers recommended.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulations****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

Remarks

Annex I: not listed.

National regulations**Other regulations**

Adhere to : TRGS 525 "Handling of hazardous substances in facilities for human medical care". BGI 754: "Safer handling with dangerous substances in the pharmaceutical industry"

15.2 Chemical safety assessment

No data available.

SECTION 16: Other information**Further information**

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.

Data in the safety data sheet refer to the substance in the tube.

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

Sources of key data used to compile the data sheet:

EC Directive 67/548/EC resp. 1999/45/EC as amended in each case.

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EC

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.

Full text of the R-, H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)

R39/23/25

Toxic: danger of very serious irreversible effects through inhalation and if swallowed.

R42/43

May cause sensitization by inhalation and skin contact.

R45

May cause cancer.

R61

May cause harm to the unborn child.

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H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H350	May cause cancer
H360D	May damage the unborn child.
H370i	Causes damage to organs if inhaled.
H370o	Causes damage to organs if swallowed.

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.