RE: **Paclitaxel Injection, USP**

30mg/5ml - NDC #51991-936-98
100mg/16.7ml - NDC #51991-937-98
300mg/50ml - NDC #51991-938-98

To Whom It May Concern:

Attached please find the SDS (Safety Data Sheet) for the above mentioned product(s).

Please contact us if you have any further questions.

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SAFETY DATA SHEET

SECTION 1 – IDENTIFICATION OF THE PRODUCT & THE COMPANY

a)	Product Name	:	Paclitaxel Injection (6 mg of Paclitaxel/mL)
b)	Common/Trade Name	:	Paclitaxel Injection
	Chemical Name	:	5β, 20-Epoxy-1,2α,4,7β,10β,13α-hexahydroxytax- 11-en-9-one 4,10-diacetate 2- benzoate 13-ester with (2R,3S)-N-benzoyl-3-phenylisoserine.
	Chemical Family	:	Anti neoplastic
c)	Product Use	:	Pharmaceutical
	Product Type	:	Regulated Prescription Drug
	Container Information	:	Vial
d)	Manufacturers Name&Address	:	Gland Pharma Limited
		:	Black-1, Phase-1
		:	VSEZ, Duvvada
		:	Visakhapatnam-530046
		:	Andhra Pradesh, India.
e)	Telephone Number for Info	:	+91-891-2747657

SECTION 2 – HAZARDS IDENTIFICATION

Carcinogenic List:

Substance	IARC	NTP	OSHA
Cremophor EL	Not Listed	Not Listed	Not Listed
Ethyl alcohol	Not Listed	Not Listed	Not Listed
Paclitaxel	Not Listed	Not Listed	Not Listed

Emergency Overview

Paclitaxel Injection, USP, contains paclitaxel, a taxane prepared semi-synthetically from a precursor derived from the needles of the European yew. Paclitaxel induces microtubule formation and stabilization of microtubules, thereby disrupting normal cell division. Clinically, paclitaxel is used to treat some types of cancers. In the workplace, this material should be considered a flammable liquid, cytotoxic, neurotoxic, a potential occupational reproductive hazard, harmful to the fetus, a potential human carcinogen, and potentially irritating to the skin, eyes, and respiratory tract. Following an accidental over-exposure, possible target organs may include the bone marrow, gastrointestinal system, peripheral nervous system, cardiovascular systems, liver, skin and the fetus.

Occupational Exposure Potential

There are scientific studies that suggest that personnel (e.g. nurses, pharmacists, etc.) who prepare and administer parenteral antineoplastics (e.g. in hospitals) may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these materials if workplace exposures are not properly controlled. The actual risk in the workplace is not known

Signs and Symptoms

During occupational use, this material should be considered irritating to the skin, eyes and respiratory

tract. In clinical use, adverse effects have included myelosuppression, nausea, vomiting and diarrhea, fatigue, hair loss, bardycardia and abnormal ECG, hepatotoxicity, peripheral neuropathy, hair loss, joint and muscle pain, and hypersensitivity reactions.

Medical Conditions Aggravated by Exposure

Pre-existing hypersensitivity to paclitaxel. Pre-existing bone marrow, blood, gastrointestinal, cardiovascular, peripheral nervous system, liver, or skin ailments; or pregnancy.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Paclitaxel
Chemical Formula $C_{47}H_{51}NO_{14}$
Preparation Hazardous ingredients present at less than 1% include citric acid.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Paclitaxel	~0.65	33069-62-4	DA8340700
Cremophor EL	~57	61791-12-6	GO5661000
Ethyl alcohol	~42	64-17-5	KQ6300000

SECTION 4 – FIRST AID MEASURES

Eye 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.

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

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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

Flammability

Flashpoint: 13.6oC (56.4oF).

