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| W. C. Heraeus | Safety Data Sheet | revised: 16.02.2006 |
| | | Rev. Nr.: 4 |
| trade name: Oxaliplatin; [(R,R-1,2-Diaminocyclohexane)oxalatoplatinum(II)] | | Ident.- Nr.: 89880044 |

1. Identification of the substance/preparation and company

Identity number : 89880044
 Empirical formula : C₈H₁₄N₂O₄Pt
 Molecular weight : 397,3 [g/Mol]

1.1 Trade name

Oxaliplatin
 Other names: [(R,R-1,2-Diaminocyclohexane)oxalatoplatinum(II)]

1.2 Application

The substance is used as cytostatica in cancer therapy.

1.3 Informations about manufacturer/supplier

W. C. Heraeus GmbH
 Chemicals Division - Pharma
 Heraeusstraße 12-14, D-63450 Hanau, Germany
 Post box 1553, D-63405 Hanau, Germany

Marketing manager: Mr. M. Schwarz Phone: 06181/35-5255
 Fax: 06181/35-4302

2. Composition/information on ingredients

Chemical characterization (substance)

[(R,R-1,2-Diaminocyclohexane)oxalatoplatinum(II)]

| CAS-No. | EINECS-No. | Index-No. | Elincs-No. |
|------------|------------|-----------|------------|
| 61825-94-3 | --- | --- | --- |

3. Hazards identification

Characterization of hazards

Warning! Avoid ingestion, inhalation, skin contact.
 As an antineoplastic agent, Oxaliplatin should be handled with extreme care. It may cause cancer and is toxic when inhaled or swallowed.

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4. First-aid measures

General information

Remove from exposure. Remove contaminated clothing and shoes.

After inhalation: Possible irritation of respiratory tract. Remove to fresh air. If not breathing give artificial respiratory. If breathing is difficult give oxygen. Obtain medical attention.

After contact with skin: Possible irritation. Flush with copious quantities of water for at least 15 minutes. Call a physician.

After contact with eyes: Possible irritation. Flush with copious quantities of water, also under the eyelids for at least 15 minutes. Summon eye specialist.

After ingestion: Possible irritation. Rinse mouth and drink plenty of water. Call a physician.

5. Fire-fighting measures

Combustible solid. This material is assumed to be combustible.

Suitable extinguishing media:

Use extinguishing media that are appropriate to the environment. Water spray, dry chemical, carbon dioxide or foam.

Not suitable extinguishing media:

Water jet.

Specific danger by the substance, its burning products or developing gases:

As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity. When heated to decomposition material emits toxic fumes of CO, CO₂ and NO_x.

Special protective equipment for fire-fighting:

As with all fires, evacuate personnel to safe area. Do not stay in dangerous zone. Firefighters should use suitable chemical protective clothing and self-contained breathing equipment.

6. Accidental release measures

Personal precautions:

Wear approved respirator, chemically compatible gloves and protective goggles. Keep unauthorized personnel away.

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Environmental precautions:

Do not allow to enter in surface and ground water, into the sewage system or in earth.

Methods for cleaning up/taking up:

Vacuum or sweep up spillage. Avoid dust. Place spillage in appropriate container for proper waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site with water.

Further information:

Sewage is disposed of in an established manner which meets all local regulations. Sewage containing drug and filters used in the process, etc. are treated in a recycling factory. Air filters and chemical wastes/refuse are burned in an incinerator or delivered to a third party Waste Dealer with a License.

Residues, which contain precious metals should be recycled in accordance to locally approved waste-disposal-regulations.

7. Handling and storage

7.1 Handling

Advice on safe handling:

Pay attention to general precautionary measures for handling potentially cytotoxic chemicals. Don't eat and drink at working place. Don't smoke. Only accessible to qualified persons.

Caution:

Oxaliplatin is potentially cytotoxic. Great care should be taken to prevent inhaling particles and exposing the skin to it. Avoid contact with eyes, skin or clothing. Avoid breathing dust or mist. Use with adequate dust control. Wash thoroughly after handling. Wear fresh clothing daily. Wash contaminated clothing before reuse.

Precautionary measures against fire and explosion:

In case of overheating decomposition is possible. Development of hazardous gases is possible.

7.2 Storage

Requirements for storage rooms and vessels:

Store in air-tight container protected from light. Avoid ultraviolet ray, as defined in the US Pharmacopoeia, European Pharmacopoeia or Japanese Pharmacopoeia. Keep away from sources of ignition. Don't smoke.

Only accessible to qualified persons.

As precious metal compound the product has a corrosive effect in direct contact with aluminium and steel.

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8. Exposure controls / Personal protection

8.1 Additional advice on system design

See to good ventilation/exhaustion at the working place; handle in a chemical fume hood.
Do not lead back the exhausted air into the working area.

8.2 Advice on limits

We recommend the reference point of 0,001 mg/m³ (calculated as Pt). This value participates to the cytostatica "Cisplatinum".

8.3 Personal protection equipment

Respiratory protection:

Absolutely necessary.
Use P3 respiratory protection filter
(push on filter EN 143 or screwed filter EN 149).

Hand protection:

For the handling of the product impermeable protective gloves for example out of latex have to be used.

Eye protection:

Use tightly fitting safety glasses / goggles.

Body protection:

Use protective clothing.
Remove immediately contaminated clothing. Wash clothes before reuse.
Avoid contact with skin, eyes and clothes.

Protective and hygiene measure:

Use only in a chemical fume hood.
The usual precautionary measures for the handling of chemicals have to be observed.
Don't eat and drink at working place. Don't smoke.
Wash hands before breaks and at the end of workday.
Take a shower after handling the product.
Contaminated working clothes should not be worn outside the work place.
Keep away from food and drinks.
Do not breathe dust.

9. Physical and chemical properties

9.1 Appearance

Form: crystalline powder
Colour: white
Odour: ---

9.2 Aspects relevant for security

Test method

pH-value: n.a.
Melting point [°C]: n.d.

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|--------------------------------------|------------------------------|
| Boiling point: | n.a. |
| Flash point: | n.a. |
| Ignition point: | n.a. |
| Ignition (solid): | no |
| Self ignition: | no |
| Explosion limits lower: | n.a. |
| upper: | n.a. |
| Vapour pressure: | n.a. |
| Bulk density: | n.d. |
| Solubility in water: | slightly soluble (7,9 mg/ml) |
| Solubility in methanol: | 2,1 mg/ml |
| Insoluble in other organic solvents. | |

9.3 Further information

n.a. = not applicable, n.d. = not determined

10. Stability and reactivity

When stored as recommended in section 7, the material is stable for at least 2 years. Exposure to light must be avoided, especially when the product is in solution.

Conditions to avoid:

In case of heating, decomposition is possible. Hazardous decomposition products: CO, CO₂, NO_x.

Materials to avoid:

Oxidizing agents, reducing agents, aluminium devices, steel and alkaline solution.

11. Toxicological information

Acute toxicity

| | |
|-------------------------------|-----------------------|
| LD ₅₀ ≤ 19,5 mg/kg | intraperitoneal-mouse |
| LD ₅₀ ≤ 17,5 mg/kg | intraperitoneal-rat |
| LD ₅₀ ≤ 22,5 mg/kg | intravenous-mouse |
| LD ₅₀ ≤ 23,4 mg/kg | intravenous-rat |
| LD _{Lo} ≤ 200 mg/kg | intravenous-dog |

May be absorbed by inhalation and ingestion. May cause irritation in the skin, eyes, mucous membranes and respiratory tract.

Oxaliplatin did not induce renal toxicity, had only slight hematologic toxicity, but displayed significant cardiac toxicity and moderate neurotoxicity in dogs, which was lethal at high doses (≥ 200 mg/m³). However Oxaliplatin showed no significant cardiotoxicity in studies performed using an in vivo assessments in rats and hamsters, and in vitro model used successfully to assess the relative cardiotoxic potential in various antitumor anthracycline analoges. Oxaliplatin showed no mutagenic activity in Ames Test.

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Chronic toxicity

Data not available for long term exposure. When administered intravenously, Oxaliplatin can produce peripheral neuropathy, characterized by paresthesias that are increased by exposure to cold. Symptoms disappear by stopping therapy one week. Other side effects are nausea and vomiting, mild leukopenia and thrombocytopenia.
Metabolite products of Oxaliplatin may cause sensitization.

12. Ecological information

Information on elimination, persistence and decomposition

No data available.

Effects on environmental compartments

No data available.

Ecotoxic effects

Quantitative data on the ecological effect of this product are not available.

Further informations:

Do not allow to enter surface and ground water, the sewage system or soil.

13. Advice on disposal

Disposal

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, the following classification is valid:

EAK-No: 180108 Cytotoxic and cytostatic medicines

Disposal of uncleaned packing / recommended detergents

Disposal in compliance with official regulations. Handle contaminated packing in the same way as the substance itself. If not officially specified differently, noncontaminated packing may be treated like household waste or recycled.

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14. Transport information

14.1 Land transport (ADR/RID/GGVS/GGVE)

UN-No.: UN 2811
Proper Shipping Name : TOXIC SOLID, ORGANIC, N.O.S.
 (CYTOSTATIC DRUG)
Class/main risk: 6.1
Subsidiary risk: ---
Packing group: II
Label: 6.1

14.2 Inland water ways transport

Not classified.

14.3 Marine transport (IMDG/GGVSee)

UN-No.: UN 2811
Proper Shipping Name : TOXIC SOLID, ORGANIC, N.O.S.
 (CYTOSTATIC DRUG)
Class/main risk: 6.1
Subsidiary risk: ---
Packing group: II
Marine pollutant: no
Label: 6.1

14.4 Air transport(IATA/ICAO)

UN-No.: UN 2811
Proper Shipping Name : TOXIC SOLID, ORGANIC, N.O.S.
 (CYTOSTATIC DRUG)
Class/main risk: 6.1
Subsidiary risk: ---
Packing group: II
Label: 6.1

14.5 Further information

15. Regulatory information

15.1 Labelling

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R-Phrases:

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.

S-Phrases:

20/21 When using do not eat, drink or smoke.
 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).
 53 Avoid exposure-obtain special instructions before use.
 61 Avoid release to the environment. Refer to special instructions/Safety data sheets.

15.2 National regulations

Germany:

Prohibition to employ: teenager under 18 years (Jugendarbeitsschutzgesetz), pregnant and nursing mothers (Mutterschutzverordnung)

Water Endangerment WGK-class: 3 strong water pollutant (regulation VwVwS, Annex 3)

16. Other information

The data given here is based on today`s state of our knowledge and experience. The purpose of this Safety Data Sheet is to describe the product in terms of its safety requirements. The data does not signify any warranty with regard to the products` properties.

Sector making out data sheet: HH-SUS