

## OXALIPLATIN

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

OXALIPLATIN

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### Use of the substance/mixture

Finished medicinal product

#### 1.3. Details of the supplier of the safety data sheet

Company name: SANDOZ Oncology Injectables  
EBEWE Pharma Ges.m.b.H. Nfg.KG  
Street: Mondseestrasse 11  
Place: A-4866 Unterach  
Telephone: +43 7665 8123 0  
Telefax: +43 7665 8123 11  
e-mail: ask.oncology@sandoz.com

Responsible for the safety data sheet: sds@gbk-ingelheim.de  
Emergency CONTACT (24-Hour-Number)  
GBK/Infotrac ID 103736: (USA domestic) 1 800 535 5053 or international (001)  
352 323 3500

**1.4. Emergency telephone number:** +49 (0) 6132 / 84463 (GBK GmbH)

#### Further Information

As a drug, the product does not need to be labelled.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

Indications of danger: T - Toxic, Xn - Harmful  
R phrases:  
May cause cancer.  
May cause heritable genetic damage.  
Harmful by inhalation, in contact with skin and if swallowed.

#### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard categories:  
Acute toxicity: Acute Tox. 4  
Germ cell mutagenicity: Muta. 1A  
Carcinogenicity: Carc. 1A  
Hazard Statements:  
Harmful if swallowed.  
May cause genetic defects.  
May cause cancer.

#### 2.2. Label elements

Signal word:

Danger

Pictograms:

GHS07-GHS08



#### Hazard statements

H302 Harmful if swallowed.  
H340 May cause genetic defects.  
H350 May cause cancer.

#### Precautionary statements

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.

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P270 Do not eat, drink or smoke when using this product.  
P281 Use personal protective equipment as required.  
P308+P313 IF exposed or concerned: Get medical advice/attention.  
P405 Store locked up.

### Additional advice on labelling

According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

### 2.3. Other hazards

Not known.

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## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Chemical characterization

Cytotoxic agent.:

Active substance: [(1R,2R)-cyclohexane-1,2-diamine](ethanedioato-O,O')platinum(II)

Sum formula: C<sub>8</sub>H<sub>14</sub>N<sub>2</sub>O<sub>4</sub>Pt

#### Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH No		
	Oxaliplatin	5 - < 10 %
61825-94-3	Carc. Cat. 1, Muta. Cat. 1, T - Toxic, Xi - Irritant R45-46-23/24/25-36/37/38	
	Carc. 1A, Muta. 1A, Acute Tox. 3, Acute Tox. 3, Acute Tox. 3, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H350 H340 H301 H311 H331 H315 H319 H335	

Full text of R-, H- and EUH-phrases: see section 16.

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## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information

Remove contaminated soaked clothing immediately and dispose of safely.

Take away from danger area and lay down affected person.

If you feel unwell, seek medical advice.

#### After inhalation

Do not breathe dust. Information on label instructions.

Remove the casualty into fresh air and keep him immobile.

Medical treatment.

#### After contact with skin

Wash off immediately with soap and plenty of water. Call a physician immediately.

#### After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Seek medical treatment by eye specialist.

#### After ingestion

If swallowed, seek medical advice immediately and show this container or label.

Rinse out mouth and give plenty of water to drink. Do not induce vomiting.

Never give anything by mouth to an unconscious person.

### 4.2. Most important symptoms and effects, both acute and delayed

May cause cancer.

May cause heritable genetic damage

### 4.3. Indication of any immediate medical attention and special treatment needed

This product is a cytostatic. In case of therapeutical use of the product, typical side effects are: Heart rhythm disturbances, Vomiting, nausea.

Treat symptoms.

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### SECTION 5: Firefighting measures

#### **5.1. Extinguishing media**

##### **Suitable extinguishing media**

Alcohol-resistant foam, dry chemical, carbon dioxide (CO<sub>2</sub>), water-spray.  
Fire-extinguishing activities according to surrounding.

##### **Unsuitable extinguishing media**

Full water jet.

#### **5.2. Special hazards arising from the substance or mixture**

In case of fire formation of dangerous gases possible.  
Fire may produce: Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>) and nitrogen oxides (NO<sub>x</sub>).

