

Carboplatin Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Carboplatin Injection

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

Use of the substance/mixture : Pharmaceutical
Other means of identification : 50 mg per 5 mL (10 mg / mL): 5 mL multiple dose vial packaged individually NDC 55150-333-01
150 mg per 15 mL (10 mg / mL): 15 mL multiple dose vial packaged individually NDC 55150-334-01
450 mg per 45 mL (10 mg / mL): 45 mL multiple dose vial packaged individually NDC 55150-335-01
600 mg per 60 mL (10 mg / mL): 60 mL multiple dose vial packaged individually NDC 55150-386-01

1.3. Details of the supplier of the safety data sheet

AuroMedics
279 Princeton Highstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Acute Tox. 4 (Oral) H302
Resp. Sens. 1 H334
Skin Sens. 1 H317
Muta. 1B H340
Repr. 2 H361

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US) :



Signal word (GHS US) :

Danger

Hazard statements (GHS US) :

H302 - Harmful if swallowed
H317 - May cause an allergic skin reaction
H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled
H340 - May cause genetic defects
H361 - Suspected of damaging fertility or the unborn child

Precautionary statements (GHS US) :

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P284 - [In case of inadequate ventilation] wear respiratory protection.
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.
P302+P352 - If on skin: Wash with plenty of water.
P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P330 - Rinse mouth.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.
P363 - Wash contaminated clothing before reuse.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in

Carboplatin Injection

Safety Data Sheet

accordance with local, regional, national and/or international regulation.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Water	(CAS-No.) 7732-18-5	< 98	Not classified
D-Mannitol	(CAS-No.) 69-65-8	< 2	Not classified
Carboplatin	(CAS-No.) 41575-94-4	0.1	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Resp. Sens. 1, H334 Skin Sens. 1, H317 Muta. 1B, H340 Repr. 1B, H360

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove to fresh air and keep patient at rest. Seek medical attention immediately.
First-aid measures after skin contact	: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
First-aid measures after eye contact	: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid measures after ingestion	: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

Symptoms/injuries after inhalation	: None anticipated during normal product use.
Symptoms/injuries after skin contact	: May cause skin irritation May cause an allergic skin reaction.
Symptoms/injuries after eye contact	: May cause eye irritation.
Symptoms/injuries after ingestion	: May be harmful if swallowed.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
-------------	---------------

5.3. Advice for firefighters

Protection during firefighting	: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
--------------------------------	---

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No special measures required.
------------------	---------------------------------

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

Carboplatin Injection

Safety Data Sheet

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.
Methods for cleaning up : Absorb spillage with suitable absorbent material. Place in a suitable container and dispose according to local, state and federal regulations.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 20° to 25°C (68° to 77°F).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Water (7732-18-5)

Not applicable

D-Mannitol (69-65-8)

Not applicable

Carboplatin (41575-94-4)

Not applicable

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : No protection is ordinarily required under normal conditions of use.
Eye protection : Wear safety glasses or goggles.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : No protection is ordinarily required under normal conditions of use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear
Color : Colorless
Odor : Odorless
Odor threshold : No data available
pH : No data available
Melting point : No data available
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butyl acetate=1) : No data available
Flammability (solid, gas) : No data available
Vapor pressure : No data available
Relative vapor density at 20 °C : No data available
Relative density : No data available
Solubility : Soluble
Partition coefficient n-octanol/water (Log Pow) : No data available
Auto-ignition temperature : No data available

Carboplatin Injection

Safety Data Sheet

Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Air contact.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Carboplatin Injection	
ATE US (oral)	500 mg/kg body weight
Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg
D-Mannitol (69-65-8)	
LD50 oral rat	13500 mg/kg
ATE US (oral)	13500 mg/kg
Carboplatin (41575-94-4)	
LD50 oral rat	343 mg/kg
ATE US (oral)	343 mg/kg body weight
ATE US (dermal)	1100 mg/kg body weight
ATE US (gases)	4500 ppmV/4h
ATE US (vapors)	11 mg/l/4h
ATE US (dust, mist)	1.5 mg/l/4h

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: May cause an allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: May cause genetic defects.
Carcinogenicity	: Not classified
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified

Carboplatin Injection

Safety Data Sheet

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

D-Mannitol (69-65-8)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Carboplatin (41575-94-4)

U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significant risk level (NSRL)
No	Yes	No	No	

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Muta. 1B	Germ cell mutagenicity Category 1B
Repr. 1B	Reproductive toxicity Category 1B
Repr. 2	Reproductive toxicity Category 2
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Sens. 1	Skin sensitization, Category 1
H302	Harmful if swallowed
H312	Harmful in contact with skin

Carboplatin Injection

Safety Data Sheet

H317	May cause an allergic skin reaction
H332	Harmful if inhaled
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled
H340	May cause genetic defects
H360	May damage fertility or the unborn child
H361	Suspected of damaging fertility or the unborn child

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.