

**MATERIAL SAFETY DATA SHEET****1. PRODUCT IDENTIFICATION**

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| <b>Product Name</b>                            | Docefrez (Docetaxel) for Injection, 20mg/vial and 80mg/vial  |
| <b>Company Name</b>                            | Sun Pharmaceutical Industries Ltd.<br>Acme Plaza, Andheri-Kurla Road, Andheri (E)<br>Mumbai – 400 059, INDIA   |
| <b>Product Use</b>                             | Medical Treatment; Antineoplastic  |
| <b>Chemical Name</b>                           | (2R,3S)-N-carboxy-3-phenylisoserine, N- <i>tert</i> -butyl ester, 13-ester with 5 $\beta$ -20-epoxy-12 $\alpha$ ,4,7 $\beta$ ,10 $\beta$ ,13 $\alpha$ -hexahydroxytax- 11-en-9-one 4-acetate 2-benzoate, anhydrous |
| <b>Chemical Formula</b>                        | C <sub>43</sub> H <sub>53</sub> NO <sub>14</sub>   |
| <b>Chemical Family</b>                         | Antineoplastic   |
| <b>Composition/ information on ingredients</b> | Active ingredient: Each Docefrez 80 mg vial contains 80 mg docetaxel anhydrous. Parallel solvent vial contains Polysorbate 80 and ethanol,anhydrous.   |

**2. HAZARD IDENTIFICATION****EMERGENCY OVERVIEW**

This product consists of Lyophilized docetaxel in glass vials with parallel vials of solvent containing 35.40% (w/w) ethanol in polysorbate 80 . 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.

**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:** If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.



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### **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, myelo suppression, leucopenia, 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.

### **3. FIRST-AID MEASURES**

**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.

### **4. FIRE-FIGHTING MEASURES**

#### **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



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**Hazardous Combustion Products:** CO, CO<sub>2</sub> 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.

### 5. ACCIDENTAL RELEASE MEASURES

**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 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 12.

### 6. HANDLING and STORAGE

**DOCEFREZ IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.**

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. 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.



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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.

Storage and Handling Practices: 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 9). Store between 2 and 8°C . Retain in the original package to protect from bright light. Freezing does not adversely affect the product.

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. EXPOSURE CONTROLS - PERSONAL PROTECTION

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.

Respiratory Protection: Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.

Eye 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.

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



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**Body Protection:** No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

**Product Preparation Instructions for Medical Personnel:** Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

#### 8. PHYSICAL and CHEMICAL PROPERTIES

**Boiling point:** (For Ethanol) 173 F

**Melting Point:** 232°C

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

**Vapor Density:** (For Ethanol) 1.59

**Solubility in Water:** Docefrez is soluble in water at approximately 0.025 mg/ml.

**Appearance:** White lyophilised powder in glass vial

#### 9. STABILITY and REACTIVITY

**Incompatibility:** Direct light and heat.

**Hazardous Decomposition Products:** No data

**Hazardous Polymerization:** Will not occur

#### 10. TOXICOLOGICAL INFORMATION

**Docefrez:** >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



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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.

#### **11. ECOLOGICAL INFORMATION**

All work practices must be aimed at eliminating environmental contamination.

Effect of Materials on Plants or Animals: This product may be harmful to contaminated plant and animal life. See Section 10 (Toxicological Information) for additional information

Effect of Chemicals on Aquatic Life: This product may be harmful to aquatic plant and animal life in contaminated bodies of water, especially if released in large quantities.

#### **12. DISPOSAL CONSIDERATIONS**

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None

#### **13. TRANSPORTATION INFORMATION**

This Materials is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not Applicable

Hazard Class Number and Description: Not Applicable

UN Identification Number: Not Applicable

Packing Group: Not Applicable

DOT Label(s) Required: Not applicable

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)