
 <b>Pharmaceutical Division</b>	<b>Paclitaxel Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>09FEB2022</b>	SDS No.: <b>SDS012</b>	Revision No: <b>04</b>	Page <b>1 of 10</b>

### Section 1 - Identification

- (a) **Product Identifier:** Paclitaxel Injection, USP (30mg/5mL, 100mg/16.7mL, 300mg/50mL)
- (b) **Product Code:** 70860-200  
70860-215
- Common/Trade Name:** Taxol
- Chemical Name:** (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-1,2a,3,4,4a,6,9,10,11,12,12a,12b-Dodecahydro-4,6,9,11,12,-12b-4a,8,13,13-tetramethyl-7,11- methano-5H-cyclodeca [3,4] benz [ diacetate, 12-benzoate, 9-ester with (2R,3S)-Nbenzoyl- 3-phenyl
- Chemical Family:** Diterpinoid taxane
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Multi-dose vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

### Section 2 - Hazards Identification


- (a) **Classification:** **GHS – Classification:**  
 Germ Cell Mutagenicity: Category 2  
 Reproductive Toxicity: Category 1B  
 Flammable liquids- Category 2

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- (b) **Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):**
- Signal Word:** Danger
- Hazard Statements:**  
H225 - Highly flammable liquid and vapor  
H360FD - May damage fertility. May damage the unborn child.  
H341 - Suspected of causing genetic defects
- Precautionary Statements:**  
P201 - Obtain special instructions before use  
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
P233 - Keep container tightly closed  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P403 + P235 - Store in a well-ventilated place. Keep cool  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations
- (c) **Description of 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.
- (d) **Unknown Acute Toxicity:** N/A

### Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-1,2a,3,4,4a,6,9,10,11,12,12a,12b-Dodecahydro-4,6,9,11,12,-12b-hexahydroxy-4a,8,13,13-tetramethyl-7,11-methano-5H-cyclodeca[3,4] benz [1,2-b] oxet-5-one 6,12b-diacetate, 12-benzoate, 9-ester with (2R,3S)-Nbenzoyl-3-phenylisoserine.	Paclitaxel	0.6	33069-62-4	N/A

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Castor Oil	Polyoxyl 35 Castor Oil, NF	52.7	61791-12-6	N/A
Citric Acid	Anhydrous	0.2	77-92-9	N/A
Dehydrated Alcohol	Ethanol	49.7	64-17-5	N/A

#### 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.
- Notes to physician** See patient package insert in carton for complete information.

#### Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.
- (b) **Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- (c) **Special Protective Equipment / Precautions:** During all fire-fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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### 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.*
- 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.
- Storage Conditions:** Store at 20° to 25°C (68° to 77°F). Retain in package to protect from light.


### Section 8 - Exposure Controls / Personal Protection

**(a) Exposure Limits**

Compound	Issuer	Type	Exposure Limit
Paclitaxel	OSHA	PEL	NE
	ACGIH	TLV	NE
Polyoxyl 35 Castor Oil, NF	OSHA	PEL	NE
	ACGIH	TLV	NE
Citric Acid	OSHA	PEL	NE
	ACGIH	TLV	NE
Dehydrated Alcohol	OSHA	PEL	1000 ppm
	ACGIH	TLV	1000 ppm

**(b) Engineering Controls**

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.


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**(c) Individual Protection Measures**

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.
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.

**Section 9 - Physical and Chemical Properties**

<b>(a) Appearance</b>	Clear Solution
<b>(b) Odor</b>	NA
<b>(c) Odor Threshold</b>	NE
<b>(d) pH</b>	3.5
<b>(e) Melting Point:</b>	NE
<b>(f) Initial Boiling Point:</b>	173° F / 78° C
<b>(g) Flash Point</b>	14.87° C
<b>(h) Evaporation Rate:</b>	NE
<b>(i) Flammability</b>	NA
<b>(j) Upper Lower Flammability or Explosion Limits</b>	NE
<b>(k) Vapor Pressure:</b>	5.8 Pa @20°C
<b>(l) Vapor Density:</b>	1.6 (anhydrous ethanol)
<b>(m) Relative Density</b>	Not available
<b>(n) Solubility(ies)</b>	Soluble in water
<b>(o) Partition Coefficient: n-octanol/water</b>	NA
<b>(p) Auto-ignition Temperature</b>	NE
<b>(q) Decomposition Temperature</b>	NE
<b>(r) Viscosity</b>	NE

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**Section 10 - Stability and Reactivity**


<b>(a)</b>	<b>Reactivity</b>	Not determined
<b>(b)</b>	<b>Chemical Stability</b>	Stable under recommended storage conditions.
<b>(c)</b>	<b>Possibility of Hazardous Reactions</b>	Not determined
<b>(d)</b>	<b>Conditions to Avoid</b>	As a precautionary measure, keep away from heat sources and electrostatic discharge. Fine particles (such as mists) may fuel fires/explosions.
<b>(e)</b>	<b>Incompatible Materials</b>	As a precautionary measure, keep away from strong oxidizers
<b>(f)</b>	<b>Hazardous Decomposition Products</b>	Not determined.

