

Trade name: Oncaspar® (peg-asparaginase)

Status: 03.06.2008

Version: 3.0.0 / GB

Date of printing: 03.06.2008

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

Identification of the substance or preparation

Trade name

Oncaspar® (peg-asparaginase)

Use of the substance/preparation

pharmaceutical products

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.
R42/43	May cause sensitisation by inhalation and skin contact.

Hazard symbols

T	Toxic
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R phrases

61	May cause harm to the unborn child.
42/43	May cause sensitisation by inhalation and skin contact.

3.) Composition / information on ingredients

Chemical characterization

pegaspargase (INN)

Substance / product identification

CAS no.	130167-69-0
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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.

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

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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.

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.

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9.) Physical and chemical properties

General information

Form	Solution
Colour	clear
Odour	odourless

10.) Stability and reactivity

Conditions to avoid

No hazardous reactions known.

Thermal decomposition

Remarks No decomposition if used as prescribed.

11.) Toxicological information

Acute toxicity

Acute oral toxicity

LD50 7500 mg/kg

Species rat
Reference substance Asparaginase

LD50 5000 mg/kg

Species mouse
Reference substance Asparaginase

Acute dermal toxicity

Remarks No data available.

Acute inhalational toxicity

Remarks No data available.

Acute toxicity / further data

LD50 7568 mg/kg

Species rat
Route of exposure i.v.
Reference substance Asparaginase

LD50 136 mg/kg

Species mouse
Route of exposure i.v.
Reference substance Asparaginase

LD50 227 mg/kg

Species cat
Route of exposure i.v.
Reference substance Asparaginase

LD50 227 mg/kg

Species dog
Route of exposure i.v.
Reference substance Asparaginase

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

Remarks No data available.

Reproduction toxicity

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

Carcinogenicity

Remarks No data available.

Experience in practice

Allergic reaction possible.

12.) Ecological information

Ecotoxicity

Fish toxicity

Remarks No data available.

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Daphnia toxicity

Remarks No data available.

Algae toxicity

Remarks No data available.

Bacteria toxicity

Remarks No data available.

13.) Disposal considerations

Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Uncontaminated packaging may be taken for recycling.
Packaging that cannot be cleaned should be disposed off as product waste.

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 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. pegaspargase (INN)

Hazard symbols

T Toxic

R phrases

61 May cause harm to the unborn child.
42/43 May cause sensitisation by inhalation and skin contact.

S phrases

53 Avoid exposure --- obtain special instructions before use.
1/2 Keep locked up and out of the reach of children.
3/7/9 Keep container tightly closed in a cool, well-ventilated place.
22 Do not breathe dust.
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).

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.

National regulations

Other regulations, restrictions and prohibition regulations

Adhere to : TRGS 525 "Handling of hazardous substances in facilities for human medical care".
BGI 754: "Safer handling with dangerous substances in the pharmaceutical industry"

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.

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.