

Trade name: Irinotecan

Version: 1.0.0 / GB

Status: 01.10.2009

Date of printing: 01.10.2009

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

**Identification of the substance or preparation**

Trade name

**Irinotecan**

Use of the substance/preparation

pharmaceutical products

**Company/undertaking identification**

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

+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.2; R61	May cause harm to the unborn child.
Repr.Cat.2; R60	May impair fertility.
Muta.Cat.2; R46	May cause hereditary genetic damage.

**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.

**3.) Composition / information on ingredients**

**Chemical characterization**

Aqueous preparation

**Hazardous ingredients**

**Irinotecan HCl trihydrate**

EC no.	-	Index no.	-	CAS no.	136572-09-3
Concentration	> 1	< 5	%-b.w.		
Classification	Carc.Cat.2; R45	Repr.Cat.2; R61	Repr.Cat.2; R60	Muta.Cat.2; R46	Xn; R22 Xi; R36/37/38
Hazard symbols	T	R phrases	45-46-60-61-22-36/37/38		

**4.) First aid measures**

**General information**

In case of accident or if you feel unwell, seek medical advice immediately. Remove contaminated, soaked clothing immediately and dispose of safely.

**After inhalation**

In the event of symptoms take medical treatment. 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**

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

Trade name: Irinotecan

Version: 1.0.0 / GB

Status: 01.10.2009

Date of printing: 01.10.2009

## 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**

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

### **Other information**

Collect contaminated firefighting water separately, must not be discharged into the drains.

## 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.

## 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

### **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**

N O N E

### **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).

Trade name: Irinotecan

Version: 1.0.0 / GB

Status: 01.10.2009

Date of printing: 01.10.2009

**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	Solution
Colour	yellow, clear
Odour	odourless

**Important health, safety and environmental information**

**pH value**

Value 3,0 - 3,8

**10.) Stability and reactivity**

**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**

LD50	867	mg/kg
Species	rat	
Reference substance	Irinotecan HCl	
Source	RTECS	

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

**Mutagenicity**

Remarks Information on genotoxicity in vivo available.

**Reproduction toxicity**

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

**Other information (chapter 11.)**

Irinotecan hydrochloride shows mutagenic behavior in vitro in the chromosome aberration test with CHO cells and in vivo in the micronucleus test with mice. In animal experiments (rat, rabbit) it affects embryotoxic, feto-toxic and teratogenic. The compound is genotoxic effective as cytostatic drug. Therefore it can be assumed that the substance is carcinogenic, mutagenic and toxic to reproduction.

**12.) Ecological information**

**Other adverse effects**

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

Trade name: Irinotecan

Status: 01.10.2009

Version: 1.0.0 / GB

Date of printing: 01.10.2009

## 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 cullents 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).

Trade name: Irinotecan

Version: 1.0.0 / GB

Status: 01.10.2009

Date of printing: 01.10.2009

**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.

**15.) Regulatory information**

**Labelling in accordance with EC directives**

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

**Hazard symbols**

T Toxic

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

Irinotecan HCl trihydrate

**R phrases**

45 May cause cancer.  
 46 May cause hereditary genetic damage.  
 60 May impair fertility.  
 61 May cause harm to the unborn child.

**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).

**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 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) 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**

UMCO Umwelt Consult GmbH  
 Georg-Wilhelm-Str. 183 b, D-21107 Hamburg  
 Tel.: +49 40 / 41 92 13 00 Fax: +49 40 / 41 92 13 57 e-mail: umco@umco.de

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.