**Section 11 - Toxicological Information**

<b>(a)</b>	<b>Likely Routes of Exposure</b>	Ingestion, Inhalation, Intravenous, Skin, Eye
<b>(b)</b>	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	No data available.
<b>(c)</b>	<b>Delayed and immediate effects and also chronic effects from short and long term exposure</b>	Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs.  <b>Known Clinical Effects:</b> Adverse effects associated with therapeutic use include decrease in blood pressure (hypotension), neutropenia, dizziness, nausea, vomiting, loss of hair, infection, blood cell changes, flushing, skin rash, and inflammation of the mouth (stomatitis).

**(d) Acute Toxicity**

**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.

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**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.


<b>Component</b>	<b>Type</b>	<b>Route</b>	<b>Species</b>	<b>Dosage</b>
Paclitaxel	LD <sub>50</sub> LD <sub>50</sub>	Intravenous Intraperitoneal Intraperitoneal	Mouse Mouse Rat	12 mg/kg 128 mg/kg 32.5 mg/kg
Castor Oil	LD <sub>50</sub>	Oral	Rat	>20g/kg
Ethanol	LD <sub>50</sub> LD <sub>50</sub> LC <sub>50</sub>	Oral Oral Inhalation	Mouse Rat Rat	3450 mg/kg 7060 mg/kg 20,000ppm 10h
Citric Acid	LD <sub>50</sub>	Oral	Rat	3000 mg/kg

**(a) Hazardous Chemical Listings**

NTP: Not Listed

IARC: Group 1 (Carcinogenic to Humans)

OSHA: Not Listed

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**Section 12 - Ecological Information**

<b>(a) Ecotoxicity</b>	Environmental properties have not been thoroughly investigated. Releases to the environment
<b>(b) Persistence and degradability</b>	No data available
<b>(c) Bioaccumulative potential</b>	Predicted: 7.4 Log D 3.95
<b>(d) Mobility in soil</b>	No data available
<b>(e) Other Adverse Effects</b>	No data available

**Section 13 - Disposal Considerations**

Dispose of in accordance with local, state and federal regulations. Wastes should be double contained (e.g. double sealed bags) and labeled indicating contents to ensure safe handling and disposal. Incineration of waste product is recommended.

**Section 14 - Transport Information**

**This material is regulated for transportation as a hazardous material/dangerous good.**

**DOT:** Hazardous material/dangerous good

**ICAO/IATA:** Hazardous material/dangerous good

**IMDG:** Hazardous material/dangerous good.

**Flash Point:** 14.87° C

<b>(a) UN Number</b>	UN 1170
<b>(b) UN Proper Shipping Name</b>	Ethanol solution
<b>(c) Transport Hazard Class(es)</b>	3
<b>(d) Packing Group</b>	II
<b>(e) Environmental Hazards</b>	N/A
<b>(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)</b>	N/A
<b>(g) Special Precautions</b>	N/A

**Section 15 - Regulatory Information**


Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division 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: Not listed

CERCLA - Not on this list



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SARA 302 - Not on this list  
SARA 313 - Not on this list

### Section 16 - Other Information


As of the date of effectiveness, 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 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:

Athenex Pharmaceutical Division  
10 N. Martingale Road, Suite 230  
Schaumburg, IL 60173  
847-886-9515

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

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration

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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
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
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
SDS	Safety Data Sheet
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)
WHMIS	Workplace Hazardous Materials Information System

## Signature Manifest

**Document Number:** SDS012  
**Title:** Paclitaxel Injection, USP  
**Effective Date:** 24 Feb 2022

**Revision:** 04

All dates and times are in Eastern Standard Time.

### Paclitaxel Injection, USP

#### Change Request

Name/Signature	Title	Date	Meaning/Reason
Emily Berdyck (EBERDYCK)	Quality Assurance Supervisor	08 Feb 2022, 01:07:11 PM	Approved

#### Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (EXT-JANDRE)	Regulatory Affairs Consultant	18 Feb 2022, 09:23:32 AM	Approved

#### Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Karen Ryan (KARENRYAN)	VP of Global Quality Assurance	24 Feb 2022, 03:26:34 PM	Approved