#### **5.3. Advice for firefighters**

Wear self-contained breathing apparatus and protective suit.

##### **Additional information**

Cool containers at risk with water spray jet.  
Collect contaminated firefighting water separately, must not be discharged into the drains.  
Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

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### SECTION 6: Accidental release measures

#### **6.1. Personal precautions, protective equipment and emergency procedures**

Get unprotected persons to safety. Do not breathe vapours. Use personal protective clothing. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Keep away sources of ignition.

#### **6.2. Environmental precautions**

Do not discharge into the drains/surface waters/ground water.

#### **6.3. Methods and material for containment and cleaning up**

Pick up mechanically, avoiding dust, and provide disposal in suitable recipients.  
Contaminated objects and floor clean thoroughly by consideration of environment regulations.  
Wear complete protection equipment (P3-mask, safety goggles, protective gloves) when cleaning the area.

#### **6.4. Reference to other sections**

Observe protective instructions (see Sections 7 and 8).  
Information for disposal see section 13.

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### SECTION 7: Handling and storage

#### **7.1. Precautions for safe handling**

##### **Advice on safe handling**

Avoid the formation and deposition of dust. Allow for sucking off.  
Handle and open container with care.  
Use personal protective clothing.

##### **Advice on protection against fire and explosion**

No specific precautions required.

##### **Further information on handling**

Take the usual precautions when handling with chemicals. At work do not eat, drink and smoke.

#### **7.2. Conditions for safe storage, including any incompatibilities**

##### **Requirements for storage rooms and vessels**

Keep only in original container. Keep container tightly closed in a dry, cool and well-ventilated place.  
Store in a cool and shaded area.

##### **Advice on storage compatibility**

Do not store together with oxidizing agents. Do not store with acids or alkalies.  
Keep away from food, drink and animal feeding stuffs.

##### **Further information on storage conditions**

Protect against direct sun radiation. Protect from light.  
Keep away from heat.

#### **7.3. Specific end use(s)**

Finished medicinal product

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### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### **Additional advice on limit values**

Avoid exposure - before application obtain special instructions.  
Handling should only be allowed by trained Personnel.

#### 8.2. Exposure controls

##### **Appropriate engineering controls**

Ensure adequate ventilation, especially in confined areas.  
Avoid the formation and deposition of dust.  
Provide emergency shower.  
Provide eye bath.

##### **Protective and hygiene measures**

Wash hands before breaks and immediately after handling the product.  
When using do not eat, drink or smoke.  
Avoid contact with skin, eyes and clothing.  
Take off immediately all contaminated clothing.

##### **Eye/face protection**

Tightly fitting goggles (EN 166).

##### **Hand protection**

Chemical-resistant gloves (EN 374). (Latex gloves.)  
Follow the recommendations of the glove manufacturer for breakthrough properties especially for workplace conditions involving mechanical stress and contact duration.

##### **Skin protection**

Protective suit.

##### **Respiratory protection**

No special protection is necessary when the product is handled inside a safety cabinet or an isolator.  
Not required under normal use. Breathing apparatus only if aerosol or dust is formed.  
Short term: filter apparatus, Filter P3

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### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state:	Crystalline powder	
Colour:	White to off white	
pH-Value:	4.0 - 6.0	
Melting point:	198.3 °C	
Initial boiling point and boiling range:	102,4 °C	OECD 103
Flash point:	> 101 °C	EU A.9
Vapour pressure: (at 20 °C)	23,50 hPa	OECD 104
Density (at 20 °C):	1.018 g/cm <sup>3</sup>	
Water solubility: (at 20 °C)	Miscible	

#### 9.2. Other information

No data available.

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### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No decomposition if stored and applied as directed.

#### 10.2. Chemical stability

Stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

Stable under normal conditions.

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### **10.4. Conditions to avoid**

Protect against direct sun radiation. Protect from light.  
Keep away from heat.

### **10.5. Incompatible materials**

Not known.

### **10.6. Hazardous decomposition products**

No decomposition if stored and applied as directed.

