

# MATERIAL SAFETY DATA SHEET

Version No: MSDS/MIC/DP-003

Effective Date: February 05, 2013

## MITOMYCIN FOR INJECTION, USP

### SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Mitomycin for Injection, USP – 5 mg/vial, 20 mg/vial and 40 mg/vial

| <b>Marketing Holder</b>   | <b>Authorisation</b> | <b>DP Manufacturer 1</b>  | <b>DP Manufacturer 2</b>  |
|---|----------------------|---|---|
| Accord Healthcare, Inc.,<br>1009 Slater Road,<br>Suite 210-B,<br>Durham, NC 27703, USA.<br>Telephone: 1-919-941-7878<br>Fax- 1-919-941-7881 |                      | Intas Pharmaceuticals Ltd.<br>Plot No. 457, 458<br>Village-Matoda,<br>Bavla Road, Ta. Sanand,<br>Dist. Ahmedabad-382 210,<br>Gujarat, India | Intas Pharma Limited. Plot<br>No. 5, 6 and 7, Pharmez,<br>Nr. Village Matoda,<br>Sarkhej-Bavla National<br>Highway NO. 8 – A,<br>Taluka-Sanand,<br>Dist.Ahmedabad-382210,<br>Gujarat, India |

#### **How Supplied:**

Mitomycin for Injection, USP

NDC 16729-115-05 Each amber vial contains 5 mg mitomycin, individually packed in single carton.

NDC 16729-108-11—Each amber vial contains 20 mg mitomycin, individually packed in single carton.

NDC 16729-116-38—Each amber vial contains 40 mg mitomycin, individually packed in single carton.

US Emergency Phone: Call CHEMTREC Day or Night: 1-800-424-9300

### SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

**Active:** Each vial contains either mitomycin 5 mg, 20 mg or 40 mg.

**Inactive:** Each Mitomycin for Injection, 5 mg, 20 mg and 20 mg vial contains vial contains Mannitol 10 mg, 40 mg and 80 mg respectively.

### SECTION 3 - HAZARDS IDENTIFICATION

**EMERGENCY OVERVIEW:** Mitomycin is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to

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administration. Mitomycin is a cytotoxic antibiotic and anticancer drug. Irritation of exposed tissue is possible. Chronic effects due to occupational exposure are not anticipated. Patients receiving this compound via injection experience effects on the following systems: bone marrow, mucus membranes, kidneys, lungs. Allergic reactions are possible.

**Signs & Symptoms of Exposure:** Mitomycin is a suspect cancer agent and may cause mutagenic teratogenic and reproductive health effects upon excessive exposure. Also, fever, nausea, vomiting, headache, drowsiness, diarrhea, shortness of breath, bronchospasms, redness of skin, irritation, and vision disturbances may occur.

**Medical Conditions Generally Aggravated by Exposure:** May aggravate respiratory, kidney, and blood conditions such as coagulation disorders.

## SECTION 4 - EMERGENCY & FIRST AID MEASURES

**Eye Exposure:** Flush eyes with large volumes of water for 15 or more minutes.

**Skin Exposure:** Wash skin with cool, soapy water.

**Ingestion:** If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting; never induce vomiting on an unconscious person.

**Inhalation:** If difficulty breathing, administer oxygen. Seek attention of a physician immediately. Overdose should be treated symptomatically and blood chemistry monitored closely.

## SECTION 5 - FIRE FIGHTING MEASURES

**Flash Point (Method Used):** Not Applicable      **LEL:** NA      **UEL:** NA

**Flammable Limits:** Not Applicable

**Extinguishing Media:** Use water or a multi-purpose ABC extinguisher.

**Special Fire Fighting Procedures:** As with all fires, evacuate personnel to a safe area. Fire fighters must wear self-contained breathing apparatus to avoid inhalation of smoke. Product is not expected to present a fire hazard concern.

**Unusual Fire/Explosion Hazards:** NONE

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## SECTION 6 - ACCIDENTAL RELEASE MEASURES

**Release to Land:** Wet Mitomycin with water to prevent dusting and absorb with proper absorbents. Prevent contact with sewers and waterways. Use a 1% bleach solution to effectively degrade and remove from non-porous surfaces.

