Biolyse Pharma

SAFETY DATA SHEET
PACLITAXEL FOR INJECTION, USP

Section 1: Identification

- **Product Name:** Paclitaxel for injection, USP
- **CAS Number:** 33069-62-4
- **Chemical Name:** Benezenepropanoic acid,β-(benzoylamino)-α-hydroxy-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-[2aα, 4β, 4aβ, 6β, 9α (αR*,βS*), 11α, 12α,12aα,12bα]]-.
- **Intended Use:** Pharmaceutical, Injectable
- **Manufacturer:** Biolyse Pharma Corporation
  59 Welland Vale Rd,
  St. Catharines ON L2S 3Y2
  Canada
  Toll free: 877-234-1880
  Fax: 905-687-4923
  Email: biolyse9@sympatico.ca
- **Emergency Contact:** 905-687-8008

Section 2: Hazard(s) Identification

- **Hazard Classification:** GHS-Classification
  Germ Cell Mutagenecity: Category 2
  Reproductive Toxicity: Category 1B
  Flammable liquids: Category 2
- **Signal Word(s):** 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
- **Pictograms:**

- **Description of other hazards:** May cause eye irritation, may cause allergic reaction in some individuals. Upon inhalation, dyspnea, chest pain, burning eyes, sore throat and nausea have been reported.

Section 3: Composition/ Information on Ingredients

Chemical Name	Synonym	CAS#	Conc. (per mL)
Benezenepropanoic_acid,β-(benzoylamino)-α-hydroxy-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-[2aα,4β,4aβ,6β,9α(αR*,βS*),11α,12α,12aα,12bα]]-	Paclitaxel	33069-62-4	6.0 mg
Castor Oil	Polyethoxylated Castor oil	61791-12-6	527.0 mg
Dehydrated Alcohol	Ethanol	64-17-5	49.7%(v/v)

Section 4: First-Aid Measures

- **Eye and Skin contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
- **Inhalation and Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Section 5: Fire-Fighting Measures

- **Flash point:** The flash point for ethyl alcohol is 14°C
- **Auto ignition temperature:** Not applicable
- **Extinguisher medium:** Carbon dioxide or foam
- **Special fire-fighting procedures:** Wear self-contained breathing apparatus and protective clothing to minimize contact with respiratory tract, skin and eyes.
- **Unusual fire and explosion hazards:** Vials may explode in fire

Section 6: Accidental Release Measures

- **Personal precautions:** Isolate area around spill and remove all sources of ignition. Put on suitable protective clothing and equipment as specified by site spill procedures (See Section 8).
- **Measures for environmental protection:** Place waste in an appropriately labeled, sealed container for disposal. Dispose of materials according to the applicable federal, state, or local regulations. Care should be taken to avoid environmental release.
- **Measures for cleaning/collecting:** Contain the source of spill if it is safe to do so. Absorb liquid with suitable material and clean affected area with soap and water. An undiluted solution of household bleach may be applied to the spill for ten minutes to inactivate paclitaxel. Absorb the liquid with an inert absorbent material (e.g. absorbent pad).
- **Additional consideration for Large Spill:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should be undertaken by trained personnel.

Section 7: Handling and Storage

- **Handling:** Prevent skin contact. Handle with care. Wear suitable protective clothing as well as laboratory gloves and eye protection.
- **Storage:** Paclitaxel for injection concentrate is stable until the date indicated on the package when unopened vials are stored between 2°C - 25°C in their original carton. Do not freeze.

Section 8: Exposure Controls/Personal Protection

- **Respiratory protection:** Liquid product- Not needed
- **Protective gloves:** Use chemically impervious gloves
- **Eye protection:** Use safety glasses or goggles
- **Ventilation required:** Sufficient to prevent breathing by aerosols
- **Other protective clothing:** Laboratory coat
- **Hygienic work practices:** Wash hands thoroughly after handling