Fire & Explosion Hazard	Flammable liquid. Keep away from flames, sparks, and other sources of ignition
Extinguishing media	As with any fire, use extinguishing media appropriate for primary cause of fire., For large fires, apply water from as far away as possible; use very large quantities of water applied as a mist or spray., For small fires, use water fog or fire extinguishing media suitable for Class B fires (e.g. dry chemical, carbon dioxide or foam).
Special Fire Fighting Procedures	Firefighters should wear self-contained breathing apparatus. Protective equipment and clothing should be worn to minimize contact with the respiratory tract, skin and eyes.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Isolate area around spill and remove all sources of ignition. Put on suitable protective clothing and equipment as specified by site spill procedures. 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). Dispose of materials according to the applicable federal, state, or local regulations.

SECTION 7 – HANDLING AND STORAGE

Handling	Paclitaxel is a cytotoxic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic antineoplastics agents to minimize potential exposures. Several guidelines on handling cytotoxic antineoplastic agents have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate. Consult your hygienist or safety professional for your site requirements. Avoid ingestion, inhalation, skin contact, and eye contact. If handling a powder, precautions may include the use of a containment cabinet during the weighing, reconstitution and/or solubilization of this antineoplastic agent. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials may be required when working with this material.
Storage	No special storage is required for hazard control. However, employees should be trained on the proper storage procedures for antineoplastic agents. For product

protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions

Persons with known hypersensitivities to paclitaxel, women who are pregnant, or women who want to become pregnant, should consult a health and/or safety professional prior to handling this material.

SECTION 8 – EXPOSURE CONTROLS/ PERSONAL PROTECTION

Respiratory protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols or vapors is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (P100 or equivalent) with an organic vapor cartridge is recommended under conditions where airborne aerosol or vapor concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required

Skin protection

When handling this material, disposable gloves should be worn at all times. Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to this material. Persons known to be allergic to latex rubber should select a non-latex glove. Gloves should be changed regularly, and removed immediately after known contamination. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.

Eye protection

As a minimum, the use of chemical safety goggles is recommended when handling this material.

Engineering Controls

When handling, local exhaust ventilation is recommended to minimize employee exposure. The use of an enclosure, such as an approved ventilated cabinet designed to minimize airborne exposures, is recommended.

SECTION 09 – PHYSICAL AND CHMICAL PROPERTIES

Appearance/Physical State Liquid

Color	Clear colorless to slightly yellow
Odor	Alcohol
Odor Threshold:	NA
pH:	NA
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range:	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	LEL 3.3% UEL 19% based on ethanol
Vapor Pressure:	NA
Vapor Density:	NA
Specific Gravity:	NA
Solubility:	The active ingredient, paclitaxel, has low solubility in water
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA
Decomposition temperature:	NA

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredients	Percent	Route	Test type	Value	Units	Species
Paclitaxel	100	Intravenous	LD50	85	mg/kg	Rat
Paclitaxel	100	Intravenous	LD50	12	mg/kg	Mouse
Paclitaxel	100	Intraperitoneal	LD50	32.5	mg/kg	Rat
Paclitaxel	100	Intraperitoneal	LD50	128	mg/kg	Mouse
Ethyl alcohol	100	Oral	LD50	3450 – 11,500	mg/kg	Guinea Pig, Rat, Mouse, Dog
Ethyl alcohol	100	Intravenous	LD50	1973	mg/kg	Mouse
Ethyl alcohol	100	Inhalation	LC50 (10h)	20,000	ppm	Rat
Ethyl alcohol	100	Inhalation	LD50 (4h)	39,000	mg/m3	Mouse
Cremophor EL	100	Oral	LD50	> 6400	mg/kg	Rat
Cremophor EL	100	Dermal	LD50	> 5000	mg/kg	Rat