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## **SECTION 11: Toxicological information**

### **11.1. Information on toxicological effects**

#### **Toxicokinetics, metabolism and distribution**

Cytotoxic agent.  
May cause genetic defects. May cause cancer.

#### **Acute toxicity**

Harmful if swallowed.  
Harmful if swallowed.  
Oxaliplatin, CAS-No. 122111-03-9  
LD50/oral/rat: > 100 mg/kg  
LD50/intravenous/Rat: < / = 23.5 mg/kg  
LD50/intravenous/mouse: < / = 22.5 mg/kg  
LD50/intraperitoneal /Rat: < / = 14.3 mg/kg  
LD50/intraperitoneal /mouse: < / = 19.5 mg/kg

#### **Irritation and corrosivity**

Based on available data, the classification criteria are not met.

#### **Sensitising effects**

Based on available data, the classification criteria are not met.

#### **STOT-single exposure**

Based on available data, the classification criteria are not met.

#### **Severe effects after repeated or prolonged exposure**

Based on available data, the classification criteria are not met.

#### **Carcinogenic/mutagenic/toxic effects for reproduction**

May cause genetic defects. (Oxaliplatin)  
May cause cancer. (Oxaliplatin)

#### **Aspiration hazard**

Based on available data, the classification criteria are not met.

#### **Additional information on tests**

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

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## **SECTION 12: Ecological information**

### **12.1. Toxicity**

Do not discharge into the drains/surface waters/ground water.

### **12.2. Persistence and degradability**

No information available.

### **12.3. Bioaccumulative potential**

No information available.

### **12.4. Mobility in soil**

No information available.

### **12.5. Results of PBT and vPvB assessment**

No information available.

### **12.6. Other adverse effects**

No information available.

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## **SECTION 13: Disposal considerations**

### **13.1. Waste treatment methods**

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### Advice on disposal

ÖNORM S 2104 (BGBl II, Nr. 262, 21.07.2008): SN 53510 g 77

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

### Waste disposal number of waste from residues/unused products

180108 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care); wastes from natal care, diagnosis, treatment or prevention of disease in humans; cytotoxic and cytostatic medicines  
Classified as hazardous waste.

### Contaminated packaging

ÖNORM S 2100: SN 53502

Empty containers should be taken for local recycling, recovery or waste disposal.

Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.

Packaging that cannot be cleaned should be disposed of like the product.

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## SECTION 14: Transport information

**Land transport (ADR/RID); Marine transport (IMDG); Air transport (ICAO); Inland waterways transport (ADN)**

### 14.1. UN number:

Not applicable. No hazardous material as defined by the transport regulations.

### 14.2. UN proper shipping name:

Not applicable. No hazardous material as defined by the transport regulations.

### 14.3. Transport hazard class(es):

Not applicable. No hazardous material as defined by the transport regulations.

### 14.4. Packing group:

Not applicable. No hazardous material as defined by the transport regulations.

### 14.5. Environmental hazards

Not applicable. No hazardous material as defined by the transport regulations.

### 14.6. Special precautions for user

Not applicable. No hazardous material as defined by the transport regulations.

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable. No hazardous material as defined by the transport regulations.

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## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU regulatory information

##### Additional information

According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

##### National regulatory information

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

### 15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

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## SECTION 16: Other information

### Changes

Section: 1 - 11

### Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

IMDG = International Maritime Code for Dangerous Goods

IATA/ICAO = International Air Transport Association / International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

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IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

REACH = Registration, Evaluation, Authorization and Restriction of Chemicals

CAS = Chemical Abstract Service

EN = European norm

ISO = International Organization for Standardization

DIN = Deutsche Industrie Norm

PBT = Persistent Bioaccumulative and Toxic

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

### Relevant R-phrases (Number and full text)

23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

36/37/38 Irritating to eyes, respiratory system and skin.

45 May cause cancer.

46 May cause heritable genetic damage.

### Relevant H- and EUH-phrases (Number and full text)

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

H340 May cause genetic defects.

H350 May cause cancer.

### Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.

The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge.

The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

(n.a. = not applicable; n.d. = not determined)

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*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*