



Semisynthetic Paclitaxel Injection

SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

1. IDENTIFICATION

Product identifier

Product Name: Semisynthetic Paclitaxel Injection

Synonyms: Semisynthetic Paclitaxel Injection, USP; Semisynthetic Paclitaxel Injection (6 mg/mL); Semisynthetic Paclitaxel Injection, USP 30 mg/5 mL; Semisynthetic Paclitaxel Injection, USP 100 mg/16.7 mL; Semisynthetic Paclitaxel Injection, USP 300 mg/50 mL

Other means of identification

Other Information: No other information

Recommended use of the chemical and restrictions on use

Recommended Use: Pharmaceutical. Use only as directed.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

Uses advised against: No information available.

Details of the supplier of the safety data sheet

Mylan Inc.

Robert J. Coury Global Center

1000 Mylan Blvd.

Canonsburg, PA 15317, USA

+1.724.514.1800

Contact e-mail:

SDScontact@mylan.com

Emergency telephone number

Emergency Telephone:

24 hr. Emergency Contact ChemTel

International: +1-813-248-0585

US & Canada: 1-800-255-3924

Mexico: 800-099-0731

Other Contact Information

FDA Adverse Events Reporting

Number:

For reporting adverse health events call:

+1 877-446-3679

2. HAZARDS IDENTIFICATION

Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

Classification

Serious eye damage/eye irritation, Category 2A

Skin sensitization, Category 1

Reproductive toxicity, Category 2

Flammable liquids, Category 2

Label elements

**Signal word:**

Danger

Hazard statements:

H225 - Highly flammable liquid and vapor
 H317 - May cause an allergic skin reaction
 H319 - Causes serious eye irritation
 H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements - Prevention:

Obtain special instructions before use
 Do not handle until all safety precautions have been read and understood
 Use personal protective equipment as required
 Wash face, hands and any exposed skin thoroughly after handling
 Avoid breathing dust/fume/gas/mist/vapors/spray
 Contaminated work clothing should not be allowed out of the workplace
 Wear protective gloves
 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
 Keep container tightly closed
 Ground/bond container and receiving equipment
 Use only non-sparking tools
 Take precautionary measures against static discharge
 Use explosion-proof electrical/ ventilating/ lighting/ equipment

Precautionary Statements - Response:

IF exposed or concerned: Get medical advice/attention
 Specific treatment (see supplemental first aid instructions on this label)

Eyes:

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Skin:

If eye irritation persists: Get medical advice/attention
 If skin irritation or rash occurs: Get medical advice/attention
 Wash contaminated clothing before reuse
 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

Fire:

In case of fire: Use CO₂, dry chemical, or foam for extinction

Precautionary Statements - Storage:

Store locked up
 Store in a well-ventilated place. Keep cool

Precautionary Statements - Disposal:

Dispose of contents/container to an approved waste disposal plant

Other Hazards

No information available.

Unknown acute toxicity

No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Chemical name	CAS No	Weight-%	Hazard statements
Ethanol	64-17-5	40-60	H225 - Highly flammable liquid and vapor H319 - Causes serious eye irritation
Paclitaxel	33069-62-4	0-2	H315 - Causes skin irritation H317 - May cause an allergic skin reaction H318 - Causes serious eye damage H341 - Suspected of causing genetic defects H361 - Suspected of damaging fertility or the unborn child

4. FIRST AID MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Description of first aid measures

Overdose: Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.

General advice: Show this safety data sheet to the doctor in attendance.

Inhalation: Remove to fresh air. Get medical attention immediately if symptoms occur.

Skin contact: May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician. Wash off immediately with soap and plenty of water for at least 15 minutes.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.

Ingestion: Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider: Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms: Itching. Rashes. Hives. Burning sensation.

Chronic symptoms: May cause sensitization by skin contact. May cause adverse reproductive effects - such as birth defect, miscarriages, or infertility.

Indication of any immediate medical attention and special treatment needed

May cause sensitization in susceptible persons. Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Extinguishing media

Suitable Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical

Fire hazard: Flammable liquid. Flammable.

Explosive hazard: Not an explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Hazardous combustion products: Carbon oxides. Nitrogen oxides.

Advice for firefighters

Precautionary measures in case of fire: Standard procedure for chemical fires.

Firefighting instructions: Use water spray or fog; do not use straight streams.

Protection of Firefighters: Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Other Information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

For non-emergency personnel

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas.

