

Trade name: Temomedac

Status: 28.04.2010

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

Identification of the substance or preparation

Trade name

Temomedac

Use of the substance/preparation

pharmaceutical products

Company/undertaking identification

Address

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Information provided by / telephone

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Advice on Safety Data Sheet

sdb_info@umco.de

2.) Hazards identification

Classification

Carc.Cat.2; R45	May cause cancer.
Muta.Cat.2; R46	May cause hereditary genetic damage.
Repr.Cat.2; R60	May impair fertility.
Repr.Cat.2; R61	May cause harm to the unborn child.
Xn; R22	Harmful 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.
60	May impair fertility.
61	May cause harm to the unborn child.
22.1	Also harmful if swallowed.
36/37/38	Irritating to eyes, respiratory system and skin.

3.) Composition / information on ingredients

Hazardous ingredients

temozolomide (INN)

EC no.	-	Index no.	-	CAS no.	85622-93-1
Concentration		< 100	%-b.w.		
Classification	Carc.Cat.2; R45	Muta.Cat.2; R46	Repr.Cat.2; R60	Repr.Cat.2; R61	Xi; R36/37/38 Xn; R22
Hazard symbols	T	R phrases	22-36/37/38-45-46-60-61		

4.) First aid measures

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.

After skin contact

When in contact with the skin, clean with soap and water. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Summon a doctor immediately. Shield unaffected eye.

After ingestion

Call a doctor. Rinse mouth thoroughly with water.

Advice to doctor

Treatment

Decontamination; Treat symptomatically.

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5.) Fire-fighting measures

Suitable extinguishing media

Alcohol resistant foam, CO₂, powders, water spray; Sand

Extinguishing media that must not be used for safety reasons

Full water jet

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. In the event of fire, the following can be released:
Carbon monoxide (CO); Sulphur oxides

Special protective equipment for fire-fighters

Use self-contained breathing apparatus. Wear full protective suit. Do not inhale explosion and/or combustion gases.

Other information

Collect contaminated firefighting water separately, must not be discharged into the drains. Fire residues and contaminated firefighting water must be disposed off in accordance with the local regulations.

6.) Accidental release measures

Personal precautions

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

Environmental precautions

Do not allow to enter drains or waterways.

Methods for cleaning up/taking up

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.

7.) Handling and storage

Handling

Advice on safe handling

Avoid dust formation. Exhaust ventilation at the object is necessary. Observe the usual precautions for handling chemicals.

Advice on protection against fire and explosion

Do not smoke. Keep away from ignition sources and provide for good ventilation.

Storage

Requirements for storage rooms and vessels

Keep only in the original container.

Advice on storage assembly

None known

Further information on storage conditions

Keep container tightly closed in a well-ventilated place. Store in a dry place. Keep under lock and key or accessible only to specialists or people who are authorized.

8.) Exposure controls / personal protection

Exposure limit values

N O N E

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Exposure controls

Occupational exposure 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): 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
- 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 > 0,2 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

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. Keep separated from food-stuffs and feed-stocks.

9.) Physical and chemical properties

General information

Form Capsule; Solid substance
 Odour odourless

10.) Stability and reactivity

Materials to avoid

None known.

Hazardous decomposition products

None, if handled according to order

11.) Toxicological information

Acute toxicity

Acute oral toxicity

LD50 315 mg/kg
 Species rat
 Source Manufacturer

Acute dermal toxicity

Remarks No data available.

Acute inhalational toxicity

Remarks No data available.

Irritant/corrosive effects

Irritant effect on skin

Evaluation irritant
 Source Manufacturer

Irritant effect on eyes

Evaluation irritant
 Source Manufacturer

Sensitisation

Remarks No data available.

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

Mutagenicity

Remarks Information on genotoxicity in vitro available.

Reproduction toxicity

Remarks Indications of toxic effects are available from reproduction studies in animals.

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Carcinogenicity

Remarks

Indications of toxic effects are available from carcinogenic studies in animals.

12.) Ecological information

Ecotoxicity

Fish toxicity

Remarks

No data available.

Daphnia toxicity

Remarks

No data available.

Algae toxicity

Remarks

No data available.

Bacteria toxicity

Remarks

No data available.

Other information

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

- 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,

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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.)

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. No hazardous material as defined by the transport regulations.

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:

temozolomide (INN)

R phrases

45 May cause cancer.
 46 May cause hereditary genetic damage.
 60 May impair fertility.
 61 May cause harm to the unborn child.
 22.1 Also harmful if swallowed.
 36/37/38 Irritating to eyes, respiratory system and skin.

S phrases

53 Avoid exposure - obtain special instructions before use.
 22 Do not breathe dust.
 36/37 Wear suitable protective clothing and gloves.
 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"

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

Remarks Annex I, part 1 + 2: not mentioned. With regard to possibly appropriate decomposition products see Chapter 10.

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. 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.

Relevant R-phrases (chapter 3):

22 Harmful if swallowed.
 36/37/38 Irritating to eyes, respiratory system and skin.
 45 May cause cancer.
 46 May cause hereditary genetic damage.
 60 May impair fertility.
 61 May cause 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.