

Trade name: Navirel 10 mg/ml Concentrate for the production of an
Version: 2.0.0 / GB

Status: 21.05.2008
Date of printing: 21.05.2008

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

Identification of the substance or preparation

Trade name

Navirel 10 mg/ml Concentrate for the production of an infusion solution

Company/undertaking identification

Address

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Advice on Safety Data Sheet

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2.) Hazards identification

Classification

Repr.Cat.2; R61 May cause harm to the unborn child.
R43 May cause sensitisation by skin contact.

Hazard symbols

T Toxic

R phrases

61 May cause harm to the unborn child.
43 May cause sensitisation by skin contact.

3.) Composition / information on ingredients

Hazardous ingredients

Vinorelbine ditartrate

EC no.	-	Index no.	-	CAS no.	125317-39-7
Concentration	= 1			%-b.w.	
Classification	Repr.Cat.3; R62	Repr.Cat.2; R61	Xi; R41	R43	
Hazard symbols	T	R phrases		61-41-43-62	

4.) First aid measures

General information

In case of persisting adverse effects, consult a physician. Change contaminated, saturated clothing.

After inhalation

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

After skin contact

Wash off immediately with soap and water.

After eye contact

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

After ingestion

Seek medical advice immediately. 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. Wear protective clothing.

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6.) Accidental release measures

Personal precautions

Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation. 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
- 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 discharge into the drains/surface waters/groundwater. Do not allow to enter drains or waterways.

Methods for cleaning up/taking up

Kittake-up of liquid drugs spill:

cover contaminated area carefully using disposable cloths 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.

; Take-up of glass breakage:

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

Clean thoroughly contaminated areas. Remove immediately and appropriately soiling. 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.

Take-up of glass breakage.

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

Clean thoroughly contaminated areas.

Additional informations (chapter 6)

cytostatic substances can be inactivated according to the Barth procedure ruling the chemist's (drugstore) production of cytostatics (chapter II-6, page 2-3).

7.) Handling and storage

Handling

Advice on safe handling

No special measures necessary if stored and handled as prescribed. Avoid formation of aerosols. [P_ID:8015380!]

Advice on protection against fire and explosion

No special measures necessary.

Storage

Requirements for storage rooms and vessels

Store product in closed containers.

Advice on storage assembly

None known

Further information on storage conditions

Keep container tightly closed. Keep in a cool place.

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).

Personal protective equipment

Respiratory protection

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. If ventilation insufficient, use a respiratory protection apparatus.

Respiratory filter (part): min. P2

Hand protection

In case of intensive contact, wear protective gloves (EN 374). Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product . Before use, the protective glove should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties).

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Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves. 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

Eye protection

Safety glasses (EN 166); Safety glasses with side protection shield (EN 166)

Skin protection

Clothing as usual in the chemical industry. Liquid-proof protective long-sleeved coat with close-fitting sleeve-band obligatory.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work. Have eye wash fountain available. Do not inhale dust. 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

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.

Acute toxicity / further data

TDL ₀	2	mg/kg
Species	rat	
Route of exposure	i.v.	
Reference substance	Vinorelbine tatrte	
Source	RTECS	

Irritant/corrosive effects

Irritant effect on eyes

Reference substance	Vinorelbine tatrte
Evaluation	irritant - risk of strong eye injuries

Sensitisation

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

Mutagenicity

Type of examination	Specific locus test
Route of exposure	oral
Reference substance	Vinorelbine ttrate
Species	Drosophila melanogaster
Duration of exposure	48 h
Administration	0,0001 mmol/l
Value	positive

Reproduction toxicity

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

Carcinogenicity

Remarks: No data available.

Experience in practice

Liver and Kidney damage is possible.

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 adverse effects

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.

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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).

14.) Transport information

Other information (chapter 14.)

The product is not defined under national/international road, rail, sea and air dangerous good transport regulations as a hazardous material.

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:

Vinorelbine ditartrate

R phrases

61 May cause harm to the unborn child.
43 May cause sensitisation by skin contact.

S phrases

53 Avoid exposure --- obtain special instructions before use.
24 Avoid contact with skin.
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"

Restriction of occupation

Observe employment restrictions for child bearing mothers and nursing mothers.
Observe employment restrictions for young people.

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).

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.

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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):

41	Risk of serious damage to eyes.
43	May cause sensitisation by skin contact.
61	May cause harm to the unborn child.
62	Possible risk of impaired fertility.

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.