

Section 1: IDENTIFICATION

Product Name:	Paclitaxel
Synonyms:	Taxol, Taxol A, BMS 181339-01, NSC 125993.
Chemical Name:	Beta- (Benzolamino-alpha-hydroxy-benzenpropanoic acid, 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, (2aR-(2a alpha, 4 beta, 4a beta, 6 beta, 9 alpha (alpha R*, beta S*), 11 alpha, 12 alpha, 12a alpha, 12b alpha), crude paclitaxel, semi-synthetic paclitaxel, recovered crude paclitaxel, paclitaxel reference standard, amorphous paclitaxel, development paclitaxel.
Product Use:	Bulk active pharmaceutical ingredient (API) for research, development or, where applicable, drug product.
Restrictions on Use:	Not available.
Manufacturer/Supplier:	Phyton Biotech LLC 1527 Cliveden Ave. Delta, BC, Canada V3M 6P7
Phone Number:	(604) 777-2340
Emergency Phone:	CANUTEC: 1-888-CAN-UTEC (226-8832), 613-996-6666 or *666 on a cellular phone
Date of Preparation of SDS:	August 20, 2021

Section 2: HAZARD(S) IDENTIFICATION

GHS INFORMATION

Classification: Skin Irritation, Category 2
 Eye Damage, Category 1
 Sensitization - Respiratory, Category 1
 Sensitization - Skin, Category 1
 Germ Cell Mutagenicity, Category 2
 Reproductive Toxicity, Category 2
 Specific Target Organ Toxicity (Single Exposure), Category 3 - Respiratory Irritation

LABEL ELEMENTS**Hazard****Pictogram(s):****Signal Word:** Danger**Hazard****Statements:**

Causes skin irritation.
 Causes serious eye damage.
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 May cause an allergic skin reaction.

Suspected of causing genetic defects.
 Suspected of damaging fertility or the unborn child.
 May cause respiratory irritation.

Precautionary Statements

Prevention: Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Avoid breathing dust.
 Wash hands thoroughly after handling.
 Use only outdoors or in a well-ventilated area.
 Contaminated work clothing should not be allowed out of the workplace.
 Wear protective gloves, protective clothing, and eye and face protection.
 Wear respiratory protection.

Response: IF ON SKIN: Wash with plenty of water.
 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 IF exposed or concerned: Get medical attention.
 Immediately call a POISON CENTER or doctor.
 If skin irritation or rash occurs: Get medical attention.
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor.
 Take off contaminated clothing and wash it before reuse.

Storage: Store in a well-ventilated place. Keep container tightly closed.
 Store locked up.

Disposal: Dispose of contents and container in accordance with applicable regional, national and local laws and regulations.

Hazards Not Otherwise Classified: Not applicable.

Ingredients with Unknown Toxicity: None.

This material is considered hazardous by the OSHA Hazard Communication Standard, (29 CFR 1910.1200).

This material is considered hazardous by the Hazardous Products Regulations.

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS
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Hazardous Ingredient(s)	Common name / Synonyms	CAS No.	% wt./wt.
Paclitaxel	Not available.	33069-62-4	100

Section 4: FIRST-AID MEASURES

Inhalation: If inhaled: Remove person to fresh air and keep comfortable for breathing.
 Call a poison center or doctor if you feel unwell. If experiencing respiratory symptoms: Call a poison center or doctor.

Acute and delayed symptoms and effects: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory

irritation. Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

Eye Contact: If in eyes: Rinse cautiously with water for at least 30 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center or doctor.

Acute and delayed symptoms and effects: Causes serious eye damage. Signs/symptoms may include cloudy appearance of the cornea, chemical burns, severe pain, tearing, ulcerations, significantly impaired vision or complete loss of vision.

Skin Contact: If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical attention. Take off contaminated clothing and wash it before reuse.

Acute and delayed symptoms and effects: May cause an allergic skin reaction. Causes skin irritation. Signs/symptoms may include localized redness, swelling, and itching.