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. Cremophor EL was non-irritating in a skin irritation study in rabbits. Ethanol may produce mild skin 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, redness and discomfort. Exposure to ethanol or Cremophor EL 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 urticaria have occurred in 2-4% of patients receiving paclitaxel. Cremophor EL was non-sensitizing in a sensitization study in guinea pigs.
Reproductive Effects	Administration of paclitaxel prior to and during mating impaired fertility in male and female rats at dosages 1 mg/kg/day. At this dosage, paclitaxel caused reduced fertility and reproductive indices, and increased embryo- and fetotoxicity. Administration of paclitaxel during the period of organogenesis to rabbits at a dosage of 3.0 mg/kg/day caused embryo- and fetotoxicity, as indicated by intrauterine mortality, increased resorptions, and increased fetal deaths. Maternal toxicity was also observed at this dose. 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". No adverse effects on fertility or fetal development were noted in studies in animals given Cremophor EL.
Mutagenicity	Paclitaxel was clastogenic in vitro (producing chromosome aberrations in human lymphocytes) and in vivo (micronucleus test in mice). Paclitaxel was not mutagenic in the Ames test or in the CHO/HGPRT gene mutation assay. No mutagenic effect was found in various tests with bacteria and mammalian cell culture with Cremophor EL; it was not mutagenic in studies with mammals.
Carcinogenicity	The carcinogenic potential of paclitaxel has not been fully evaluated in long-term studies in animals. Cremophor EL was not carcinogenic in chronic dietary studies in animals.
Target Organ Effects	This material 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

Aquatic Toxicity	Not determined for the product. Information for ingredients is provided below: LC50 > 0.74 mg/L in Daphnia for paclitaxel IC50 > 1000 mg/L for inhibition of respiration in activated sludge for paclitaxel. LC50(24 hr) = 12,900 - 15,300 mg/L in rainbow trout for ethanol LC50 (24 hr) = 11,200 mg/L in fingerling trout for ethanol LC50(48 hr) = 9,268 - 14,221 mg/L in Daphnia magna for ethanol EC50 = 9310 mg/L in Chlorella pyrenoidosa (green algae) for ethanol.
Persistence/Biodegradability	Not determined for the product. Information for ingredients is provided below: Paclitaxel undergoes anaerobic degradation. Ethanol was reported to be degraded between 45% and 74% in five days in two aqueous biodegradation assays.
Bioaccumulation	Not determined for the product. Information for ingredients is provided below: Because of its low octanol:water partition coefficient, ethanol is not anticipated to bioaccumulate.
Mobility in Soil	Not Applicable

SECTION 13 – DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements. Product is classified as hazardous waste (D001) based on flashpoint testing.
Container Handling and Disposal	Dispose of containers and unused contents in accordance with federal, state and local regulations.

SECTION 14 – TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:	Regulated
Proper Shipping Name:	Ethanol Solution
Hazard Class:	3
UN number:	UN1170
Packing group:	II
Reportable Quantity:	N/A
IMDG STATUS:	Regulated
Proper Shipping Name:	Ethanol Solution
Hazard Class:	3
UN number:	UN1170
Packing group:	II
Reportable Quantity:	N/A
ICAO/IATA STATUS:	Regulated
Proper Shipping Name:	Ethanol Solution
Hazard Class:	3
UN number:	UN1170

Packing group: II
Reportable Quantity: N/A
Transport Comments: None

Substance	TSCA Status	CERCLA	SARA 302	SARA 313	PROP 65
Cremophor EL	Listed	Not Listed	Not Listed	Not Listed	Not Listed
Ethyl Alcohol	Listed	Not Listed	Not Listed	Not Listed	Not Listed
Paclitaxel	Not Listed	Not Listed	Not Listed	Not Listed	Listed

RCRA Status Classified as D001 hazardous waste based on ignitability.

U.S. OSHA Classification Possible Carcinogen Target Organ Toxin Reproductive Toxin Flammable Liquid Possible Irritant

GHS Classification *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class Not Applicable
Hazard Category Not Applicable
Signal Word Not Applicable
Symbol Not Applicable
Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
Hazard Statement Not Applicable
Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.
Wash hands after handling.
Get medical attention if you feel unwell.

EU Classification*
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Paclitaxel .
Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable

SECTION 16 – OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for

product literature which may accompany the finished product.

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
DOT	Department of Transportation
EEL	Employee Exposure Limit
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not Applicable/Not available
NE	Not Established
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PROP65	California Proposition 65
RCRA	Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted