



Paclitaxel Protein- Bound Particles for Injectable Suspension (Albumin-Bound) Lyophilized Powder

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Date of Issue: 04/10/2023

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Paclitaxel Protein- Bound Particles for Injectable Suspension (Albumin-Bound) Lyophilized Powder

Product Code: 0517-4300-01

1.2. Intended Use of the Product

Use of the Substance/Mixture:

- Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
- Locally advanced or metastatic non-small cell lung cancer (NSCLC), as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
- Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

1.3. Name, Address, and Telephone of the Responsible Party

Company

American Regent, Inc.

5 Ramsey Dr.

P.O. Box 9001

Shirley, NY 11967

1-800-645-1706

www.americanregent.com

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Skin corrosion/irritation Category 2	H315
Serious eye damage/eye irritation Category 1	H318
Skin sensitization, Category 1	H317
Reproductive toxicity Category 2	H361
Reproductive toxicity, Additional category, Effects on or via lactation	H362

Combustible dust

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

- : May form combustible dust concentrations in air.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H361 - Suspected of damaging fertility or the unborn child.
H362 - May cause harm to breast-fed children.

Precautionary Statements (GHS-US)

- : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe vapors, mist, or spray.
P263 - Avoid contact during pregnancy/while nursing.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.

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P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P310 - Immediately call a poison center or doctor.
P321 - Specific treatment (see section 4 on this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
Albumins, human	Albumins, human (A class of simple proteins found in living human tissue.) / Albumin human / Human albumin	(CAS-No.) 70024-90-7	90	Comb. Dust
Paclitaxel	Benzenepropanoic acid, .beta.-(benzoylamino)-.alpha.-hydroxy-, (2.alpha.,4.alpha.,6.alpha.,9.alpha.,11.alpha.,12.alpha.,12b)-6,12b-bis(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-4,11-dihydroxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (.alpha.R,.beta.S) / Benzenepropanoic acid, .beta.-(benzoylamino)-.alpha.-hydroxy-, (2.alpha.R,4S,4.alpha.S,6R,9S,11S,12S,12.alpha.R,12bS)-6,12b-bis(acetyloxy)-12-(benzoyloxy)-2.alpha.,3,4,4.alpha.,5,6,9,10,11,12,12.alpha.,12b-dodecahydro-4,11-dihydroxy-4.alpha.,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (.alpha.R,.beta.S) / paclitaxel	(CAS-No.) 33069-62-4	10	Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317 Repr. 2, H361 Lact., H362 STOT SE 3, H335 Aquatic Chronic 4, H413
Hydrochloric acid	HYDROCHLORIC ACID / Hydrochloric acid, anhydrous / Muriatic acid / Hydrogen chloride / hydrochloric acid	(CAS-No.) 7647-01-0	< 1*	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
Sodium hydroxide	SODIUM HYDROXIDE / Sodium hydroxide (Na(OH)) / Caustic soda / LYE	(CAS-No.) 1310-73-2	< 1*	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 3, H402

Full text of H-phrases: see section 16.

* - For pH adjustment.

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Wash affected area with soap and water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

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First-aid Measures After Eye Contact: Immediately rinse with water for at least 30 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children. Skin sensitization. Causes skin irritation. Causes serious eye damage.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction. Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Causes permanent damage to the cornea, iris, or conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive. Product dusts may be explosive if a dust cloud is formed.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon and nitrogen oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe dust. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. Use non-sparking tools when cleaning up powder to prevent dust ignition.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Use dust suppressant such as water to prevent dust. Follow institutional protocols for use of appropriate cleansing agents when removing residues. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Material may be biologically contaminated with pathogenic organisms. Product is a combustible dust. Product is also a cytotoxic/potent pharmaceutical agent; use due care during all procedures involving product.

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Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do NOT breathe (dust, vapor, mist, gas). Avoid contact during pregnancy/while nursing. Do not dry clean any dust contaminated surfaces; use appropriate cleaning agent and water.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area. Protect from light.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: Store at controlled room temperature 20° to 25 °C (68° to 77°F).

Storage Area: Keep cool. Protect from sunlight.

