

Section 1: IDENTIFICATION

Product Name:	Docetaxel
Synonyms:	Taxotere.
Chemical Name:	(α R, β S)- β -[[[(1,1-Dimethylethoxy) carbonyl] amino]- α -hydroxybenzenepropanoic acid (2aR, 4S, 4aS, 6R, 9S, 11S12S, 12aR, 12bS)-12b-(acetyloxy)-12(benzoyloxy)-2a, 3,4,4a, 6,9,10,11,12,12a, 12b-dodecahydro-4, 6,11-trihydroxy-4a, 8,13,13-tetramethyl-5-oxo-7, 11-methano-1H-cyclodeca [3,4] benz [1,2-b] oxet-9-yl ester, Crude Docetaxel, Recovered Docetaxel, Docetaxel API, Docetaxel Anhydrous, Purified Docetaxel.
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: Eye Irritation, Category 2A
 Germ Cell Mutagenicity, Category 2
 Reproductive Toxicity, Category 1B
 Specific Target Organ Toxicity (Single Exposure), Category 3 - Respiratory Irritation

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

Hazard Statements: Causes serious eye irritation.
 Suspected of causing genetic defects.
 May damage 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.
 Wear protective gloves, protective clothing and eye protection.

Response: 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.
 Call a POISON CENTER or doctor if you feel unwell.
 If eye irritation persists: Get medical attention.

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.
Docetaxel	Not available.	114977-28-5	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.

Acute and delayed symptoms and effects: 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 20 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.

Acute and delayed symptoms and effects: Causes serious eye irritation.
 Signs/symptoms may include redness, swelling, pain, tearing, and blurred or hazy vision.

Skin Contact: If on skin: Wash with plenty of water. Call a poison center or doctor if you feel unwell.

Acute and delayed symptoms and effects: May cause 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 sensitive to static discharge at temperatures at or above the flash point.

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 dust. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. 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**

Docetaxel [CAS No. 114977-28-5]

ACGIH: No TLV established.

OSHA: No PEL established.

Fastrac™ OEL: 1 µg/m³ (OEL); 3 µg/day (ADE)

PEL: Permissible Exposure Limit

TLV: Threshold Limit Value

OEL: Occupational Exposure Limit

ADE: Acceptable Daily Exposure

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. Indirect vented, dust-tight goggles are required if dust is generated when handling this product. Ensure that eyewash stations 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:

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

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:	232 °C (449.6 °F)
Initial Boiling Point:	Not available.
Boiling Range:	Not available.
Flash Point:	Not available.
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:	188 °C (370.4 °F)
Viscosity:	Not available.

SAFETY DATA SHEET

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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**EFFECTS OF ACUTE EXPOSURE****Product Toxicity**

Oral:	Not available.
Dermal:	Not available.
Inhalation:	Not available.
Intravenous:	LD50 = 2.5 mg/kg (dog) LD50 = 156 mg/kg (mouse) LDLo = 20 mg/kg (rat) LDLo = 24 mg/kg (man)

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)**

Toxic effects noted from acute toxicity 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 respiratory irritation. Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

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- Eye:** Causes serious eye irritation. Signs/symptoms may include redness, swelling, pain, tearing, and blurred or hazy vision.
- Skin:** May cause 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:** Prolonged or repeated exposure may cause allergic reaction.
- Respiratory Sensitization:** Prolonged or repeated exposure may cause allergic reaction.
- Medical Conditions Aggravated By Exposure:** Not available.

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

- Target Organs:** Skin. Eyes. Gastrointestinal tract. Respiratory system. Liver. Reproductive system. Bone marrow.
- Chronic Effects:** Prolonged or repeated contact may dry skin and cause irritation. Repeat exposure studies show both reversible and irreversible effects in animals. The reversible effects were reduced body weight and food consumption, lympho-hematopoietic changes (including RBC, WBC, platelet and reticulocyte counts, bone marrow hypocellularity, thymic and lymph node atrophy) and abnormal mitosis/single cell necrosis in multiple organs. The irreversible effects were testicular changes characterized by degeneration of seminiferous tubular epithelium.
- Carcinogenicity:** This product does not contain any carcinogens or potential carcinogens above reportable thresholds as listed by ACGIH, IARC, OSHA, or NTP. Carcinogenicity studies with Docetaxel have not been performed. Second primary malignancies have been reported in patients treated with Docetaxel-containing regimens. These adverse reactions may occur several months or years after Docetaxel-containing therapy.
- Mutagenicity:** Suspected of causing genetic defects. Docetaxel was clastogenic in the in vitro chromosome aberration test in Chinese hamster ovary K1 cells and in the in vivo micronucleus test in mice. Docetaxel was not mutagenic in the Ames test or the Chinese hamster ovary/hypoxanthine-guanine phosphoribosyltransferase gene mutation assay.
- Reproductive Effects:** May damage fertility or the unborn child. Docetaxel did not reduce fertility in animals, but decreased testicular weights.
- Testicular atrophy or degeneration**
Rats 5 mg/kg (intravenous)
Dogs 0.375 mg/kg (intravenous)
about 1/3 and 1/15 the recommended human dose on a mg/m³ basis, respectively).

Developmental Effects

Teratogenicity: Docetaxel can cause fetal harm when administered to a pregnant woman. Studies in animals where Docetaxel was administered (≥ 0.3 and 0.03 mg/kg/day) during organogenesis have shown that it is embryotoxic and fetotoxic. The doses also caused maternal toxicity.

Embryotoxicity: Not available.

Toxicologically Synergistic Materials: Not available.

Other Adverse Reactions: Infections, neutropenia, anemia, febrile neutropenia, hypersensitivity, thrombocytopenia, neuropathy, dysgeusia, dyspnea, constipation, anorexia, nail disorders, fluid retention, asthenia, pain, nausea, diarrhea, vomiting, mucositis, alopecia, skin reactions, myalgia.

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.

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