



300 Northfield Road  
 Bedford, OH 44146  
 Telephone: (440) 232-3320  
 -or- (800) 562-4797

**MATERIAL SAFETY DATA SHEET**

**Section I - IDENTITY**

**Common/Trade Name:** Paclitaxel Injection 5mL/vial; 16.7ml/vial; 50ml/vial; 6mg/mL  
**Chemical Names:** Benzenepropanoic acid, beta-(benzoylamino)-alpha-hydroxy-,6,12b-bis(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-4,11-dihydroxy-4 a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca(3,4)benz(1,2-b)oxet-9-yl ester,(2aR-(2a-alpha,4-beta,4a-beta,6-beta,9-alpha(alpha-R\*,beta-S\*),11-alpha,12-alpha,12a-alpha,12b-alpha))-  
**Synonyms:** BMS 181339-01, NSC-125973, Taxol, Taxol A  
**Manufacturer's Name:** BEN VENUE LABORATORIES, INC.  
**Address:** 300 NORTHFIELD ROAD  
 BEDFORD, OH 44146  
**Emergency Telephone Number:** Chemtrec: 1(800) 424-9300  
**Telephone Number for Info.:** (800) 562-4797 or (440) 232-3320  
**Medical Emergency:** Professional Services 1(800) 521-5169  
**Date Prepared:** January 3, 2001  
**Date Revised:** December 27, 2001  
**Date Revised:** March 17, 2003  
**Date Revised:** April 26, 2004

**Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION**

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Paclitaxel	0.6	33069-62-4	NONE	NONE	NONE
Polyoxyl 35 Castor					
Oil – ELP	52.7	61791-12-6	NONE	NONE	NONE
Dehydrated Alcohol	46.7	64-17-5	1000 ppm	1000 ppm	NONE

Paclitaxel is a sterile injectable liquid drug provided in a vial.

**Section III - HEALTH HAZARD DATA**

**ROUTE(S) OF ENTRY:** Paclitaxel may be absorbed in the system by inhalation, ingestion, injection and skin contact.  
**Health Hazard (Acute & Chronic):** Paclitaxel is a potent, cytotoxic drug used in the treatment of ovary and breast cancers. It affects the blood, digestive system, reproductive systems, liver, and bone marrow. It is mutagenic, teratogenic, and possibly carcinogenic.

**Carcinogenicity:** NTP? NO IARC Monographs? NONE

**OSHA Regulated?** NO

**Signs & Symptoms of Exposure:** Excessive exposure may cause changes in blood count, fatigue, hair loss, weakness, muscle pain, nausea and vomiting. May cause irritation to eyes, skin and respiratory tract.

**Medical Conditions Generally Aggravated by Exposure:** Conditions of the blood forming systems and cardioarrhythmia. May be harmful to the fetus.

**BVL Hazard Category:** 4

---

#### Section IV - FIRST AID MEASURES

---

**Eye Exposure:** Flush eyes with large volumes of water for 15 minutes. Seek medical attention.

**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. If necessary provide artificial respiration.

Treat overdose symptomatically and monitor blood chemistry

---

#### Section V - FIRE AND EXPLOSION HAZARD DATA

---

**Flash Point (Method Used):** 60°F

**Flammable Limits:** LEL: 4.4% UEL: 19%

**Extinguishing Media:** Use a multi-purpose fire extinguisher, carbon dioxide extinguisher or a foam extinguisher appropriate for alcohol.

**Special Fire Fighting Procedures:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.

**Unusual Fire/Explosion Hazards:** Dehydrated alcohol is flammable. Keep this product away from ignition sources such as sparks or open flame.

---

#### Section VI - ACCIDENTAL RELEASE INFORMATION

---

**Release to Land:** Since Paclitaxel Injection is a flammable solution, remove all sources of ignition. Absorb solution with activated charcoal or absorbent pads.

**Release to Air:** If aerosolized, reduce exposures by ventilating area. Clean up spill immediately to prevent evaporation.

**Release to Water:** Refer to local water authority. Drain disposal must not occur.

---

#### Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

---

**Steps to be taken in case material is released or spilled:** See Section VI above. Wear nitrile gloves and safety glasses. If vapors are generated, an appropriate respirator with organic vapor/HEPA (P100) cartridges should be worn. For larger spills, additional protective clothing and respiratory protection may be needed such as chemical protective overalls, boots, double gloves (nitrile/neoprene), and self-contained breathing apparatus SCBA.

