MATERIAL SAFETY DATA SHEET

Version No: MSDS/DOCE/DP-001 Effective Date: June 22, 2012

Product Name

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name:

Docetaxel Injection 20 mg and 80 mg (Two vial formulation)

Docetaxel Injection 20 mg/1 mL, 80 mg/4 mL and 160 mg/8 mL(One vial formulation)

Marketing Authorisation Holder	**Manufacturer**
Accord Healthcare, Inc., 1009 Slater Road, Suite 210-B, Durham, NC 27703, USA. Telephone: 1-919-941-7878 Fax- 1-919-941-7881	Intas Pharmaceuticals Ltd. Plot No. 457, 458 Village-Matoda, Bavla Road, Ta. Sanand, Dist. Ahmedabad-382 210, Gujarat, India

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

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Two vial formulation
Active: Docetaxel

INACTIVE: Citric acid, Dehydrated alcohol and Polysorbate 80

Parallel diluent vial contains 13% Polyethylene glycol 400 (PEG 400) and water.

One vial formulation
Active: Docetaxel

INACTIVE: Anhydrous Citric acid, Dehydrated alcohol and Polysorbate 80

SECTION 3 - HAZARDS IDENTIFICATION

Docetaxel Injection 20 mg and 80 mg (Two vial formulation)

EMERGENCY OVERVIEW: This product consists of docetaxel and citric acid in dehydrated alcohol and polysorbate 80 solution in glass vials with parallel vials of diluent containing 13% Polyethylene glycol 400 in water. If the integrity of the vial is maintained, there is no hazard in handling. If the vials are broken, clean-up personnel should wear Solvex nitrile NBR gloves and eye protection. If the potential exists for splashing, impervious clothing and face protection is advised.

Docetaxel Injection 20 mg/1 mL, 80 mg/4 mL and 160 mg/8 mL(One vial formulation)

EMERGENCY OVERVIEW: This product consists of docetaxel and anhydrous citric acid in ethanol and polysorbate solution in glass vials. If the integrity of the vial is maintained, there is no hazard in handling. If the vials are broken, clean-up personnel should wear Solvex nitrile NBR gloves and eye protection. If the potential exists for splashing, impervious clothing and face protection is advised.

Applicable for both one vial and two vial formulation.

POTENTIAL HEALTH HAZARDS

Eye: Irritating to the eyes in the event of an inadvertent splash.

Skin: Not irritating to the skin but may be absorbed and made available systemically.

Ingestion: Moderately toxic if inadvertently ingested.

Inhalation: Compound is supplied in aqueous solution therefore this is not an expected route of exposure.

Chronic Effects: If the compound is bioavailable via the route of exposure and exposure occurs for prolonged periods of time, potential adverse effects include neurotoxicity, myelosuppression, leucopenia, and necrosis of the intestinal epithelium, testicular atrophy and lymphoid organ depletion. The compound was negative in the Ames test but positive in other genotoxicity assays. The Guinea-Pig Anaphylaxis assay was negative.

SECTION 4 - EMERGENCY & FIRST AID MEASURES

Applicable for both one vial and two vial formulation.

Eyes: Immediately flush eyes with plenty of water for fifteen minutes. Seek medical attention.

Skin: Wash with copious amounts of soap and water. Seek medical attention.

Ingestion: Seek medical attention. Induce only as directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: If mist is inhaled, remove to fresh air and seek medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Note to Physicians: Consult the Physicians' Desk Reference for additional details.

SECTION 5 - FIRE FIGHTING MEASURES

Applicable for both one vial and two vial formulation.

Flammable Properties:
Flash Point: (Ethanol) 55 F Method: TCC

Flammable Limits:
Lower flammable limit: (Ethanol) 3.3%
Upper flammable limit: (Ethanol) 19%

Autoignition Temperature: (Ethanol) 685 F

Hazardous Combustion Products: CO, CO2 and oxides of nitrogen may be generated in a fire.

Extinguishing Media: Packaging material fires may be extinguished with water, carbon dioxide, or dry chemical.

Firefighting Instructions: Firefighting in confined spaces requires full protective gear and supplied air respiratory protection.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Applicable for both one vial and two vial formulation.

Small Spill: Don Solvex nitrile NBR gloves and eye protection. Absorb liquid.

Large Spill: Don Solvex nitrile NBR gloves, tyvek outer clothing and face protection. Absorb liquid.

