

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

- **Product identifier**
- **Trade name:** Diammin(cyclobutane-1,1-dicarboxylato)platinum(II); "Carboplatin"
- **Article number:** 89730036
- **CAS Number:**
41575-94-4
- **EC number:**
255-446-0
- **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**
 - Muta. 1B H340 May cause genetic defects.
 - Carc. 1A H350 May cause cancer.
 - Repr. 2 H361d Suspected of damaging the unborn child.
 - Met. Corr.1 H290 May be corrosive to metals.
 - Acute Tox. 4 H302 Harmful if swallowed.
 - 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: May cause cancer. May cause heritable genetic damage.
 - Xn; Harmful
 - R22-63: Harmful if swallowed. Possible risk of harm to the unborn child.
 - 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.

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Hazard pictograms

GHS05 GHS07 GHS08

Signal word Danger**Hazard statements**

- May be corrosive to metals.
- Harmful if swallowed.
- Causes skin irritation.
- Causes serious eye irritation.
- May cause genetic defects.
- May cause cancer.
- Suspected of damaging the unborn child.
- May cause respiratory irritation.
- Restricted to professional users.

Precautionary statements

- Obtain special instructions before use.
- Wear protective gloves/protective clothing/eye protection/face protection.
- Keep only in original container.
- Do not eat, drink or smoke when using this product.
- Do not breathe dust.

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**

41575-94-4 Diammin(cyclobutane-1,1-dicarboxylato)platinum(II);
"Carboplatin"

Identification number(s)

EC number: 255-446-0

4 First aid measures**Description of first aid measures**

General information: In case of accident or if you feel unwell, seek medical advice immediately.

After inhalation:

- Supply fresh air.
- Call a doctor immediately.

After skin contact:

- Immediately wash with water and soap and rinse thoroughly.
- Immediately remove all soiled and contaminated clothing
- 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.

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- Call for 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

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.
Carbon monoxide (CO)
Nitrogen oxides (NO_x)
- **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 formation of dust.
Use respiratory protective device against the effects of fumes/dust/aerosol.
Avoid contact with substance.
- **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:**
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**
Wear protective equipment. Keep unprotected persons away.
Work only in fume cupboard.
Store under lock and key and with access restricted to technical experts or their assistants only.
Open and handle receptacle with care.
- **Information about fire - and explosion protection:**
see chapter 5
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:**
 - Corrosive action on metals.
 - Store in a cool location.
 - Store in dry conditions.
- **Information about storage in one common storage facility:**
 - Store away from flammable substances.
 - Store away from foodstuffs.
- **Further information about storage conditions:**
 - Protect from exposure to the light.
 - 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:**
 - Ensure good ventilation/exhaustion at the workplace.
 - Work only in fume cupboard.
 - Waste air is to be released into the atmosphere only via suitable separators.
- **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.
 - Immediately remove all soiled and contaminated clothing
 - Shower or take a bath 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:**
 - Impervious gloves
 - 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

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9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Solid
· Colour:	White
· Odour:	Odourless

· Change in condition

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Product is not flammable.

· Ignition temperature:

· **Decomposition temperature:** >200°C

· **Self-igniting:** Product is not self igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Vapour pressure:** Undetermined.

· Density:

· **Bulk density:** Not determined.

· Solubility in / Miscibility with

· **water at 20°C:** 18 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:** Corrosive action on metals.

· **Hazardous decomposition products:** Nitrogen oxides (NO_x)

11 Toxicological information

· Information on toxicological effects

· Acute toxicity:

· LD/LC50 values relevant for classification:

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Oral	LD50	343 mg/kg (rat)
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· Primary irritant effect:

· **on the skin:** Irritant to skin and mucous membranes.

· **on the eye:** Irritating effect.

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- **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.
- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
Muta. 1B, Carc. 1A, Repr. 2

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**
After prior treatment product has to be disposed of in an incinerator for hazardous waste adhering to the regulations pertaining to the disposal of particularly hazardous waste.
 - **European waste catalogue**
- | | |
|-----------|------------------------------------|
| 18 01 08* | cytotoxic and cytostatic medicines |
|-----------|------------------------------------|
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|----------------------------------|---|
| · UN-Number | |
| · ADR, IMDG, IATA | 2923 |
| · UN proper shipping name | |
| · ADR | 2923 CORROSIVE SOLID, TOXIC, N.O.S. (Diammin(cyclobutane-1,1-dicarboxylato)platinum(II); "Carboplatin") |
| · IMDG, IATA | CORROSIVE SOLID, TOXIC, N.O.S. (Diammin(cyclobutane-1,1-dicarboxylato)platinum(II); "Carboplatin") |

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· **Transport hazard class(es)**

· **ADR**



· **Class** 8 Corrosive substances.
· **Label** 8+6.1

· **IMDG, IATA**



· **Class** 8 Corrosive substances.
· **Label** 8+6.1

· **Packing group**

· **ADR, IMDG, IATA** III

· **Environmental hazards:**

· **Marine pollutant:** No

· **Special precautions for user** Warning: Corrosive substances.

· **Danger code (Kemler):** 86

· **EMS Number:** F-A,S-B

· **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":** UN2923, CORROSIVE SOLID, TOXIC, N.O.S., 8 (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 juveniles must be observed.

Employment restrictions concerning pregnant and lactating women 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

EINECS: European Inventory of Existing Commercial Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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