

ABRAXANE™
 (paclitaxel protein-bound particles for injectable suspension)
 (albumin-bound)

Date Prepared: 1/21/2005
 Date Reviewed: 2/1/2005

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Identifier:

General Use: Antineoplastic

MANUFACTURER:

American Pharmaceutical Partners, Inc
 1501 E. Woodfield Rd. Ste, 300 E
 Schaumburg, IL 60173-5837
 (847) 969-2700

EMERGENCY TELEPHONE NUMBER:

(800) 564-0216

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component: **Albumin (Human)** CAS Registry #: 70024-90-7

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: N/A Note: Approximately 900 mg / vial

Component: **Paclitaxel** CAS Registry #: 33069-62-4

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: N/A Note: 100 mg / vial

3. HAZARD IDENTIFICATION

PRIMARY ROUTES OF EXPOSURE – Inhalation, Eye/Skin Absorption and Ingestion.

ABRAXANE is a cytotoxic anticancer drug and, as with other potentially toxic paclitaxel compounds, caution should be exercised in handling ABRAXANE.

ABRAXANE contains albumin (human), a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob Disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

The carcinogenic potential of ABRAXANE has not been studied.

COMPONENT CHEMICAL LISTING AS CARCINOGEN:

<u>COMPONENT</u>	<u>CAS NO.</u>	<u>NTP</u>	<u>IARC</u>	<u>OSHA</u>
Albumin (Human)	70024-90-7	NO	NO	NO
Paclitaxel	33069-62-4	NO	NO	NO

4. EMERGENCY AND FIRST AID PROCEDURES

INHALATION: Remove individual(s) promptly to clean air. Observe individual(s) for signs of respiratory distress (coughing, labored breathing, etc.) and systemic effects (see Section 11). Administer artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek Medical Attention.

INGESTION: Flush mouth immediately with water to remove residual material and induce vomiting. Provide supportive treatment. No specific antidote available. Seek medical attention.

SKIN CONTACT: Remove contaminated clothing immediately. Thoroughly wash area with soap and water. Seek medical attention. Chemically decontaminate clothing and then launder before reuse or incinerate.

EYE CONTACT: Immediately flush with water for at least 15 minutes. Seek Medical Attention or consult an ophthalmologist.

For Adverse Drug Experience Information, call (800) 564-0216.

5. FIRE FIGHTING MEASURES

Fire and Explosion Data: NE
Closed Cup Flash Pt. NE
Open Cup Flash Pt. NE
Fire Point NE
Autoignition NE
Lower Explosion Limit NE
Upper Explosion Limit NE

GENERAL HAZARD: No unusual fire or explosion hazard known to exist.

FIRE FIGHTING INSTRUCTION: Evacuate personnel to safe area. Water, carbon dioxide, or dry chemical as appropriate to the surrounding fire.

FIRE FIGHTING EQUIPMENT: Wear self-contained breathing apparatus and protective clothing.

HAZARDOUS COMBUSTION PRODUCTS: Thermal decomposition may yield carbon monoxide and other toxic fumes. Since specific products of combustion are unknown, as a precaution, assume they are hazardous.

6. ACCIDENTAL RELEASE MEASURES

CLEAN-UP: Evacuate area. Wear recommended personal protective equipment (rubber or double latex gloves, safety goggles, disposable gown, respirator). Avoid raising aerosols by promptly covering the spilled compound with wet paper towels. Pick up the compound with additional towels, place in a bag and hold for waste disposal. Ventilate area and wash spill site after compound pick up is complete. Dispose of contaminated clean-up materials properly.

7. HANDLING AND STORAGE

HANDLING:

Handling solids or solutions should be carried out with extreme care to avoid personal exposure. Avoid contact with skin, eyes, nostrils, and mouth. Hazards associated with exposure to ABRAXANE may as yet, be unknown. This material should only be handled by individuals trained in handling potentially hazardous materials.

There is limited but increasing information that personnel involved in the preparation and administration of parenteral antineoplastics may be at some risk because of potential mutagenicity, teratogenicity and/or carcinogenicity of these agents, although the actual risk is unknown. The USP Advisory Panel recommends caution during preparation and disposal of antineoplastic agents. Precautions that have been suggested include:

- Use of a biological safety cabinet (BSC) during reconstitution and dilution of parenteral medications and wearing disposable surgical gloves and mask.
- Use of proper technique to prevent contamination of medication, work area, and operator during transfer between containers.
- Cautious and proper disposal of needles, syringes, vials, ampules, and unused medication.

OSHA instruction TED 1-0.15A, Section VI, Chapter 2, Controlling Occupational Exposure to Hazardous Drugs, should be viewed prior to handling this product.

ABRAXANE contains albumin (human), a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob Disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

STORAGE:

Store the vials in original cartons at controlled room temperature 20° C - 25° C (68° F - 77° F)
(See USP Controlled Room Temperature). Retain in the original package to protect from bright light.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

Use local exhaust ventilation when necessary.

PERSONAL PROTECTION:

RESPIRATOR – Wear NIOSH-OSHA approved respirator.

EYES – Chemical safety glasses or goggles recommended.

GLOVES – Rubber or latex gloves recommended.

CLOTHING – Protective laboratory coat, apron, or disposable garment recommended.

SAFETY STATIONS – Safety shower and eye bath should be accessible.

The protective equipment listed above should be worn when handling ABRAXANE. Avoid inhalation and contact to mucous membranes. If ABRAXANE contacts mucous membranes, the membranes should be flushed thoroughly with water.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Odor other characteristics: White – yellow, lyophilized powder

Boiling Point:	NE	Vapor Density:	NE
Melting Point:	NE	Percent Volatiles:	NE
Freezing Point:	NE	pH:	6-7.5 (recon.)
Vapor Pressure:	NE	Molecular Weight:	853.91
Note:		Solubility:	Insoluble in water (paclitaxel)

10. STABILITY AND REACTIVITY

STABILITY: Stable under most conditions. On decomposition, obnoxious odor and microbial growth may be present.

CONDITIONS/MATERIALS TO AVOID: No conditions contributing to instability are known to exist. Avoid contact with oxidizing agents.

HARZARDOUS POLYMERIZATION: Not known to occur.

11. TOXICOLOGY INFORMATION

The carcinogenic potential of ABRAXANE has not been studied.

Paclitaxel has been shown to be clastogenic in vitro (chromosome aberrations in human lymphocytes) and in vivo (micronucleus test in mice). ABRAXANE was not mutagenic in the Ames test or the CHO/HGPRT gene mutation assay.

SIGNS & SYMPTOMS OF OVER-EXPOSURE MAY INCLUDE:

There is no known antidote for ABRAXANE overdosage. The primary anticipated complications of overdosage would consist of bone marrow suppression, sensory neurotoxicity, and mucositis.

This product is intended for therapeutic use only when prescribed by a physician. The following adverse reactions have been reported following therapeutic administrations of ABRAXANE: sever neutropenia, sensory neuropathy, abnormal ECG, myalgia/arthritis, asthenia, nausea and vomiting, alopecia, hypersensitivity reactions, elevations in hepatic laboratory values, and dyspnea/cough. Refer to full prescribing information for the complete adverse reaction information.

12. TRANSPORT INFORMATION

UN/NA Number:	NA
DOT Hazard Class:	NA
Shipping Name:	NA
Shipping Label:	NA

13. WASTE DISPOSAL

Dispose of in accordance with federal, state, and local regulations.

14. OTHER INFORMATION

KEY TO ABBREVIATIONS:

ACGIH – American Conference of Governmental industrial Hygienists

HEPA – High-Efficiency Particulate Air

IARC – International Agency for Research on Cancer

NA – Not Applicable

NE – Not Established

NG – Not Given

NIOSH – National Institute for Occupational Safety & Health

NTP – National Toxicology Program

OSHA – Occupational Safety and Health Administration

PEL – Permissible Exposure Limit

PPM – Parts Per Million

QS – Quality Sufficient

RCRA – Resource Term Exposure Limit

STEL – Short Term Exposure Limit

TLV – Threshold Limit Value

The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. American Pharmaceutical Partners, Inc. and Abraxis Oncology, assumes no liability resulting from the use of, or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guarantee or specification of the product.