

Trade name: Hydroxycarbamide medac 500 mg

Status: 21.05.2008

Version: 2.0.0 / GB

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

Hydroxycarbamide medac 500 mg

Use of the substance/preparation

pharmaceutical products

Company/undertaking identification

Address

medac Gesellschaft für klinische Spezialpräparate mbH

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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.

Muta.Cat.2; R46

May cause hereditary genetic damage.

Hazard symbols

T

Toxic

R phrases

46

May cause hereditary genetic damage.

61

May cause harm to the unborn child.

3.) Composition / information on ingredients

Hazardous ingredients

hydroxycarbamide

EC no.

204-821-7

Index no.

-

CAS no.

127-07-1

Concentration

> 70

< 90

%-b.w.

Classification

Repr.Cat.2; R61

Muta.Cat.2; R46

Hazard symbols

T

R phrases

46-61

4.) First aid measures

After inhalation

Ensure supply of fresh air. In case of respiratory arrest induce breathing with a respiratory device. Seek medical advice.

After skin contact

Remove contaminated clothing immediately, even underwear and shoes. In case of contact with skin wash off immediately with copious amounts of water. Seek medical attention.

After eye contact

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

After ingestion

Rinse mouth thoroughly with water. Seek medical attention.

Advice to doctor

Symptoms

Nausea; Headache; Vomiting; CNS disorders; Anorexia; Fever; Hyperglycaemia

Hazards

Risk of pancreas inflammation. Risk of medulla atrophy.

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

Fire gas of organic material has to be classed invariably as respiratory poison.

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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.

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
- 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. 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.

7.) Handling and storage

Handling

Advice on safe handling

Work only in fume cupboards. Production of the drug prepared for application using the Laminar Air Flow (safety bench category 2). Open and handle container with care. Only qualified and trained persons are authorised to handle

Storage

Advice on storage assembly

Adhere to the drug storage ruling provisions.

Further information on storage conditions

Keep container tightly closed in a well-ventilated place. Protect from heat and direct sunlight.

8.) Exposure controls / personal protection

Exposure limit values

N O N E

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™)

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.

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General protective and hygiene measures

Do not eat, drink or smoke during work time. Remove soiled or soaked clothing immediately. 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	crystalline powder
Colour	white
Odour	characteristic

Important health, safety and environmental information

Changes in physical state

Type	Melting range			
Value	144	-	146	°C

Solubility in water

Remarks	soluble
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10.) Stability and reactivity

Conditions to avoid

Reactions with strong oxidizing agents.

Hazardous decomposition products

Carbon monoxide and carbon dioxide; Nitrous oxides (NOx)

Thermal decomposition

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

Acute toxicity

Acute oral toxicity

LD50	5760	mg/kg
Species	rat	
Source	RTECS	
LD50	7330	mg/kg
Species	mouse	
LD50	> 2000	mg/kg
Species	dog	
Source	RTECS	

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	> 4700	mg/kg
Species	rat	
Route of exposure	intraperitoneal	
LD50	5800	mg/kg
Species	mouse	
Route of exposure	intraperitoneal	
LD50	4730	mg/kg
Species	rat	
Route of exposure	i.v.	
LD50	2350	mg/kg
Species	mouse	
Route of exposure	i.v.	
LD50	> 1000	mg/kg
Species	dog	
Route of exposure	i.v.	

Irritant/corrosive effects

Irritant effect on skin

Remarks	No data available.
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Irritant effect on eyes

Remarks	No data available.
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Sensitisation

Remarks	No data available.
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Effects after repeated or prolonged exposition (subacute, subchronic, chronic)

Mutagenicity

Value

Information on genotoxicity in vivo available.

Reproduction toxicity

Remarks

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

Experience in practice

Highly effective pharmaceutical agent.

12.) Ecological information

Other adverse effects

Ecological data are not available.

Product is not allowed to discharge into aquatic environment, drains or sewage treatment plants.

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

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- wipes
- empty cytostatic 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**Other information (chapter 14.)**

No hazardous material as defined by the transport regulations.

Containerise toxic drugs in unbreakable, liquid-proof and tight closing containers

Marking of transport containers:

Name and address of patient or surgery or hospital ward

if necessary label: „Caution CMR-substance“

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:

hydroxycarbamide

R phrases

46 May cause hereditary genetic damage.

61 May cause harm to the unborn child.

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).

Special labelling for certain preparations

"Restricted to professional users"

Restriction of occupation

Observe employment restrictions for young people.

Observe employment restrictions for child bearing mothers and nursing mothers.

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

Remarks Annex I: not listed.

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.

Processing notes

Please read packing specification of the drug for additional drug related information.

Data in the safety data sheet refer to the substance in the tube.

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):

46 May cause hereditary genetic damage.

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.