

# Carboplatin Accord 10 mg/ml

## Material Safety Data Sheet

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Carboplatin 10 mg/ml concentrate for solution for infusion

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

Medical Treatment: Anticancer Agent

#### 1.3. Details of the supplier of the safety data sheet

Manufacturer: Accord Healthcare Limited  
Sage House 319, Pinner Road, North Harrow, Middlesex, HA1 4HF, UK  
phone: +44 (0)208 863 1427 - fax: +44 (0)208 863 1426  
between: 9 am to 17:30 pm  
e-mail: skadaru@accord-healthcare.com

#### 1.4. Emergency telephone number

Emergency telephone number: +442089013370

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP):  
Muta. 1B , H340  
Carc. 1A, H350

#### 2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP):



Contains diammin(cyclobutane-1,1-dicarboxylato)platinum(II).

Signal word:

Danger

Hazard statement(s):

H340 - May cause genetic defects.

H350 - May cause cancer.

Precautionary statement(s):

P201 - Obtain special instructions before use.

P281 - Use personal protective equipment as required.

P308+P313 - IF exposed or concerned: Get medical advice/attention.

P405 - Store locked up.

## 2.3. Other hazards

This mixture do not meet the criteria for PBT and vPvB.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable.

### 3.2. Mixtures

diammin(cyclobutane-1,1-dicarboxylato)platinum(II) - Contains 1%

CAS number: 41575-94-4

EC number: -

Index number: -

Registration number: Not applicable.

Classification according to Muta. 1B, H340

Regulation (EC) No Carc. 1A, H350

1272/2008 (CLP): Repr. 2, H361d

Met. Corr.1, H290

Acute Tox. 4, H302

STOT SE 3, H335

Skin Irrit. 2, H315

Eye Irrit. 2, H319

The full text of H code(s) is given in section 16.

## SECTION 4: First aid measures

### 4.1. Description of first-aid measures

After inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

After skin contamination: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

After contamination of eyes: If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water and seek medical attention.

After consumption: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

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

This material is intended for intravenous injection under the supervision of physicians.

**INHALATION:** Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

**CONTACT WITH SKIN OR EYES:** Contact may cause irritation. Effects may include stinging, watering, redness and swelling of the eyes and redness and a burning sensation.

**INGESTION:** Ingestion is not an anticipated route of occupational exposure. However, the active ingredient, Carboplatin, is toxic if swallowed. Symptoms similar to those identified under injection may occur.

**INJECTION:** Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience overexposures to the therapeutic doses of this product. However, effects including decreased blood platelets, granulocytes and white blood cells, fever, anemia, nausea, vomiting, abdominal pain, diarrhea, constipation, peripheral neuropathy, visual disturbances, change in taste, abnormal renal and liver function tests, decreased serum electrolytes, rash, hives, redness, itching, hearing loss, vision changes, bronchospasms and decreased blood pressure may occur. Severe injection overexposure may be fatal. See package insert for other adverse reactions associated

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

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

The product is non-flammable.

In the case of fire use extinguishing media suitable for materials stored in immediate vicinity. Water spray, CO<sub>2</sub>, dry chemical, Halon, Foam can be used as the extinguish media.

Not recommended extinguishing media: no data available.

#### 5.2. Special hazards arising from the substance or mixture

There is no data available about hazardous substances which may occur during fire thermal decomposition of the mixture.

#### 5.3. Advice for firefighters

For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Avoid contamination with the product. Notify the effected individuals of the emergency, to be aware of the issues associated. Avoid contact of the mixture with skin and eyes. Remove contaminated clothing and wash before reuse.

#### 6.1.2. For emergency responders

For small releases of this product, wear latex or nitrile gloves and safety glasses.

#### 6.2. Environmental precautions

Avoid entering the product into drains, surface water and groundwater, reservoirs and waterways.

#### 6.3. Methods and material for containment and cleaning up

Absorb spilled liquid and rinse area thoroughly with soap and water. For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

#### 6.4. Reference to other sections

Use the control measures and personal protective equipment described in section 8 of this MSDS. Refer to section 13 of this MSDS for adequate release measures.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

While working with the preparation, one should use appropriate means of personal protection (see pt. 8). Avoid contact of the preparation with skin and eyes, as well as inhaling its mists. Secure efficient local ventilation. CARBOPLATIN IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.

##### Industrial hygiene:

Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes

##### PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT:

When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

#### 7.2. Conditions for safe storage, including any incompatibilities

Employees must be trained to properly use the product.

Ensure vials are properly labeled.

Store only in approved containers.

Keep away from sources of ignition and any incompatible materials or conditions (see Section 10).

Store at room temperature 25°C.

Do not refrigerate or freeze.

Keep vial in the outer carton in order to protect from light.

Do not store with food or animal feed.



### 7.3. Specific end use(s)

No data available.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Does not contain materials with occupational exposure limit values at workplace.

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

Use with adequate ventilation. Follow standard medical product handling procedures.

#### 8.2.2. Individual protection measures, such as personal protective equipment

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

Eye / Face protection: Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

Skin protection: Hand protection: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

Body protection: A full body gown which is closed at the front and has long sleeves is recommended.

Respiratory protection: Use reagent in well-ventilated rooms, avoid inhaling product mists, respiratory tract protective agents are not required.

Thermal hazards: Not applicable.

#### 8.2.3. Environmental exposure controls

No data available.