**Waste Disposal Method:** Incineration in an approved, permitted incinerator for flammable liquids according to local, state, and federal guidelines.

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

**Other Precautions:** Follow OSHA guidelines on the safe handling of anti-cancer drugs.  
(See Section XVI).

---

## Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

---

**Respiratory Protection:** Under normal use, respirators are not required. If aerosols/vapors are generated, an air-purifying respirator with organic vapor/HEPA (P100) cartridges may be necessary. For large spills, emergency SCBA may be necessary. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Ventilation:** Handle in a Type II Biological Safety Hood or in a well-ventilated area

**Protective Gloves:** Nitrile

**Eye Protection:** Safety glasses or splash goggles

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

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

---

## Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

---

**Physical State:** Liquid

**Appearance and Odor:** Clear and odorless

**Boiling Point:** 173°F (78°C)

**Vapor Pressure:** Not available

**Vapor Density:** Greater than air if evaporated

**Specific Gravity:** Not available

**Melting Point:** Not applicable

**Evaporation Rate:** Not available

**Solubility in Water:** Soluble (0.252 mg/L@ pH of 5;  
0.172 mg/L@ pH of 7; 0.249 mg/L@ pH of 9)

---

## Section X - STABILITY AND REACTIVITY DATA

---

**Stability:** Product is stable at room temperature.

**Incompatibility (Materials to Avoid):** Paclitaxel Injection should not be stored with oxidizers, acids, and bases. Keep away from heat and ignition sources.

**Hazardous Decomposition or Byproducts:** Decomposition products may include nitrogen oxides, carbon monoxide and carbon dioxide and other possibly carcinogenic compounds.

**Hazardous Polymerization:** Will not occur.

**Conditions to Avoid:** Keep away from ignition sources. Paclitaxel Injection is a flammable liquid.

---

## Section XI - TOXICOLOGICAL INFORMATION

---

Toxicity for Paclitaxel:

LD<sub>50</sub> rat, intraperitoneal = 32.5 mg/kg

LD<sub>50</sub> mouse, intraperitoneal = 128 mg/kg

LD<sub>50</sub> mouse, intravenous = 12 mg/kg

LD<sub>50</sub> rat, intravenous = 85 mg/kg

For Ethanol

LD<sub>50</sub> mouse, intraperitoneal = 528 mg/kg

LD<sub>50</sub> mouse, subcutaneous = 8285 mg/kg

LD<sub>50</sub> mouse, intravenous = 1973 mg/kg

LD<sub>50</sub> rabbit, oral = 6300 mg/kg

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

---

## **Section XII - ENVIRONMENTAL IMPACT INFORMATION**

---

Acute toxicity of Paclitaxel to daphnia has been determined to be greater than 0.74mg Paclitaxel per liter. The activated sludge respiration inhibition is greater than 1000mg/L. Paclitaxel has anaerobic degradation life cycle in water of 3.8 days. Handle in a manner to prevent spills or releases to the environment.

---

## **Section XIII - DISPOSAL INFORMATION**

---

Dispose of product as a hazardous waste by incineration at an approved and permitted facility. Follow local, state and federal regulations. Paclitaxel is a flammable waste with an EPA code of D001.

---

## **Section XIV - TRANSPORTATION INFORMATION**

---

Paclitaxel is a Hazardous Material per 49 CFR 172.101

Proper Shipping Name: Ethanol Solutions

Hazard class: 3 (Flammable liquid)

UN ID Number: UN 1170

Label and Placards: Flammable Liquid

Packing Group: II

Emergency Response Guide: 131

The chemicals in this product are not classified as DOT Marine Pollutants

---

## **Section XV - REGULATORY INFORMATION**

---

SARA 313 listed?: NO

CERCLA listed?: NO

RCRA listed?: YES, as a D001 hazardous waste for alcohol content and flammability.

Paclitaxel is listed on California, Proposition 65 list as Code DFM

---

## **Section XVI - OTHER DATA**

---

1. Use of this product should be through or under the direction of a physician.  
This MSDS does not address the therapeutic use of this material.

2. Hospital personnel preparing or administering parenteral antineoplastic agents should wear disposable latex gloves, safety glasses, a closed-front gown with cuffs, and respiratory protection. Preparation of all antineoplastic agents should be done in a Class II laminar flow hood or biological safety cabinet with exhaust air discharged external to the room environment. All needles, syringes, vials, and other equipment or disposable clothing that have contacted this agent should be segregated for incineration.
3. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.