

Trade name: Topotecan medac 1,0 mg/ml,
Concentrate for the production of a solution

Version: 1.0.0 / GB

Status: 18.10.2011
Date of printing: 18.10.2011

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

Trade name

Topotecan medac 1,0 mg/ml, Concentrate for the production of a solution

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses of the substance or mixture
pharmaceutical products

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

Emergency telephone

For medical advice (in German and English):
+49 (0)551 192 40 (Giftinformationszentrum Nord)

Advice on Safety Data Sheet

sdb_info@umco.de

2.) Hazards identification

Classification of the substance or mixture

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

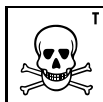
Carc.Cat.2; R45

Muta.Cat.2; R46

Label elements

Labelling according to Directive 1999/45/EC

Hazard symbols



Toxic

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

topotecan-hydrochloride (INN)

R phrases

45 May cause cancer.

46 May cause hereditary genetic damage.

S phrases

53 Avoid exposure - obtain special instructions before use.

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).

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.

3.) Composition / information on ingredients

Substance / product identification

Chemical characterization

aqueous solution

Hazardous ingredients

hydrogen chloride

EC no.	231-595-7	Index no.	017-002-01-X	CAS no.	7647-01-0
Concentration	> 0,5	<	5	%-b.w.	
Classification	C; R34	Xi; R37			
Hazard symbols	C	R phrases	34-37		

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topotecan-hydrochloride (INN)

EC no.	-	Index no.	-	CAS no.	119413-54-6
Concentration	< 0,5			%-b.w.	
Classification	Carc.Cat.2; R45	Muta.Cat.2; R46			
Hazard symbols	T	R phrases		45-46	

4.) First aid measures

General information

In case of accident or if you feel unwell, seek medical advice immediately. Change contaminated, saturated clothing.

After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air.

After skin contact

In case of contact with skin wash off immediately with soap and water.

After eye contact

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

After ingestion

Call in a physician immediately and show him the Safety Data Sheet. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

5.) Fire-fighting measures

Suitable extinguishing media

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

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

No risks known.

Special protective equipment for fire-fighters

Use self-contained breathing apparatus.

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.

Additional informations (chapter 6)

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.

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7.) Handling and storage

Handling

Advice on safe handling

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

Advice on protection against fire and explosion

No special measures necessary.

Storage

Further information on storage conditions

Keep container tightly closed. Protect from heat and direct sunlight. Storage: cool and dry

8.) Exposure controls / personal protection

Exposure limit values

hydrogen chloride

CAS no. 7647-01-0
EC no. 231-595-7

List of approved workplace exposure limits (WELs) / EH40

Hydrogen chloride

gas and aerosol mists

TWA	2	mg/m ³	1	ml/m ³
STEL	8	mg/m ³	5	ml/m ³

2000/39/EWG

Hydrogen chloride

TWA	8	mg/m ³	5	ml/m ³
STEL	15	mg/m ³	10	ml/m ³

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	liquid
Colour	clear
Odour	odourless

Important health, safety and environmental information

Flash point

Remarks not applicable

Density

Value appr. 1,0 g/ml

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10.) Stability and reactivity**Conditions to avoid**

None, if handled according to order.

Materials to avoid

None known.

Hazardous decomposition products

No hazardous decomposition products known.

Thermal decomposition

Remarks No decomposition if used as prescribed.

11.) Toxicological information**Acute toxicity****Acute oral toxicity**

Remarks No data available.

Acute dermal toxicity

Remarks No data available.

Acute inhalational toxicity

Remarks No data available.

Irritant/corrosive effects**Irritant effect on skin**

Remarks No data available.

Irritant effect on eyes

Remarks No data available.

Sensitisation

Remarks No data available.

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

Muta.Cat. 2

Carcinogenicity

Carc.Cat. 2

Other information

The toxicological information is based on the main components.

12.) Ecological information**Other information**

Ecological data are not available. Do not allow to enter soil, waterways or waste water canal.

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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, 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 cullers 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

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.

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15.) Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

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

Remarks Annex I, part 2, category 2

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.

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), 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 R-phrases referred to under section 3

R34	Causes burns.
R37	Irritating to respiratory system.
R45	May cause cancer.
R46	May cause hereditary genetic damage.

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.