## SECTION 9: Physical and chemical properties

a) Appearance:	Physical state: Clear solution. - Colour: Colourless to pale yellow
b) Odour:	Odourless
c) Odour threshold :	No data available
d) pH:	5-7
e) Melting point/ freezing point	0°C (32°F)
f) Initial boiling point and boiling range:	100°C (212°F)
g) Flash point:	No data available
h) Evaporation rate:	No data available
i) Flammability (solid,	Incombustible
j) Upper/lower flammability or explosive	No data available
k) Vapour pressure:	No data available
l) Vapour density:	No data available
m) Relative density:	No data available

n) Solubility(ies):	Sparingly
o) Partition coefficient (n-octanol/water):	No data available
p) Auto-ignition temperature:	No data available
q) Decomposition temperature:	No data available
r) Viscosity:	No data available
s) Explosive properties:	No data available
t) Oxidising properties:	No data available

## 9.2. Other information

No other relevant information.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is stable in conditions provided by the manufacturer.

### 10.2. Chemical stability

The product is stable when normal handling in accordance with conditions provided by the manufacturer.

### 10.3. Possibility of hazardous reactions

Not known.

### 10.4. Conditions to avoid

The product is stable in conditions provided by the manufacturer.

### 10.5. Incompatible materials

May react with strong oxidizing agents. Aluminum can react with carboplatin causing precipitate formation and loss of potency.

### 10.6. Hazardous decomposition products

Oxides of carbon and nitrogen and platinum- containing compounds with possible carcinogenic potential.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

No data for the mixture. Toxicological problems should not be expected if the product were used and applied appropriately. The product should be handled with the care usual when dealing with chemicals.

a) acute toxicity:	Data for Diammin(cyclobutane-1,1-dicarboxylato)platinum(II); "Carboplatin": <b>LD 50 (oral – rat): 343 mg/kg</b>
b) irritation:	This product is expected to be irritating to contaminated skin, eyes and other tissues. The active ingredient is irritating to the eyes and the skin
c) corrosivity:	No data available.
d) sensitisation:	No data available.
e) repeated dose toxicity:	No data available.
f) carcinogenicity:	The carcinogenic potential of Carboplatin has not been examined in test animals; however, compounds with similar mechanisms of action (e.g.,

- g) mutagenicity: Carboplatin is reportedly mutagenic in both in vitro and in vivo mutagenesis assays, and the mouse lymphoma assay.
- h) toxicity for reproduction: In male and female rats, a dose of up to 4 mg/kg/day produced suppression of body weight in adults; when the dose was increased to 6 mg/kg/day, a corresponding increase in congenital and/or skeletal anomalies was observed. Doses of 24 mg/kg/day administered to rats between the sixth and ninth days of pregnancy were associated with specific developmental abnormalities of the central nervous system, musculoskeletal system, and body wall. Carboplatin is presently listed as a Proposition 65 developmental toxin by the state of California.

## SECTION 12: Ecological information

### 12.1. Toxicity

No data for the mixture. Ecological problems should not be expected if you use and apply the product appropriately. The product should be handled with the care usual when dealing with chemicals.

Ecotoxicity: No data available.

Further ecological data: Prevent disposal into water, sewage or soil.

### 12.2. Persistence and degradability

No data available.

### 12.3. Bioaccumulative potential

No data available.

### 12.4. Mobility in soil

No data available.

### 12.5. Results of PBT and vPvB assessment

No data available.

### 12.6. Other adverse effects

No data available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product: Chemical residues, in general, are included into special waste. Disposing of the latter is regulated by appropriate laws and ordinances. We recommend contacting the appropriate authorities, or waste disposal enterprises that will advise you on how to dispose of special waste.

Packing: Remove in accordance with official regulations. Treat contaminated packages in the same way as the substance itself. If the regulations do not provide otherwise, noncontaminated packages can be treated like household waste or forward them to be utilized.

## SECTION 14: Transport information

### 14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

## SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture  
Material Safety Data Sheet Regulation (EC) No 1907/2006 of European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH); Regulation (EC) No 1272/2008 of the European Parliament and Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

15.2. Chemical safety assessment

Chemical safety assessment has been no carried out for the product.

## SECTION 16: Other information

Full text of abbreviations and acronyms: Muta. 1B, Germ cell mutagenicity (category 1B)  
Carc. 1A, Carcinogenicity (category 1A)  
Repr 2 - Reproductive toxicity (category 2)  
Met. Corr.1 - Substance or mixture corrosive to metals (category 1)  
Acute Tox. 4 - Acute toxicity (category 4)  
STOT SE3 - Specific target organ toxicity - single exposure (category 3)  
Skin Irrit. 2 - Skin irritation (category 2)  
**Eye Irrit. 2 – Serious eye irritation (category 2)**

Text of H-code(s): H340 May cause genetic defects.  
H350 May cause cancer.  
H361d Suspected of damaging the unborn child.  
H290 May be corrosive to metals.  
H302 Harmful if swallowed.  
H335 May cause respiratory irritation.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.

Methods of evaluating information for the purpose of classification: calculation method. The foregoing information is based on the present state of our knowledge. It characterizes the product with respect to the appropriate safety measures. They do not guarantee the properties of the product. We do not take responsibility for damage and losses that may result from inappropriate use of the product.

Reason of changes: Change of mixture classification according to Regulation (EC) No 1272/2008 (CLP). Changing the MSDS in accordance with Annex II to Commission Regulation (EU) No 453/2010.

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