

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

- **Product identifier**
- **Trade name:** *cis-Diamminedichloroplatinum(II); "Cisplatin" - pharmaceutical grade*
- **Article number:** 89730021
- **CAS Number:**
15663-27-1
- **EC number:**
239-733-8
- **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. 2 H300 Fatal if swallowed.
Acute Tox. 3 H331 Toxic if inhaled.
Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Muta. 1B H340 May cause genetic defects.
Carc. 1A H350 May cause cancer.
Met. Corr.1 H290 May be corrosive to metals.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.*
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
*T; Toxic
R45-46-23/25: May cause cancer. May cause heritable genetic damage. Toxic by inhalation and if swallowed.
Xn; Sensitising
R42/43: May cause sensitisation by inhalation and skin contact.
Xi; Irritant
R36/37: Irritating to eyes and respiratory system.*
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.

(Contd. on page 2)

Printing date 30.08.2011

Version: 5

Revision: 26.08.2011

Trade name: cis-Diamminedichloroplatinum(II); "Cisplatin" - pharmaceutical grade

(Contd. of page 1)

Hazard pictograms

GHS05 GHS06 GHS08

Signal word Danger**Hazard statements***May be corrosive to metals.**Fatal if swallowed.**Toxic if inhaled.**Causes serious eye irritation.**May cause allergy or asthma symptoms or breathing difficulties if inhaled.**May cause an allergic skin reaction.**May cause genetic defects.**May cause cancer.**May cause respiratory irritation.**Restricted to professional users.***Precautionary statements***Obtain special instructions before use.**Do not breathe dust/fume/gas/mist/vapours/spray.**In case of inadequate ventilation wear respiratory protection.**Wear protective clothing and eye protection.**IF ON SKIN: Wash with plenty of soap and water.**Get medical advice/attention if you feel unwell.***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**

15663-27-1 cis-Diamminedichloroplatinum(II)

Identification number(s)**EC number:** 239-733-8**4 First aid measures****Description of first aid measures****General information:***In case of accident or if you feel unwell, seek medical advice immediately.**Immediately remove any clothing soiled by the product.**Remove breathing equipment only after contaminated clothing have been completely removed.**In case of irregular breathing or respiratory arrest provide artificial respiration.***After inhalation:***Supply fresh air.**Call a doctor immediately.***After skin contact:***Immediately rinse with water.*

(Contd. on page 3)

Trade name: cis-Diamminedichloroplatinum(II); "Cisplatin" - pharmaceutical grade

(Contd. of page 2)

- Call a doctor immediately.
- **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

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)
Hydrogen chloride (HCl)
Chlorine
- **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.
Mount respiratory protective device.
Avoid formation of dust.
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:**
Pick up mechanically.
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**
Wear protective equipment. Keep unprotected persons away.
Work only in fume cupboard.
Prevent formation of dust.

(Contd. on page 4)

Trade name: cis-Diamminedichloroplatinum(II); "Cisplatin" - pharmaceutical grade

(Contd. of page 3)

Store under lock and key and with access restricted to technical experts or their assistants only.

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

· **Information about fire - and explosion protection:**

see chapter 5

Keep respiratory protective device available.

· **Conditions for safe storage, including any incompatibilities**

· **Storage:**

· **Requirements to be met by storerooms and receptacles:**

Corrosive action on metals.

Store in dry conditions.

Store in a cool location.

· **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:**

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.

· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

We recommend the reference point of 1 µg/m³ for cytostatic drug.

15663-27-1 cis-Diamminedichloroplatinum(II); "Cisplatin" - pharmaceutical grade

WEL	Long-term value: 0.002 mg/m ³ as Pt
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· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Work only in fume cupboard.

Do not eat or drink while working.

Shower or take a bath at the end of work.

Immediately remove all soiled and contaminated clothing

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

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**

Natural rubber, NR

(Contd. on page 5)

Printing date 30.08.2011

Version: 5

Revision: 26.08.2011

Trade name: *cis-Diamminedichloroplatinum(II)*; "Cisplatin" - pharmaceutical grade

(Contd. of page 4)

· **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:	Powder
· Colour:	Yellow
· Odour:	Odourless

· **pH-value at 20°C:** 5-7· **Change in condition**· **Boiling point/Boiling range:** Undetermined.· **Flash point:** Not applicable.· **Flammability (solid, gaseous):** Undetermined.· **Ignition temperature:**· **Decomposition temperature:** >285°C· **Danger of explosion:** Product does not present an explosion hazard.· **Vapour pressure:** Not applicable.· **Density at 20°C:** 3.7 g/cm³· **Bulk density at 20°C:** 850 kg/m³· **Solubility in / Miscibility with**· **water at 20°C:** 2.5 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:** No dangerous decomposition products known.

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(Contd. on page 6)

Trade name: *cis-Diamminedichloroplatinum(II)*; "Cisplatin" - pharmaceutical grade

(Contd. of page 5)

11 Toxicological information

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

· LD/LC50 values relevant for classification:		
Oral	LD50	25.8 mg/kg (rat)
	LD50 intravenous	11 mg/kg (mouse)
	LD50 subcutan	8.1 mg/kg (rat)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Irritating effect.
- **Sensitization:**
Platinum-chloro-compounds are well known to act as sensitizer by inhalation or skin contact. If sensitized and re-exposed, subject may show symptoms of rhinitis, asthma, conjunctivitis or contact dermatitis.
- **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 (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** Contact manufacturer for recycling information.

· European waste catalogue	
18 01 08*	cytotoxic and cytostatic medicines

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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(Contd. on page 7)

Printing date 30.08.2011



Version: 5

Revision: 26.08.2011

Trade name: cis-Diamminedichloroplatinum(II); "Cisplatin" - pharmaceutical grade

(Contd. of page 6)

14 Transport information

· UN-Number	3288
· ADR, IMDG, IATA	
· UN proper shipping name	3288 TOXIC SOLID, INORGANIC, N.O.S. (cis-Diamminedichloroplatinum(II))
· ADR	
· IMDG, IATA	TOXIC SOLID, INORGANIC, N.O.S. (cis-Diamminedichloroplatinum(II))
· 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	II
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Toxic substances.
· Danger code (Kemler):	60
· EMS Number:	F-A,S-A
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Tunnel restriction code	D/E
· UN "Model Regulation":	UN3288, TOXIC SOLID, INORGANIC, N.O.S., 6.1, II

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.

(Contd. on page 8)

Printing date 30.08.2011

Version: 5

Revision: 26.08.2011

Trade name: cis-Diamminedichloroplatinum(II); "Cisplatin" - pharmaceutical grade

Employment restrictions concerning pregnant and lactating women must be observed.

(Contd. of page 7)

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**

· **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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