

Trade name: Taxomedac®

Version: 3.1.0 / GB

Status: 18.02.2009

Date of printing: 18.02.2009

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

Identification of the substance or preparation

Trade name

Taxomedac®

Company/undertaking identification

Address

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Advice on Safety Data Sheet

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2.) Hazards identification

Classification

R10	Flammable.
Repr.Cat.2; R60	May impair fertility.
Muta.Cat.2; R46	May cause hereditary genetic damage.

Hazard symbols

T	Toxic
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R phrases

46	May cause hereditary genetic damage.
60	May impair fertility.
10	Flammable.

3.) Composition / information on ingredients

Hazardous ingredients

ethanol

EC no.	200-578-6	Index no.	603-002-00-5	CAS no.	64-17-5
Concentration	~ 40		%-b.w.		
Classification	F; R11				
Hazard symbols	F	R phrases	11		

paclitaxel (INN)

EC no.	-	Index no.	-	CAS no.	33069-62-4
Concentration	0,6		%-b.w.		
Classification	Repr.Cat.2; R60	Muta.Cat.2; R46	Xi; R41	Xi; R37/38	
Hazard symbols	T	R phrases	46-60-37/38-41		

4.) First aid measures

General information

In case of persisting adverse effects, consult a physician.

After inhalation

In the event of symptoms take medical treatment. Ensure supply of fresh air.

After skin contact

When in contact with the skin, clean 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.

5.) Fire-fighting measures

Suitable extinguishing media

Water spray jet; Alcohol-resistant foam; ABC powder

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

None 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.

Chemical inactivating method and combustion temperature of Paclitaxel:

- Deactivation: none
- Thermal destruction with more than 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

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. Keep in a cool place. Store in a dry place.

8.) Exposure controls / personal protection

Exposure limit values

ethanol

CAS no. 64-17-5
EC no. 200-578-6

Occupational Exposure Standards (OESs) / EH40

Ethanol				
TWA	1920	mg/m ³	1000	ml/m ³

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Personal protective equipment

Respiratory protection

If ventilation insufficient, use a respiratory protection apparatus.

Respiratory filter (part): P3

Hand protection

When handling cytostatics / virostatics, always use protective gloves, tested according to EN 374. Take care that the gloves used cover the sleeves of the coat. Change gloves at least every 20 minutes; in case of visible contamination or damage, change gloves immediately.

Appropriate Material nitrile

Eye protection

Safety glasses (EN 166)

Skin protection

Impermeable protective clothing; apron

General protective and hygiene measures

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). At work do not eat, drink, smoke or take drugs.

9.) Physical and chemical properties

General information

Form	Solution
Colour	clear
Odour	alkohol-like

Important health, safety and environmental information

Flash point

Value	>	21	°C
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10.) Stability and reactivity

Hazardous decomposition products

No hazardous decomposition products known.

Thermal decomposition

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

Acute toxicity

Acute oral toxicity

Remarks	No data available.
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Acute dermal toxicity

Remarks	No data available.
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Acute inhalational toxicity

Remarks	No data available.
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Acute toxicity / further data

LD50	32,53	mg/kg
Species	rat	
Route of exposure	intraperitoneal	
Reference substance	Paclitaxel	
Source	RTECS	
LD50	12	mg/kg
Species	mouse	
Route of exposure	i.v.	
Reference substance	Paclitaxel	
Source	RTECS	

Irritant/corrosive effects

Irritant effect on skin

Evaluation	non-irritant
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Irritant effect on eyes

Evaluation	non-irritant
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Sensitisation

Evaluation	non-sensitizing
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Effects after repeated or prolonged exposition (subacute, subchronic, chronic)

Type of examination	TDLo		
Route of exposure	intraperitoneal		
Reference substance	Paclitaxel		
Species	rat		
Duration of exposure	11		d
Value	11		mg/kg/d
Source	RTECS		
Type of examination	TDLo		
Route of exposure	intravenous		
Reference substance	Paclitaxel		
Species	rat		
Duration of exposure	5		d
Value	42,5		mg/kg/d
Source	RTECS		

Mutagenicity

Type of examination	Micronucleus test		
Species	mouse		
Value	20		mg/kg
Source	RTECS		

Reproduction toxicity

Type of examination	TDLo		
Route of exposure	i.v.		
Reference substance	Paclitaxel		
Species	rat		
Duration of exposure	17		d
Value	66		mg/kg
Source	RTECS		

12.) Ecological information

Other adverse effects

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

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.

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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 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

Land transport ADR/RID

Remarks No dangerous good due to special provision 601.

Marine transport IMDG

Class	3
Packaging group	III
UN number	1170
Proper shipping name	Ethanol (ethyl alcohol) solution
EmS	F-E,S-D
MARPOL	-
Label	3

Air transport ICAO/IATA

Class	3
Packaging group	III
UN number	1170
Proper shipping name	Ethanol (Ethyl alcohol), solution
Label	3

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:

paclitaxel (INN)

R phrases

46	May cause hereditary genetic damage.
60	May impair fertility.
10	Flammable.

S phrases

53	Avoid exposure - obtain special instructions before use.
45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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Special labelling for certain preparations

"Restricted to professional users"

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).

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):

11	Highly flammable.
37/38	Irritating to respiratory system and skin.
41	Risk of serious damage to eyes.
46	May cause hereditary genetic damage.
60	May impair fertility.

Department issuing safety data sheet

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