Spill Waste Disposal: Spilled liquid can be destroyed by mixing with a caustic ethanol solution (30% ethanol/70% water/1N sodium hydroxide) with sufficient caustic added to raise the solution pH above 11, stirring at room temperature for 5 hours. Solution volume must be sufficient enough to prevent precipitation of docetaxel. The residual destruction products of docetaxel do not possess cytotoxic activity. The resultant solution can be disposed of as waste in accordance with all federal, state, and local regulations as specified in Section 14.

SECTION 7 - HANDLING AND STORAGE

Docetaxel Injection 20 mg and 80 mg (Two vial formulation)

Handling: Protect package from damage.

Storage: Store between 15-25°C (59-77°F) [see USP Controlled Room Temperature]. Retain in the original package to protect from bright light.

Docetaxel Injection 20 mg/1 mL, 80 mg/4 mL and 160 mg/8 mL(One vial formulation)

Handling: Protect package from damage.

Storage: Store between 15°C and 25°C (59°F and 77°F). Retain in the original package to protect from light. Freezing does not adversely affect the product.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Applicable for both one vial and two vial formulation.

Engineering Controls: Operations should be designed to offer no significant exposure to the liquid.

Respiratory Protection: Recommended to protect against vapor inhalation for manufacturing operations without local exhaust ventilation or when cleaning up a very large spill.

Skin Protection: Solvex nitrile NBR gloves are recommended if potential exists for significant hand/wrist exposure. Latex gloves will offer temporary protection from small splashes but should be changed immediately if vomiting splash occurs.

Eye Protection: Safety glasses recommended. Full-face protection recommended for spill cleanup if potential exists for splashing.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Boiling point: (For Ethanol) 173 F

Melting Point: Not applicable

Vapor Pressure: (For Ethanol) 40 mm Hg @ 19 C

Vapor Density: (For Ethanol) 1.59

Docetaxel Injection 20 mg and 80 mg (Two vial formulation)

Specific Gravity: 1.034 g/mL to 1.076 g/mL

pH: Between 3.0 and 4.0

Appearance: A clear yellow to brownish yellow viscous solution in clear glass vial

Docetaxel Injection 20 mg/1 mL, 80 mg/4 mL and 160 mg/8 mL(One vial formulation)

Specific Gravity: 0.920 g/mL to 0.958 g/mL

pH: Between 2.5 and 4.0

Appearance: A clear pale yellow to brownish yellow solution in clear glass vial

SECTION 10 - STABILITY AND REACTIVITY

Applicable for both one vial and two vial formulation.

Incompatibility: Direct light and heat.

Hazardous Decomposition Products: No data

Hazardous Polymerization: Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Applicable for both one vial and two vial formulation.

>2000 mg/kg p.o. rat LD50. Moderately toxic by ingestion. Sub-chronic animal bioassays indicate potential for neurotoxicity, myelosuppression, leucopenia, necrosis of the intestinal epithelium, testicular atrophy and lymphoid organ depletion. The compound was negative in the Ames test but positive in the in vitro and in vivo Micronucleus assay. The Guinea-pig Anaphylaxis assay was negative.

Ethanol: 20,000 ppm/10 hrs inhalation-rat LC50; 2000 mg/kg oral-child LDLo. Slightly toxic by inhalation and ingestion. Central nervous system depressant; hepatotoxin.

Polyethylene glycol 400:
Polyethylene glycol 400: ORAL (LD50): Acute: 30200 mg/Kg (Rat): 28915 mg/Kg (Mouse). 26800 mg/Kg (Rabbit) DERMAL (LD50): Acute: 20000 mg/kg (Rabbit). VAPOR (LC50): 13 ppm 8 hours (Rat).

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Applicable for both one vial and two vial formulation.

Based upon water solubility and Log P (octanol/water partition coefficient), the compound should partition to the aquatic compartment fairly exclusively.

SECTION 13 - DISPOSAL INFORMATION

Applicable for both one vial and two vial formulation.

Waste must be disposed of in accordance with all federal, state, and local regulations. Incineration is the preferred method.

SECTION 14 - TRANSPORTATION INFORMATION

Applicable for both one vial and two vial formulation.

For the finished product in consumer packaging:

DOT:
TDG:
IATA:
IMDG:

SECTION 15 - REGULATORY INFORMATION

Docetaxel Injection 20 mg and 80 mg (Two vial formulation) and Docetaxel Injection 20 mg/1 mL, 80 mg/4 mL and 160 mg/8 mL(One vial formulation) are regulated under the Food, Drug and Cosmetic Act.

SECTION 16 - OTHER DATA

Applicable for both one vial and two vial formulation.

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.