

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Car-AUS/DP-004

Effective Date: 14th October 2024

CARBOPLATIN SOLUTION FOR INJECTION
50 MG/5 ML, 150 MG/15 ML, AND 450 MG/45 ML

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Carboplatin Accord Solution of Injection
50 mg/5 mL, 150 mg/15 mL, and 450 mg/45 mL

Sponsor	Manufacturer-1	Manufacturer-2
Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia Telephone: 1800 222 673 (hours 8:30am – 4:30pm)	Intas Pharmaceuticals Ltd. Plot No. 457, 458 Village-Matoda, Bavla Road, Ta. Sanand, Dist. Ahmedabad-382 210, Gujarat, India	Intas Pharmaceuticals Ltd. Plot No. 5, 6 and 7, Pharmedz, Near Matoda Village, Ahmedabad-382 213, Gujarat, India

SECTION 2 – HAZARD(S) IDENTIFICATION

Classification of the Substance or Mixture:

GHS – Classification:

Germ Cell Mutagenicity : Category 2
Reproductive Toxicity : Category 1B



Label Elements:

Signal Word: Danger

Hazard Statements:

H341 - Suspected of causing genetic defects
H360D - May damage the unborn child

Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Car-AUS/DP-004

Effective Date: 14th October 2024

- P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards: An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Active: Carboplatin.

Inactive: Water for Injection.

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Carboplatin	41575-94-4	255-446-0	Acute Tox. 4 (H302) Repr. 1B (H360D) Muta. 2 (H341)	1
Water for Injection	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

SECTION 4 - FIRST AID MEASURES

Description of Necessary First Aid Measures:

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Car-AUS/DP-004

Effective Date: 14th October 2024

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known.

Medical Attention and Special Treatment: None.

SECTION 5 - FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture: Formation of toxic gases is possible during heating or fire.

Special Protective Equipment and Precautions for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

SECTION 7 - HANDLING AND STORAGE

Precautions for Safe Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Car-AUS/DP-004

Effective Date: 14th October 2024

Conditions for Safe Storage, Including any Incompatibilities: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product used as Antineoplastic.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters – Exposure Standards, Biological Monitoring:

Caboplatin:

OEL TWA-8 Hr : 60 µg/m³

Appropriate Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Solution
Colour	: Clear, colourless
Odour	: No data available
Odour Threshold	: No data available

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Car-AUS/DP-004

Effective Date: 14th October 2024

Solvent Solubility	: No data available
Water Solubility	: No data available
pH	: 5-7
Melting/Freezing Point (°C)	: No data available
Boiling Point and boiling range (°C)	: No data available
Partition Coefficient (<i>n</i>-octanol/water)	: No data available
Decomposition Temperature (°C)	: No data available
Evaporation Rate (Gram/s)	: No data available
Vapour Pressure (kPa)	: No data available
Vapour Density (g/ml)	: No data available
Relative Density	: No data available
Viscosity	: No data available
Auto-ignition Temperature (Solid) (°C)	: No data available
Flammability (Solids)	: No data available
Flash Point (Liquid) (°C)	: No data available
Upper Flammability or Explosive Limits (Liquid) (% by Vol.)	: No data available
Lower Flammability or Explosive Limits (Liquid) (% by Vol.)	: No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials and Possible Hazardous Reactions: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: No data available.

SECTION 11 – TOXICOLOGICAL INFORMATION

The information included in this section describes the potential hazards of the active ingredient.

Information on Toxicological Effects:

Short Term: Harmful if swallowed (based on animal data) Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. In the workplace, platinum compounds have been reported to cause allergic skin and respiratory reactions.

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Car-AUS/DP-004

Effective Date: 14th October 2024

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on testes the developing fetus. May cause effects on blood and blood forming organs.

Acute Toxicity:

Carboplatin:

Species	Route	End Point	Dose
Rat	Oral	LD 50	343 mg/kg
Rat	Para-periosteal	LD 50	72 mg/kg
Rat	Intraperitoneal	LD 50	118 mg/kg

Repeated Dose Toxicity:

Carboplatin:

Duration	Species	Route	Dose	End Point
26 Week(s)	Dog	Intravenous	140 mg/kg	LOAEL

Reproduction & Development Toxicity:

Carboplatin:

Study Type	Species	Route	Dose	End Point	Effect(s)
Embryo / Fetal Development	Rat	Oral	4 mg/kg/day	LOAEL	Fetotoxicity, Developmental toxicity
Embryo / Fetal Development	Rat	Oral	6 mg/kg/day	LOAEL	Fertility, Teratogenic

Genetic Toxicity:

Carboplatin:

Study Type	Cell Type/Organism	Result
<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Positive
<i>In Vivo</i> Mammalian Cell Mutagenicity	Hamster	Positive
<i>In Vivo</i> Micronucleus	Mouse	Positive

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity: No data available.