For emergency responders

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

Other Information: Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Prevent further leakage or spillage if safe to do so.

Methods and material for containment and cleaning up

Methods for containment: Prevent further leakage or spillage if safe to do so.

Methods for cleaning up: Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.

Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections

See section 8 for more information. See section 13 for more information.

7. HANDLING AND STORAGE

Precautions for safe handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing.

Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Remove contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Keep at temperatures between 20 and 25 °C (68 and 77 °F). Keep out of the reach of children. Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place.

Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Control parameters

Exposure Limits: No information available

Exposure controls

Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Hand protection: Wear suitable gloves. Impervious gloves.

Eye/face protection: Wear safety glasses with side shields (or goggles). If splashes are likely to occur, wear safety glasses with side-shields.

Skin and body protection: Skin sensitizer. Avoid contact with skin. Wear suitable protective clothing. Wash thoroughly after handling.

Respiratory protection: Use appropriate respiratory protection.

General hygiene considerations: Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Wear suitable gloves and eye/face protection. Avoid contact with skin, eyes or clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Liquid
Appearance:	clear
Color:	colorless or slight yellow
Odor:	No data available
Odor threshold:	No data available
pH:	No data available
Melting point / freezing point:	No data available
Boiling point / boiling range:	No data available
Flash point:	= 16 °C / 61 °F
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Water solubility:	No data available
Solubility in other solvents:	No data available
Partition coefficient:	No data available
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Kinematic viscosity:	No data available
Dynamic viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available
<u>Other Information</u>	
VOC Content (%):	<60%

10. STABILITY AND REACTIVITY**Reactivity**

Hazardous reactions will not occur under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Extremes of temperature and direct sunlight.

Incompatible materials

Strong acids. Strong bases. Strong oxidizing agents.

Hazardous decomposition products

Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION**Information on toxicological effects****Information on likely routes of exposure**

Inhalation: Not an expected route of exposure. May cause irritation of respiratory tract.

Ingestion: Not an expected route of exposure. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Eye contact: Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes serious eye irritation.

Skin contact: May cause sensitization by skin contact. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). Causes skin irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: Itching. Rashes. Hives. Burning sensation.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation: Irritating to skin.

Serious eye damage/eye irritation: Irritating to eyes.

Respiratory or skin sensitization: May cause sensitization by skin contact.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Contains a known or suspected reproductive toxin. May cause adverse reproductive effects - such as birth defect, miscarriages, or infertility.

STOT - single exposure: Based on available data, the classification criteria are not met.

STOT - repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Numerical measures of toxicity

Acute toxicity: No information available

12. ECOLOGICAL INFORMATION**Ecotoxicity**

No information available.

Persistence and degradability

No information available.

Bioaccumulation

No information available.

Mobility

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods**

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

US EPA Waste Number: D001

California Hazardous Waste Status

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical name	Weight-%	California Hazardous Waste Status
Ethanol (CAS #: 64-17-5)	40-60	Toxic Ignitable

14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

In accordance with DOT / ICAO / IATA / TDG**UN Number**

UN 1993 UN 1170

UN proper shipping name

Flammable liquid, n.o.s. Ethanol solution (Ethyl alcohol solution)

Transport hazard class(es)

Hazard Class: 3

**Packing group**

II

Environmental hazards

No

Special precautions for user

No information available

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Special Provisions

Shipper, please take note that in addition to limited and/or excepted quantity exemptions, the following Special Provisions may apply to this product.

US DOT: DOT - ORM-D; DOT - 150

TDG: TDG - 150; TDG - 16

IMDG: IMDG - 223; IMDG - 274; IMDG - 955

IATA: IATA - A3

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture****International Regulations**

Ozone-depleting substances (ODS): Not applicable

Persistent Organic Pollutants: Not applicable

The Rotterdam Convention: Not applicable

US Federal Regulations

SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Right-to-Know Regulations

US State Regulations:

Chemical name	New Jersey	Massachusetts	Pennsylvania
Ethanol (CAS #: 64-17-5)	X	X	X

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

16. OTHER INFORMATION

Revision Date: 29-November-2019

Other Information: This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

Key or legend to abbreviations and acronyms used in the safety data sheet:**Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA: TWA (time-weighted average)

STEL: STEL (Short Term Exposure Limit)

Party responsible for the preparation of this document:

Mylan Global Environmental, Health, and Safety Department - Occupational Toxicology

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This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product.

Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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