Ingestion: If swallowed: Call a poison center or doctor if you feel unwell. If vomiting occurs naturally, have victim lean forward to reduce the risk of aspiration. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Acute and delayed symptoms and effects: May cause gastrointestinal irritation. Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

General Advice: In case of accident or if you feel unwell, seek medical advice immediately (show the label or SDS where possible).

Note to Physicians: Symptoms may not appear immediately.

Section 5: FIRE-FIGHTING MEASURES

FLAMMABILITY AND EXPLOSION INFORMATION

Not flammable or combustible by OSHA/WHMIS criteria.

Sensitivity to Mechanical Impact: This material is not sensitive to mechanical impact.

Sensitivity to Static Discharge: This material is not sensitive to static discharge.

MEANS OF EXTINCTION

Suitable Extinguishing Media: Small Fire: Dry chemical, CO₂, water spray or regular foam.

Large Fire: Water spray, fog or regular foam. Move containers from fire area if you can do it without risk.

Unsuitable Extinguishing Media: Not available.

Products of Combustion: Oxides of carbon. Oxides of nitrogen.

Protection of Firefighters: Fire may produce irritating, corrosive and/or toxic gases. Runoff from fire control or dilution water may cause pollution. Wear positive pressure self-contained breathing apparatus (SCBA). Structural firefighters' protective clothing will only provide limited protection.

Section 6: ACCIDENTAL RELEASE MEASURES

Emergency Procedures:	Keep unauthorized personnel away. Stay upwind. Keep out of low areas. Ventilate closed spaces before entering.
Personal Precautions:	Do not touch or walk through spilled material. Use personal protection recommended in Section 8.
Environmental Precautions:	Keep out of drains, sewers, ditches, and waterways.
Methods for Containment:	Do not flush to sewer or allow to enter waterways.
Methods for Clean-Up:	Sweep up and shovel into suitable containers for disposal. Decontaminate area with sodium carbonate solution (1% for trace material remaining on surfaces, 10% for larger quantities or for solutions containing paclitaxel) for 30 minutes or methanolic potassium hydroxide (30% IN KOH and 70% methanol) for 5 minutes. (CAUTION – Methanolic KOH is both flammable and corrosive. Due to the alkalinity of methanolic KOH particular care should be taken to protect skin and eyes from contact). After either procedure wash twice with detergent and water.
Other Information:	See Section 13 for disposal considerations.

Section 7: HANDLING AND STORAGE**Handling:**

Do not swallow. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing mist, vapours, or spray. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Contaminated work clothing should not be allowed out of the workplace. See Section 8 for information on Personal Protective Equipment.

Storage:

Store in a well-ventilated place. Keep container tightly closed. Store between 20 to 25 °C (68 to 77 °F), and excursion of 15 to 30 °C (59 to 86 °F). Store locked up. Store away from incompatible materials. See Section 10 for information on Incompatible Materials. Keep out of the reach of children.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**Exposure Guidelines****Component**

Paclitaxel [CAS No. 33069-62-4]

ACGIH: No TLV established.

OSHA: No PEL established.

Fastrac™ OEL: 1 µg/m³ (OEL); 4 µg/day (ADE); 40 µg/100 cm³ (ASL)

PEL: Permissible Exposure Limit

TLV: Threshold Limit Value

OEL: Occupational Exposure Limit

ADE: Acceptable Daily Exposure

ASL: Acceptable Surface Limit

Engineering Controls: Use ventilation adequate to keep exposures (airborne levels of dust, fume, vapour, gas, etc.) below recommended exposure limits.

PERSONAL PROTECTIVE EQUIPMENT (PPE)


Eye/Face Protection: Wear chemical safety goggles, and full face shield. Indirect vented, dust-tight goggles are required if dust is generated when handling this product. Ensure that eyewash stations and safety showers are close to the workstation location. Use equipment for eye protection that meets the standards referenced by CSA Standard CAN/CSA-Z94.3 and OSHA regulations in 29 CFR 1910.133 for Personal Protective Equipment.

Hand Protection: Wear protective gloves. Consult manufacturer specifications for further information.

