	Sagent Pharmaceuticals, Inc.				
	Paclitaxel Injection, USP			Material Safety Data Sheet (MSDS)	
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Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Paclitaxel Injection, USP
Product Code: 25021-213
Common/Trade Name: Taxol
Chemical Name: 5 β ,20-Epoxy-1,2 α ,4,7 β ,10 β ,13 α -hexahydroxytax-11-en-9-one 4,10-diacetate 2-benzoate 13-ester with (2*R*,3*S*)-*N*-benzoyl-3-phenylisoserine
Chemical Family: Diterpinoid taxane
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vials

Section 2 - Composition / Information on Ingredients

Ingredient	mg/mL	CAS No.
Paclitaxel	6	33069-62-4
Ethanol	48.7% (v/v)	64-17-5
Citric Acid	2	77-92-9
Cremophor EL*	527	61791-12-6


* Cremophor® EL (Macrogolglycerol ricinoleate) is the registered trademark of BASF Aktiengesellschaft.

Section 3 - Hazards Identification

Primary Physical and Health Hazards:

The primary health effects in an occupational setting include possible irritation of eyes and skin as well as redness and local swelling after accidental injection.

Paclitaxel is a potent Cytotoxic drug and potential carcinogen.

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Routes of Entry: Inhalation, skin and eye contact, and ingestion of large quantities would not be expected to occur. However, there is the potential for the outside of the drug vials to be contaminated with the drug, or if the vials break or spill may occur.

Signs & Symptoms of Exposure: Repeated exposure to paclitaxel in sufficient dose may affect the bone marrow, the peripheral nervous system, gastrointestinal tract and reproductive systems.

Chemical Listed as Carcinogen: **NTP:** No **IARC:** No **OSHA:** No

Medical Conditions Generally Aggravated by Exposure: Pre-existing asthma, anemia/other forms of bone marrow suppression, cardiac arrhythmias.

Section 4 - First Aid Measures


Eye Exposure: Risk of serious damage to eyes. If irritation or redness develops, move victim away from source of exposure and into fresh air. Flush eyes with clean water and seek medical attention.

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Injection: See patient package insert in carton for complete information.

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

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Notes to Physician: See patient package insert in carton for complete information.

Section 5 - Fire Fighting Measures


Flash Point:	Not established
Auto-ignition Temperature:	Not established
Flammable Limits in Air:	Lower %: Not established Upper %: Not established
Flammable Limits:	The product contains ethanol that is a flammable product. However, flashpoint test has been complete on this product and the product is considered as non-explosion hazard.
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 and open flames.

Section 6 - Accidental Release Measures

Spill:	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 is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

General Handling: **PACLITAXEL IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.**

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General Handling (con't): Employees must be trained to properly use the product. Ensure vials are properly labeled. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling this product. Wash hands thoroughly after handling. Particular care in working with this product must be practiced in pharmacies and other preparation areas, and during patient administration.

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

Storage Conditions: Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] **Protect from light.** Retain in carton until time of use.

Section 8 - Exposure Controls / Personal Protection

Respiratory Protection: Not normally required for routine, medical administration of this product.

Eye Protection: Approved eye protection (e.g., safety glasses with side shields) to safeguard against potential eye contact, irritation or injury is recommended.

Ventilation: Use with adequate ventilation.


Skin Protection: A full body gown which is closed at the front and has long sleeves is recommended.

Other Protective Equipment: Not established

Additional Exposure Precautions: Avoid contact with skin, eyes and clothing. Wash hands following use before breaks and immediately after handling the product.

Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Paclitaxel	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

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Ethanol	OSHA ACGIH -----	PEL TLV STEL	1000 ppm 1000 ppm NE
Citric Acid	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Cremophor EL*	OSHA ACGIH -----	PEL TLV STEL	NE NE NE


* Cremophor® EL (Macrogolglycerol ricinoleate) is the registered trademark of BASF Aktiengesellschaft

Section 9 - Physical and Chemical Properties

Physical State:	Liquid	Specific Gravity:	0.926
Appearance and Odor:	Clear colorless to slightly yellow viscous solution	Evaporation Rate:	Not available
Boiling Point:	173°F (78°C)	Melting Point:	Not applicable
Vapor Pressure:	5.8 Pa @20°C	Solubility in Water:	Soluble in water
Vapor Density:	1.6 (anhydrous ethanol)	pH:	3.5
		Molecular Weight:	853.9

Section 10 - Stability and Reactivity

Stability:	Product is stable under normal conditions of storage and handling.
Incompatibility (Materials to avoid):	Paclitaxel Injection should not be stored with oxidizers, acids, and bases. Keep away from heat and ignition sources.
Hazardous Decomposition:	Carbon oxides, nitrogen oxides and possibly other compounds with carcinogenic potential
Hazardous Polymerization:	Will not occur.
Conditions to Avoid:	Avoid exposure to heat, oxidizers or open flame.

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Section 11 - Toxicological Information

Toxicity information is for the Active Pharmaceutical ingredient: PACLITAXEL

Acute Toxicity (oral, inhalation, dermal): Can cause severe cardiotoxicity and bone marrow suppression. Nausea, headache and vomiting. Damage to the kidneys. Damage to the liver. Alopecia.

Corrosivity/irritation (eye, skin, respiratory tract): Hazardous in case of skin contact (irritant), of inhalation (lung irritant). Material is irritating to mucous membranes and upper respiratory tract

Sensitization (skin, respiratory):

Skin – may cause allergic skin reaction

Respiratory – may cause allergic respiratory reaction

Repeated-dose toxicity: Repeated exposure to the highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

Mutagenicity: Laboratory experiments have shown mutagenic effects

Carcinogenicity: Studies not performed to date. However, because of its mechanism of action, the drug should be considered a POTENTIAL carcinogen.

Reproductive toxicity (fertility, developmental): Classified reproductive system/toxin/female and Reproductive system/toxin/male {proven}. May cause congenital malformations in the fetus.

Acute Toxicity


Component	Type	Route	Species	Dosage
Paclitaxel	LD ₅₀	Intravenous	Mouse	12 mg/kg
Paclitaxel	LD ₅₀	Intraperitoneal	Mouse	128 mg/kg

Section 12 - Ecological Information

No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Used vials and other items that have come into contact with the product must be treated as Hazardous Waste. The waste must be disposed of by a licensed waste contractor preferably by incineration.

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Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

TSCA - *No*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*


SARA 313 - *Not on this list*

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)