

Material Safety Data Sheet

Docetaxel Injection concentrate and diluent

SECTION 1 - PRODUCT

MSDS NAME: Docetaxel Injection

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

ACTIVE: Docetaxel

INACTIVE: Citric acid, Dehydrated alcohol and Polysorbate 80

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

SECTION 3 - HAZARDS IDENTIFICATION

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.

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

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

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

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

Handling: Protect package from damage.

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

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Specific Gravity: 1.034 g/ml to 1.076 g/ml at 25°C

pH: Between 3.0 and 4.0

Odor: Characteristic alcohol odor.

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

SECTION 10 - STABILITY AND REACTIVITY

Incompatibility: Direct light and heat.

Hazardous Decomposition Products: No data

Hazardous Polymerization: Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

>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

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

SECTION 13 - TRANSPORTATION INFORMATION

No classification currently assigned

SECTION 14 - DISPOSAL INFORMATION

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

SECTION 15 – REGULATORY INFORMATION

TSCA Status: N0
CERCLA Section 103: No
SARA Section 302: No
SARA Section 304: No
SARA Section 313: No

SECTION 16 - OTHER DATA

Report to the manufacturer any allegations of adverse effects related to handling or accidental contact with this material.

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Firm shall not be held liable for any damage resulting from handling or from contact with the above product.