

Trade name: Oxaliplatin

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

**Oxaliplatin**

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.3; R40

Limited evidence of a carcinogenic effect.

Repr.Cat.2; R61

May cause harm to the unborn child.

Muta.Cat.2; R46

May cause hereditary genetic damage.

Xi; R37

Irritating to respiratory system.

R42/43

May cause sensitisation by inhalation and skin contact.

### Hazard symbols

T

Toxic

### R phrases

46

May cause hereditary genetic damage.

61

May cause harm to the unborn child.

37

Irritating to respiratory system.

40

Limited evidence of a carcinogenic effect.

42/43

May cause sensitisation by inhalation and skin contact.

## 3.) Composition / information on ingredients

### Chemical characterization

oxaliplatin (INN)

### Substance / product identification

CAS no. 61825-94-3

## 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

Foam; extinguishing powder; ABC powder

### 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**  
Use self-contained breathing apparatus.

## 6.) Accidental release measures

### Personal precautions

Use personal protective clothing. Cordon and mark contaminated area.

### Environmental precautions

Do not allow to enter drains or waterways.

### Methods for cleaning up/taking up

Cover contaminated areas and collect spillage using spongy material (chemical pulp). After collection: clean possibly dried area using 70 % alcohol impregnated chemical pulp. Carry out final cleaning using soap solution impregnated pulp. Do not spray water or detergents directly onto the contaminated area and do not use a broom or vacuum cleaner; risk of aerosol or dust formation to which persons may be exposed.

### Additional informations (chapter 6)

Information regarding Waste Disposal, see chapter 13.

## 7.) Handling and storage

### Handling

#### Advice on safe handling

Avoid the formation and deposition of dust. 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

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 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 (min. 0,3 mm)

Appropriate Material butyl

Appropriate Material rubber

#### 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 powder

Colour whitish

## 10.) Stability and reactivity

### Hazardous decomposition products

No hazardous decomposition products known.

Trade name: Oxaliplatin

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## Thermal decomposition

Remarks No decomposition if used as prescribed.

## 11.) Toxicological information

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

#### Mutagenicity

Value Can cause malformations.

Remarks Information on genotoxicity in vivo available.

#### Reproduction toxicity

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

#### Carcinogenicity

Value probable carcinogen

#### Experience in practice

Irritates respiratory tract.  
Possible sensitisation potential with human beings.

## 12.) Ecological information

### Other adverse effects

Do not discharge product unmonitored into the environment.  
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.

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

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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 transport regulations as a hazardous material.

## 15.) Regulatory information

### Labelling in accordance with EC directives

The product is classified and labelled in accordance with EC Directive 67/548/EC.  
oxaliplatin (INN)

### Hazard symbols

T Toxic

### R phrases

46 May cause hereditary genetic damage.  
61 May cause harm to the unborn child.  
37 Irritating to respiratory system.  
40 Limited evidence of a carcinogenic effect.  
42/43 May cause sensitisation by inhalation and skin contact.

### S phrases

53 Avoid exposure --- obtain special instructions before use.  
22 Do not breathe dust.  
24 Avoid contact with skin.  
36/37 Wear suitable protective clothing and gloves.  
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.

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

Remarks Annex I no. 2

## 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.

### 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

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