Section 9: Physical and Chemical Properties

- **Form:** non-aqueous solution
- **Color:** Clear to light yellow
- **Molecular formula:** $C_{47}H_{51}NO_{14}$
- **Molecular weight:** 853.9 g/mol
- **Solvent solubility:** soluble in organic solvents
- **Water solubility:** insoluble in water
- **Odor:** No data available
- **Odor threshold:** No data available
- **pH:** 3-7
- **Melting point/melting range:** No data available
- **Boiling point/boiling range:** 78°C
- **Flash point:** 14.87°C
- **Evaporation rate:** Paclitaxel and Polyethoxylated castor oil do not evaporate; evaporation rate for dehydrated alcohol is 1.7
- **Auto ignition temperature:** No data available
- **Danger of explosion:** No data available
- **Vapor pressure:** No data available
- **Vapor density:** No data available
- **Relative density:** No data available
- **Solubility in/Miscibility with water:** No data available

Section 10: Stability and Reactivity

- **Stability:** Stable
- **Conditions to avoid:** Flame
- **Incompatibility (materials to avoid):** As a precautionary measure, keep away from strong oxidizers
- **Hazardous decomposition products:** None known
- **Hazardous polymerization:** Will not occur
- **Reactivity:** No data available

Section 11: Toxicological Information

Aspiration Hazard	None anticipated from normal handling of this product. However, inadvertent inhalation of the product aerosol may produce respiratory irritation.
Dermal irritation/Corrosion	None anticipated from normal handling of this product. Following inadvertent skin contact, this product may produce irritation with itching and redness. Polyethoxylated castor oil was non-irritating in a skin irritation study in rabbits. Ethanol may produce mild irritation with redness and dryness.
Ocular irritation/Corrosion	None anticipated from normal handling of this product. Following inadvertent eye contact, this product may produce irritation with itching, redness, and discomfort. Exposure to ethanol or Polyethoxylated castor oil may produce eye irritation. Exposure to ethanol has produced severe eye irritation in studies in animals.
Dermal or Respiratory sensitization	No data found. In clinical use, anaphylaxis and severe hypersensitivity reactions including dyspnea, hypotension requiring treatment, angioedema and generalized uticarial have occurred in 2-4% of patients receiving paclitaxel. Polyethoxylated castor oil was non-sensitizing in sensitization study in guinea pigs.
Reproductive effects	Administration of Paclitaxel in rats at dosages of 1 mg/kg and 3 mg/kg, respectively, during organogenesis revealed evidence of maternal toxicity, and fetotoxicity. Paclitaxel resulted in intrauterine mortality, increased reabsorptions, and increased fetal deaths. No teratogenic effects were noted at a dosage of 1.0 mg/kg/day; the teratogenic potential could not be assessed at higher doses due to extensive fetal mortality. Ethanol has been shown to produce fetotoxicity in the embryo or fetus of laboratory animals. Chronic prenatal exposure to ethanol has been associated with a distinct pattern of congenital malformations that have collectively been termed the “fetal” alcohol syndrome.
Mutagenecity	Paclitaxel has shown to induce chromosome aberrations in human lymphocytes in vitro and was mutagenic in the micronucleus test in mice in vivo. Paclitaxel was not mutagenic in the Ames test or the CHO/HGPRT gene mutation assay.

Target organ effects	Paclitaxel should be considered irritating to the skin, eyes and respiratory tract. Following an accidental over-exposure, possible target organs may include the bone marrow, peripheral nervous system, cardiovascular system, gastrointestinal system, liver, skin and the fetus.

Section 12: Ecological Information (non-mandatory)

- **Toxicity:** Avoid release into the environment.
  Runoff from fire control or dilution water may cause pollution.
- **Mobility:** No information available
- **Biodegradation:** No information available
- **Bioaccumulation:** No information available

Section 13: Disposal Considerations (non-mandatory)

Dispose of materials according to the applicable federal, state, or local 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 (non-mandatory)

The following refers to all modes of transportation unless specified below.
This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 1170
UN proper shipping name: Ethanol solution
Transport hazard class(es): 3
Packing group: II
Flash point (°C): 14.87
IMDG
Flash Point (°C): 14.87

Section 15: Regulatory Information (non-mandatory)

Paclitaxel
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: developmental toxicity 8/26/1997
Female reproductive toxicity 8/26/97
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS/ELINCS List: Not Listed

Ethyl alcohol (Ethanol)
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: carcinogen 4/29/2011 in alcoholic beverages
Developmental toxicity 10/1/1978 in alcoholic beverages
Inventory – United States TSCA – Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 200-578-6

Castor oil, ethoxylated
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory – United states TSCA – Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: Not Listed

Section 16: Other Information

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