

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** Oxaliplatin,
[(R,R-1,2-Diaminocyclohexane)oxalatoplatinum(II)]
- **Article number:** 89880044
- **CAS Number:**
61825-94-3
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Active pharmaceutical ingredients
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Heraeus Precious Metals GmbH & Co. KG
Chemicals Division - Pharmaceutical Ingredients
Heraeusstr. 12-14, D-63450 Hanau
Germany/ Deutschland
- **Further information obtainable from:**
Herr Dr. Friedrich Wissmann
Phone: +49 6181 35-4303
mobile: +49 151 12543294
Fax: +49 6181 35-4302
E-Mail: friedrich.wissmann@heraeus.de
- **Emergency telephone number:** Tel: +49 151 12543294

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Acute Tox. 3 H301 Toxic if swallowed.
Acute Tox. 3 H311 Toxic in contact with skin.
Acute Tox. 3 H331 Toxic if inhaled.
Muta. 1B H340 May cause genetic defects.
Carc. 1A H350 May cause cancer.
Met. Corr.1 H290 May be corrosive to metals.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
STOT SE 3 H335 May cause respiratory irritation.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
T; Toxic
R45-46-23/24/25: May cause cancer. May cause heritable genetic damage. Toxic by inhalation, in contact with skin and if swallowed.
Xi; Irritant
R36/37/38: Irritating to eyes, respiratory system and skin.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS05



GHS06



GHS08

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- **Signal word** *Danger*
- **Hazard statements**
 - May be corrosive to metals.*
 - Toxic if swallowed.*
 - Toxic in contact with skin.*
 - Toxic if inhaled.*
 - Causes skin irritation.*
 - Causes serious eye irritation.*
 - May cause genetic defects.*
 - May cause cancer.*
 - May cause respiratory irritation.*
 - Restricted to professional users.*
- **Precautionary statements**
 - Obtain special instructions before use.*
 - Wear protective gloves/protective clothing/eye protection/face protection.*
 - Avoid release to the environment.*
 - Keep only in original container.*
 - Do not eat, drink or smoke when using this product.*
 - IF exposed or concerned: Get medical advice/attention.*
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**
 - 61825-94-3 Oxaliplatin*

4 First aid measures

- **Description of first aid measures**
- **General information:**
 - Immediately remove any clothing soiled by the product.*
 - Remove breathing equipment only after contaminated clothing have been completely removed.*
 - In case of accident or if you feel unwell, seek medical advice immediately.*
- **After inhalation:** *Call a doctor immediately.*
- **After skin contact:**
 - Immediately wash with water and soap and rinse thoroughly.*
 - Seek immediate medical advice.*
- **After eye contact:** *Rinse opened eye for several minutes under running water. Then consult a doctor.*
- **After swallowing:**
 - Rinse mouth with water.*
 - Call a doctor immediately.*
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** *No further relevant information available.*
- **Indication of any immediate medical attention and special treatment needed** *Cytostatic drug*

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5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** *Water with full jet*
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
Nitrogen oxides (NO_x)
Carbon monoxide (CO)
- **Advice for firefighters**
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Avoid contact with substance.
Use respiratory protective device against the effects of fumes/dust/aerosol.
- **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Prevent formation of dust.
Send for recovery or disposal in suitable receptacles.
Dispose contaminated material as waste according to item 13.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Work only in fume cupboard.
Ensure good ventilation/exhaustion at the workplace.
Waste air is to be released into the atmosphere only via suitable separators.
Air of exhaustion lead not back to the working room.
Wear protective equipment. Keep unprotected persons away.
Store under lock and key and with access restricted to technical experts or their assistants only.
Open and handle receptacle with care.
Prevent formation of dust.
- **Information about fire - and explosion protection:**
Flammable.
Formation of toxic gases is possible during heating or in case of fire.
Keep respiratory protective device available.

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- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store only in the original receptacle.
Corrosive action on metals.
- **Information about storage in one common storage facility:**
Store away from foodstuffs.
Store away from flammable substances.
- **Further information about storage conditions:**
Store in dry conditions.
Protect from exposure to the light.
Store under lock and key and with access restricted to technical experts or their assistants only.
Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
We recommend the reference point of 1 µg/m³ for cytostatic drug.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Work only in fume cupboard.
Do not eat or drink while working.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Store protective clothing separately.
Avoid contact with the eyes and skin.
- **Respiratory protection:**
If dust or aerosol is present use respiratory protection filter P3 (push on filter EN 143 or screwed filter EN 149).
- **Protection of hands:** Long cuffed gloves
- **For the permanent contact gloves made of the following materials are suitable:** Natural rubber, NR
- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
Form: Crystalline

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Colour:	White
· Odour:	Odourless
· pH-value:	Undetermined.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Not applicable.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Undetermined.
· Danger of explosion:	Product does not present an explosion hazard.
· Density:	Not determined.
· Solubility in / Miscibility with water at 20°C:	7.9 g/l
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
Protect from exposure to the light.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values relevant for classification:	
61825-94-3 Oxaliplatin	
LD50 intraperitoneal	≤19.5 mg/kg (mouse) ≤17.5 mg/kg (rat)
LD50 intravenous	≤22.5 mg/kg (mouse) ≤23.5 mg/kg (rat)

- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Subacute to chronic toxicity:**
The substance effects in a genotoxic way. Therefore it may be carcinogenic, mutagenic or/and reproductive toxic. Cytostatic drugs are classified in category 1 or 2 concerning the carcinogenic potential under german regulation (TRGS 905). This means the substance is carcinogenic for human or animal.

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- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
Muta. 1B, Carc. 1A

12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** No data available.
- **Additional ecological information:**
- **General notes:** Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Product or residue of product should be recycled because of precious metal content (national regulations must be observed). Material can be returned to supplier or other recycling companies.
If residues of products are classified as waste from administrative bodies or recycling of precious metal is not intended use the legal requirements to assign the European Waste Code (depending on branche of industry and industrial process).
- **Uncleaned packaging:**
- **Recommendation:**
Uncleaned or with product residues contaminated packing should be treated like the product itself.
Packages, which do not contain product residues, should be recycled; if there does not exist a collecting system, packages can be treated as rubbish.

14 Transport information

- | | |
|----------------------------------|---|
| · UN-Number | |
| · ADR, IMDG, IATA | UN2811 |
| · UN proper shipping name | |
| · ADR | 2811 TOXIC SOLID, ORGANIC, N.O.S. (Oxaliplatin) |
| · IMDG, IATA | TOXIC SOLID, ORGANIC, N.O.S. (Oxaliplatin) |

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· Transport hazard class(es)

· ADR



· Class 6.1 Toxic substances.
· Label 6.1

· IMDG, IATA



· Class 6.1 Toxic substances.
· Label 6.1

· Packing group

· ADR, IMDG, IATA III

· Environmental hazards:

· Marine pollutant: No

· Special precautions for user

Warning: Toxic substances.

· Danger code (Kemler):

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· EMS Number:

F-A,S-A

· Transport in bulk according to Annex II of

MARPOL 73/78 and the IBC Code Not applicable.

· Transport/Additional information:

· ADR

· Tunnel restriction code E

· UN "Model Regulation":

UN2811, TOXIC SOLID, ORGANIC, N.O.S. (Oxaliplatin), 6.1, III

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· National regulations:

· Information about limitation of use:

Employment restrictions concerning pregnant and lactating women must be observed.

Employment restrictions concerning juveniles must be observed.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Department issuing MSDS: HH-US

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· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

· * Data compared to the previous version altered.

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