Persistence and Degradability: No data available.

Bio-accumulative Potential: No data available.

Mobility in Soil: No data available.

Other Adverse Effects: No data available.

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Car-AUS/DP-004

Effective Date: 14th October 2024

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14 - TRANSPORTATION INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Carboplatin:

CERCLA/SARA 313 Emission reporting	: Not Listed
California Proposition 65	: Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons	: Schedule 4
EU EINECS/ELINCS List	: Not Listed

Water for Injection:

CERCLA/SARA 313 Emission reporting	: Not Listed
California Proposition 65	: Not Listed
Inventory - United States TSCA - Sect. 8(b)	: Present
Australia (AICS)	: Present
REACH - Annex IV - Exemptions from the obligations of Register	: Present
EU EINECS/ELINCS List	: 231-791-2

SECTION 16 - OTHER INFORMATION

Full text of H phrases and GHS classifications:

ATO4	- Acute Toxicity (Oral) Category 4.
Carc1B	- Carcinogenicity Category 1B.
STOT-R1	- Specific Target Organ Toxicity Following Repeat Exposure Category 1.
RT1B	- Reproductive toxicity Category 1B.

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Car-AUS/DP-004

Effective Date: 14th October 2024

- GCM2 - Germ Cell Mutagenicity Category 2.
- AA1 - Acute aquatic toxicity Category 1.
- CA1 - Chronic Aquatic Toxicity Category 1.
- H302 - Harmful if swallowed.
- H341 - Suspected of causing genetic defects.
- H350 - May cause cancer.
- H360FD - May damage fertility. May damage the unborn child.
- H372 - Causes damage to hematological and gastrointestinal systems through prolonged or repeated exposure.
- H400 - Very toxic to aquatic life.
- H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations:

- ACGIH : American Conference of Governmental Industrial Hygienists
- AICS : Australian Inventory of Chemical Substances
- AIHA : American Industrial Hygiene Association
- ANSI : American National Standards Institute
- CAS : Number Chemical Abstract Service Registry Number
- CERCLA : Comprehensive Environmental Response Compensation and Liability Act
- CHAN : Chemical Hazard Alert Notice
- CHEMTREC : Chemical Transportation Emergency Center
- DOT : Department of Transportation
- DSL : Domestic Substances List
- ECHA : European Chemicals Agency
- EINECS : European Inventory of Existing Commercial Chemical Substances
- ELINCS : European List of Notified Chemical Substances
- EPA : Environmental Protection Agency
- GHS : Globally Harmonized System of Classification and Labelling of Chemicals
- HEPA : High Efficiency Particulate Air (Filter)
- HMIS : Hazardous Materials Identification System
- IARC : International Agency for Research on Cancer
- ICAO/IATA : International Civil Aviation Organization/International Air Transport
- IMO : International Maritime Organization
- KOW : Octanol/Water Partition Coefficient
- LEL : Lower Explosive Limit
- MSDS : Material Safety Data Sheet
- MSHA : Mine Safety and Health Administration
- NA : Not Applicable, except in Section 14 where NA = North America
- NE : Not Established
- NADA : New Animal Drug Application
- NAIF : No Applicable Information Found
- NCI : National Cancer Institute
- NDSL : Non-Domestic Substances List
- NFPA : National Fire Protection Association
- NIOSH : National Institute for Occupational Safety and Health
- NPDES : National Pollutant Discharge Elimination System
- NOS : Not Otherwise Specified

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Car-AUS/DP-004

Effective Date: 14th October 2024

NTP	: National Toxicology Program
OSHA	: Occupational Safety and Health Administration
OEL	: Occupational Exposure Limit
PEL	: Permissible Exposure Limit (OSHA)
RCRA	: Resource Conservation and Recovery Act
RQ	: Reportable Quantity
RTECS	: Registry of Toxic Effects of Chemical Substances
SARA	: Superfund Amendments and Reauthorization Act
SDS	: Safety Data Sheet
STEL	: Short Term Exposure Limit
TLV	: Threshold Limit Value (ACGIH)
TPQ	: Threshold Planning Quantity
TSCA	: Toxic Substances Control Act
TWA	: Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	: Upper Explosive Limit
UN	: United Nations
USP	: United States Pharmacopeia
WEEL	: Workplace Environmental Exposure Level (AIHA)
WHMIS	: Workplace Hazardous Materials Information System

Data Sources: Information from published literature.

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall INTAS be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if INTAS has been advised of the possibility of such damages.