**Release to Air:** If dust is generated, reduce exposures by ventilating and prevent the generation of dust.

Wear respiratory protection.

**Release to Water:** Refer to local water authority; drain disposal is not recommended. Refer to local, state, and federal guidelines.

## SECTION 7 - HANDLING AND STORAGE

**Steps to be taken in case material is released or spilled:** See Section VI above.

Wear all necessary protective equipment including nitrile or latex gloves, protective clothing, safety glasses, and air-purifying respirator with HEPA (P100) cartridges. Large spills require the use of SCBA.

**Waste Disposal Method:** Mitomycin is a RCRA listed hazardous waste; EPA Code: U010 Reportable Quantity (RQ) =10 lbs. Dispose of via hazardous waste disposal laws and regulations.

**Precautions to be taken in handling and storing:** Store at 15°- 30°C.

Other Precautions: Follow OSHA guidelines on the safe handling of cytotoxic products

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

**Respiratory Protection:** Under normal use, respirators are not required. If dust generation is likely, an air-purifying respirator with HEPA (P100) cartridges must be worn. For large spill emergencies, SCBA may be required. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard, 29 CFR 1910.134.

**Ventilation:** Use with adequate ventilation such as in a Class II Type B biological safety cabinet.

**Protective Gloves:** Nitrile or latex

**Eye Protection:** Safety glasses or goggles

**Other Protective Clothing or Equipment:** Lab coat

**Work/Hygienic Practices:** Wash hands following use. No eating, drinking, or smoking when handling this product.

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## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### Description of Injection:

Mitomycin for Injection is a sterile dry mixture of mitomycin and mannitol, which when reconstituted with Sterile Water for Injection provides a solution for intravenous administration.

## SECTION 10 - STABILITY AND REACTIVITY

**Stability:** Stable

**Incompatibility (Materials to Avoid):** Oxidizers

**Hazardous Decomposition or Byproducts:** Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide and sulfur dioxide.

**Hazardous Polymerization:** Will not occur.

**Conditions to Avoid:** Avoid contact with oxidizers.

## SECTION 11 - TOXICOLOGY INFORMATION

For active ingredient Mitomycin: RTECS # CN0700000

LD<sub>50</sub> oral, rat = 30 mg/kg

LD<sub>50</sub> oral, mouse = 23 mg/kg

LD<sub>50</sub> subcutaneous, rat = 3250 ug/kg

LD<sub>50</sub> intraperitoneal, mouse = 4 mg/kg

LD<sub>50</sub> intraperitoneal, rat = 1 mg/kg  
ug/kg

LD<sub>50</sub> subcutaneous, mouse = 7300

LD<sub>50</sub> intravenous, rat = 3 mg/kg

LD<sub>50</sub> intravenous, dog = 720 ug/kg

Microsomal mutagenicity assay = 5 mcg/plate

Cytogenic analysis system test (human, fibroblast) = 100 mcg/L

Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

## SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Mitomycin.  
Handle in a manner that prevents spills or releases to the environment.

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## SECTION 13 - DISPOSAL INFORMATION

Mitomycin is an EPA listed hazardous waste, Code Number U010.  
Dispose of according to local, state, and federal guidelines for RCRA Hazardous Wastes.

## SECTION 14 - TRANSPORTATION INFORMATION

Mitomycin is a DOT hazardous material according to 49 CFR 172.101  
Proper Shipping Name: Medicine, solid, toxic,n.o.s.,  
(Mitomycin) Hazard Class: 6.1 (Poisonous solid)  
UN I.D. Number: NA 3249  
Packing Group: III  
DOT Labels required: Refer to CFR 173.4 (Small Quantity Exemptions)  
Emergency Response Guide No.: 151

## SECTION 15 - REGULATORY INFORMATION

### Hazard Symbols:

### Classification

Not applicable

### Risk Phrases:

Not applicable

### Safety Phrases:

Not applicable

## SECTION 16 - OTHER DATA

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.