

**MATERIAL DATA SHEET**

MSDS Date: 03/19/2003

Revision# 4

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**1. PRODUCT AND COMPANY IDENTIFICATION****Product Name:** Taxotere®**Aventis Pharmaceuticals, Inc.**  
**Route 202-206**  
**Bridgewater, NJ 08807-0800**

<b>Technical Information, M-F, 8 AM – 5 PM EST:</b>	<b>(908) 231-4829</b>
<b>24-Hour Transport Emergency, US (Chemtrec):</b>	<b>(800) 424-9300</b>
<b>24-Hour Transport Emergency, outside US (Chemtrec) :</b>	<b>(703) 527-3887</b>
<b>24-Hour Emergency, Aventis:</b>	<b>(908) 231-2666</b>

**2. COMPOSITION/INFORMATION ON INGREDIENTS**

Active ingredient: Each **Taxotere®** vial contains docetaxel (about 4%), ethanol (less than 2%) and polysorbate 80 (complete to 100%) for injection. Parallel diluent vial contains 13% ethanol and water.

**3. HAZARDS IDENTIFICATION****EMERGENCY OVERVIEW**

This product consists of docetaxel in ethanol and polysorbate 80 solution in glass vials with parallel vials of diluent containing 13% ethanol 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, 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.

## 4. 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.

## 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, 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.

## 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 13.

## 7. HANDLING AND STORAGE

**Handling:** Protect package from damage.

**Storage:** Store between 2 and 25°C (36 and 77°F). Retain in the original package to protect from bright light. Freezing does not adversely affect the product.

## 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 ethanol 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.

## 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

**Solubility in Water:** Taxotere® is soluble in water at approximately 0.1 mg/ml.

**Specific Gravity:** 1.08

**pH:** Approximately neutral (6.5 at 250 g/l in water)

**Odor:** Characteristic alcohol odor.

**Appearance:** Amber colored viscous liquid in glass vial

## 10. STABILITY AND REACTIVITY

**Incompatibility:** Direct light and heat.

**Hazardous Decomposition Products:** No data

**Hazardous Polymerization:** Will not occur

## 11. TOXICOLOGICAL INFORMATION

**Taxotere®:** >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.

## 12. ECOLOGICAL INFORMATION

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

## 13. DISPOSAL CONSIDERATIONS

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

## 14. TRANSPORT INFORMATION

No classification currently assigned

## 15. REGULATORY INFORMATION

TSCA Status: N0

CERCLA Section 103: No

SARA Section 302: No

SARA Section 304: No

SARA Section 313: No

## 16. OTHER INFORMATION

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

The information contained herein is based upon data considered true and accurate. Aventis Pharmaceuticals makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation, and verification.

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Revision# 4

Revised by Stuart Dearden, CIH