Skin and Body Protection: Wear protective clothing.

Respiratory Protection: Wear respiratory protection. If engineering controls and ventilation are not sufficient to control exposure to below the allowable limits then an appropriate NIOSH/MSHA approved air-purifying respirator that meets the requirements of CSA Standard CAN/CSA-Z94.4, with particulate filter, or self-contained breathing apparatus must be used.

General Hygiene Considerations: Handle according to established industrial hygiene and safety practices. Consult a competent industrial hygienist to determine hazard potential and/or the PPE manufacturers to ensure adequate protection.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES
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Appearance:	Powder, solid, white to off-white.
Colour:	White to off-white.
Odour:	Odourless.
Odour Threshold:	Not available.
Physical State:	Solid.
pH:	Not available.
Melting Point / Freezing Point:	213 °C (415.4 °F)
Initial Boiling Point:	Not available.
Boiling Range:	Not available.
Flash Point:	Not available.

SAFETY DATA SHEET

Evaporation Rate:	Not available.
Flammability (solid, gas):	See Section 5.
Lower Flammability Limit:	Not available.
Upper Flammability Limit:	Not available.
Vapor Pressure:	Not available.
Vapor Density:	Not available.
Relative Density:	Not available.
Solubilities:	Insoluble in water.
Partition Coefficient: n-Octanol/Water:	Not available.
Auto-ignition Temperature:	Not available.
Decomposition Temperature:	Not available.
Viscosity:	Not available.
Percent Volatile, wt. %:	Not available.
VOC content, wt. %:	Not available.
Density:	Not available.
Coefficient of Water/Oil Distribution:	Not available.

Section 10: STABILITY AND REACTIVITY

Reactivity:	Contact with incompatible materials. Exposure to heat.
Chemical Stability:	Stable under normal storage conditions.
Possibility of Hazardous Reactions:	None known.
Conditions to Avoid:	Contact with incompatible materials. Exposure to heat. UV radiation.
Incompatible Materials:	Acids. Bases. Oxidizers.
Hazardous Decomposition Products:	Not available.

Section 11: TOXICOLOGICAL INFORMATION
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EFFECTS OF ACUTE EXPOSURE
Product Toxicity

Oral:	Not available.
Dermal:	Not available.
Inhalation:	Not available.
Intravenous:	LD50 = 12 mg/kg (mouse)
Intraperitoneal:	LD50 = 32.53 mg/kg (rat) LD50 = 128 mg/kg (mouse)

Likely Routes of Exposure: Eye contact. Skin contact. Inhalation. Ingestion. Skin absorption.

Target Organs: Skin. Eyes. Gastrointestinal tract. Respiratory system.

Symptoms (including delayed and immediate effects)

Studies in the dog, rat and mouse include behavioral – general depressed activity and ataxia, (muscle in-coordination); respiratory stimulation and depression, and dyspnea; hair and weight loss or decreased weight gain; leukopenia, reticulocytopenia, slight decreases in lymphocyte numbers and changes in erythrocyte values and platelet counts; atrophy of the thymus, testes, epididymides, seminal vesicle and prostate.

Subacute

Intravenous Rat (5-day interval for one month) dosages of 1.3, 3 and 10 mg/kg/day, resulted in a no-toxic-effect level of 1 mg/kg/day.

Inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation. Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

Eye: Causes serious eye damage. Signs/symptoms may include cloudy appearance of the cornea, chemical burns, severe pain, tearing, ulcerations, significantly impaired vision or complete loss of vision.

Skin: May cause an allergic skin reaction. Causes skin irritation. Signs/symptoms may include localized redness, swelling, and itching.

Ingestion: May cause gastrointestinal irritation. Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

Skin Sensitization: May cause an allergic skin reaction.

Respiratory Sensitization: Anaphylaxis and severe hypersensitivity reactions characterized by trouble breathing and low blood pressure requiring treatment, swelling around the face, and generalized itching have occurred. Fatal reactions have also occurred.

Medical Conditions Not available.

Aggravated By Exposure:

EFFECTS OF CHRONIC EXPOSURE (from short and long-term exposure)

Target Organs: Skin. Eyes. Gastrointestinal tract. Respiratory system. Bone marrow. Liver. Reproductive system.

Chronic Effects: Prolonged or repeated contact may dry skin and cause irritation. Paclitaxel produces severe bone marrow depression, infections, hypertension, thrombotic events, myocardial infarction, heart failure, paralytic ileus, optic nerve disturbances, severe skin reactions, hepatic necrosis, interstitial pneumonia, convulsions and hepatic encephalopathy.

Carcinogenicity: This product does not contain any carcinogens or potential carcinogens above reportable thresholds as listed by ACGIH, IARC, OSHA, or NTP.

Mutagenicity: Suspected of causing genetic defects. Paclitaxel was not mutagenic in the Ames assay and in the mammalian cell forward mutation assay.

Paclitaxel was clastogenic in vitro in chromosomal aberration assay in human lymphocytes and genotoxic in vivo micronucleus test in mice.

Reproductive Effects: Suspected of damaging fertility or the unborn child. Paclitaxel reduced fertility in rats. It inhibited spermatogenesis and sperm transport.

In rat, intravenous doses of 0.1-1 mg/kg/day were administered to males 63 days prior to mating, to males and females during the mating period, and to females during days 0-7 of gestation. Fertility indices were lower in both male and female rats at doses of one mg/kg/day, and the total embryo-fetal deaths were increased. The NOEL was 0.3 mg/kg/day.

In rabbits, intravenous doses of 0.3-3 mg/kg/day on days 6-18 of gestation caused dose-related maternal toxicity and embryo toxicity. No fetal malformations were observed, although there were increased resorption and abortion. No significant findings were reported at doses of 1 mg/kg or less.

Developmental Effects

Teratogenicity: Administration of Paclitaxel during organogenesis to rabbits caused embryotoxicity and fetotoxicity in the presence of maternal toxicity.

Embryotoxicity: Not available.

Toxicologically Synergistic Materials: At therapeutic doses of paclitaxel a cumulative, but not dose-limiting, neurotoxic effect, i.e., induction of sensory nerve damage may occur in patients previously treated with Cisplatin. There have been two reports of radiation pneumonitis in patients treated with both paclitaxel and radiation therapy to the lungs. It may be possible for paclitaxel in combination with radiation therapy to predispose certain patients to radiation pneumonitis.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: Not available.

Persistence / Degradability: Not available.

Bioaccumulation / Accumulation: Not available.

Mobility in Environment: Not available.

Other Adverse Effects: Not available.

Section 13: DISPOSAL CONSIDERATIONS

Disposal Instructions: Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

Section 14: TRANSPORT INFORMATION**U.S. Department of Transportation (DOT)**

Proper Shipping Name: Not regulated.
Class: Not applicable.
UN Number: Not applicable.
Packing Group: Not applicable.
Placard(s): Not applicable.

Canada Transportation of Dangerous Goods (TDG)

Proper Shipping Name: Not regulated.
Class: Not applicable.
UN Number: Not applicable.
Packing Group: Not applicable.
Placard(s): Not applicable.

Section 15: REGULATORY INFORMATION**Federal Regulations****United States**

This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SARA Title III

No components are listed.

State Regulations**Massachusetts**

US Massachusetts Commonwealth's Right-to-Know Law (Appendix A to 105 Code of Massachusetts Regulations Section 670.000)

No components are listed.

New Jersey

US New Jersey Worker and Community Right-to-Know Act (New Jersey Statute Annotated Section 34:5A-5)

No components are listed.

Pennsylvania

US Pennsylvania Worker and Community Right-to-Know Law (34 Pa. Code Chap. 301-323)

No components are listed.

Section 16: OTHER INFORMATION**Disclaimer:**

The information contained in this document applies to this specific material as supplied. It may not be valid for this material if it is used in combination with any other materials. It is the user's responsibility to satisfy oneself as to the suitability and completeness of this information for their own particular use.

Date of Preparation of SDS: August 20, 2021

Version: 1.0