7.3. Specific End Use(s)

- Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
- Locally advanced or metastatic non-small cell lung cancer (NSCLC), as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
- Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (Ceiling)	7 mg/m ³
USA NIOSH	NIOSH REL C [ppm]	5 ppm
USA IDLH	IDLH [ppm]	50 ppm
USA OSHA	OSHA PEL (Ceiling)	7 mg/m ³
USA OSHA	OSHA PEL C [ppm]	5 ppm
Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH OEL Ceiling	2 mg/m ³
USA NIOSH	NIOSH REL (Ceiling)	2 mg/m ³
USA IDLH	IDLH	10 mg/m ³
USA OSHA	OSHA PEL (TWA) [1]	2 mg/m ³

8.2. Exposure Controls

Appropriate Engineering Controls

- : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

- : Gloves. Protective clothing. Protective goggles or glasses. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

- : Chemically resistant materials and fabrics.

Hand Protection

- : Wear protective gloves.

Eye and Face Protection

- : Chemical safety goggles or safety glasses with side shields.

Skin and Body Protection

- : Wear suitable protective clothing.

Respiratory Protection

- : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Consumer Exposure Controls

- : Avoid contact during pregnancy/while nursing.

Other Information

- : When using, do not eat, drink or smoke.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: White to yellow lyophilized powder
Odor	: Odorless
Odor Threshold	: No data available
pH	: 6.0 – 7.5 (In solution)
Evaporation Rate	: No data available
Melting Point	: 216 °C (420.8 °F)
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: Insoluble in water.
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products

Thermal decomposition may produce: Carbon and nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg
Paclitaxel (33069-62-4)	
LD50 Intravenous Mouse	447 mg/kg
LD50 Intravenous Rat	>120 mg/kg
LD50 Intravenous Dog	>8.4 mg/kg
LD50 Intravenous Pig	> 6 mg/kg

Skin Corrosion/Irritation: Causes skin irritation.

pH: 6.0 – 7.5 In solution

Serious Eye Damage/Irritation: Causes serious eye damage.

pH: 6.0 – 7.5 (In solution)

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

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Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3

Reproductive Toxicity: Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children. (This material or its emissions may appear in breast milk of nursing mothers.)

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction. Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Causes permanent damage to the cornea, iris, or conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)
Paclitaxel (33069-62-4)	
LC50 Fish 1	>7.1 mg/l (Exposure time: 96 h - Species: Pimephales promales [static]). Structurally or pharmacologically related substance.
EC50 - Crustacea [1]	>0.74 mg/l (Species: Daphnia magna). Structurally or pharmacologically related substance.
Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	40 mg/l

12.2. Persistence and Degradability

Paclitaxel Protein- Bound Particles for Injectable Suspension (Albumin-Bound) Lyophilized Powder	
Persistence and Degradability	BCF = 3.0; Expected to be biodegradable.

12.3. Bioaccumulative Potential

Paclitaxel Protein- Bound Particles for Injectable Suspension (Albumin-Bound) Lyophilized Powder	
Bioaccumulative Potential	Not expected to bioaccumulate.

12.4. Mobility in Soil

Paclitaxel Protein- Bound Particles for Injectable Suspension (Albumin-Bound) Lyophilized Powder	
Ecology - Soil	Leaches into groundwater.

12.5. Other Adverse Effects

Other Adverse Effects : None known.

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Treatment Methods: Can be landfilled or incinerated, when in compliance with local regulations.

Sewage Disposal Recommendations: Do not dispose of waste into sewer.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Biologically contaminated materials should be incinerated.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

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14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Paclitaxel Protein- Bound Particles for Injectable Suspension (Albumin-Bound) Lyophilized Powder	
SARA Section 311/312 Hazard Classes	Health hazard - Reproductive toxicity Health hazard - Respiratory or skin sensitization Health hazard - Skin corrosion or Irritation Health hazard - Serious eye damage or eye irritation
Albumins, human (70024-90-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
CERCLA RQ	1000 lb

15.2. US State Regulations

Hydrochloric acid (7647-01-0)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
Sodium hydroxide (1310-73-2)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

California Proposition 65



WARNING: This product can expose you to Paclitaxel, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

Chemical Name (CAS No.)	Carcinogenicity	Developmental Toxicity	Female Reproductive Toxicity	Male Reproductive Toxicity
Paclitaxel (33069-62-4)		X	X	X

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision

: 04/10/2023

Other Information

: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H335	May cause respiratory irritation

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H361	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H413	May cause long lasting harmful effects to aquatic life

Refer to American Regent prescribing information for further information at: <http://www.americanregent.com/AllProducts.aspx>

The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall American Regent, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if American Regent has been advised of the possibility of such damages.

SDS US (GHS HazCom)