

# MATERIAL SAFETY DATA SHEET

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

Effective Date: 17<sup>th</sup> April 2020

## OXALIPLATIN 50 MG/10 ML AND 100 MG/20 ML CONCENTRATE FOR SOLUTION FOR INFUSION

### SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Oxaliplatin 50 mg/10 mL and 100 mg/20 mL concentrate for solution for infusion.

#### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as Antineoplastic

#### Details of the Supplier of the Safety Data Sheet

##### Manufacturer:

- |   |  |
|---|--|
| <b>1. Intas Pharmaceuticals Ltd.</b><br>Plot No. 457, 458<br>Village-Matoda,<br>Bavla Road, Ta. Sanand,<br>Dist. Ahmedabad-382 210,<br>Gujarat, India | <b>2. Intas Pharmaceuticals Ltd.</b><br>Plot No. 5, 6 and 7,<br>Pharmez, Nr. Village<br>Matoda,<br>Ahmedabad-382210,<br>Gujarat, India |
|---|--|

##### Sponsor:

**Accord Healthcare Pty Ltd**  
Level 24, 570 Bourke Street,  
Melbourne, VIC, 3000,  
Australia

### SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

#### Hazardous:

Active Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Oxaliplatin	61825-94-3	Not Listed	Repr.1B (H360D) Muta.1B (H340)	0.5

Inactive Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
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**

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## SECTION 3 - HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture:

#### GHS – Classification:

**Germ Cell Mutagenicity:** Category 1B

**Reproductive Toxicity:** Category 1B

#### Label Elements:

**Signal Word:** Danger

**Hazard Statements:** H360D - May damage the unborn child

H340 - May cause genetic defects.

**Precautionary Statements:** P201 - Obtain special instructions before use

P281 - Use personal protective equipment as required

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

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 4 - FIRST AID MEASURES

### Description of 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.

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## Most Important Symptoms and Effects, Both Acute and Delayed:

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 3 – Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions:** None known

**Aggravated by Exposure:**

## Indication of the Immediate Medical Attention and Special Treatment Needed:

**Notes to Physician:** None

### SECTION 5 - FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture:

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:**

Fine particles (such as mists) may fuel fires/explosions.

**Advice for Fire-Fighters:** During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 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:

**Measures for Cleaning / Collecting:** 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.

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## 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.

**Conditions for Safe Storage, Including any Incompatibilities:**

**Storage Conditions:** Store as directed by product packaging

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

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control parameters:**

**Oxaliplatin:**

**Occupational Exposure Band (OEB):** OEB 4 (control exposure to the range of  $1\mu\text{g}/\text{m}^3$  to  $<10\mu\text{g}/\text{m}^3$ )

**Refer to available public information for specific member state Occupational Exposure Limits.**

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

**Exposure Controls**

**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.

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**Hands:** Impervious gloves (e.g. Nitrile, etc.) are 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 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

<b>Physical State:</b>	Solution
<b>Color:</b>	No data available.
<b>Odor:</b>	Odorless.
<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	4.8-7
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	100
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	
<b>Water for Injection:</b>	No data available
<b>Lactose NF, monohydrate:</b>	No data available
<b>Oxaliplatin:</b>	No data available
<b>Decomposition Temperature (°C):</b>	No data available
<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Viscosity:</b>	No data available
<b>Flammability:</b>	
<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available

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Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

## SECTION 10 - STABILITY AND REACTIVITY

<b>Reactivity</b>	: No data available
<b>Chemical Stability</b>	: Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties</b>	: No data available
<b>Conditions to Avoid</b>	: Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
<b>Incompatible Materials</b>	: As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products</b>	: No data available

## SECTION 11 - TOXICOLOGY INFORMATION

### Information on Toxicological Effect:

**General Information:** The information included in this section describes the potential hazards of the active ingredient

**Short Term:** 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.

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

**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include vomiting, nausea, diarrhea, bone marrow suppression, decreased red blood cell count (anemia), decreased white blood cells (leukopenia), decrease in platelets and red/white blood cells (pancytopenia), nervous system/brain toxicity (neurotoxicity), and skin and acute mucous membrane irritation

### Acute Toxicity:

#### **Oxaliplatin:**

Species:	Route	End Point	Dose
Rat	Oral	LD50	> 100 mg/kg
Rat	IP	LD50	14.3mg/kg
Mouse	Intraperitoneal	LD50	19.8mg/kg

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**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

## Irritation / Sensitization:

### **Oxaliplatin**

Study Type	Species	Severity
Eye Irritation	( <i>In vitro</i> , BCOP)	Irritant
Skin Irritation	( <i>In vitro</i> , RhE)	Negative

## Reproduction & Development Toxicity:

<b>Oxaliplatin</b>					
Study Type	Species	Route	Dose	End Point	Effect (s)
Fertility and Embryonic Development	Rat	No route specified	1 mg/kg/day	NOAEL	Fetotoxicity

## Genetic Toxicity:

<b>Oxaliplatin</b>		
Study Type	Cell Type/Organism	Severity
Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Mammalian Cell Mutagenicity	Mouse Lymphoma	Positive
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Positive
<i>In Vitro</i> Micronucleus	Mouse Bone Marrow	Positive

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

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

**Toxicity** No data available

**Persistence and Degradability** No data available

**Bio-accumulative Potential** No data available

**Mobility in Soil** No data available

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## SECTION 13 - DISPOSAL INFORMATION

**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**

**Oxaliplatin:**

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

**Lactose NF, monohydrate:**

CERCLA/SARA 313 Emission reporting : Not Listed

California Proposition 65 : Not Listed

Australia (AICS) : Present

REACH- Annex IV- Exemptions from the obligations of Register : Present

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



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## SECTION 16 - OTHER DATA

### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

**Data Sources:** Publicly available toxicity information. Safety data sheets for individual ingredients.

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