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Product Name	Paclitaxel Injection USP 30 mg/5 mL, 100 mg/16.7 mL & 300 mg/50 mL (6 mg/mL)	

1. Identification of the substance/mixture and the company/undertaking

Product Name: Paclitaxel Injection USP 30 mg/5 mL, 100 mg/16.7 mL & 300 mg/50 mL (6 mg/mL)

Chemical Family: Mixture

Intended use: pharmaceutical product used as Antineoplastic drug

Details of the manufacturer:

MSN Laboratories Private Limited.

Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324

Nandigama Village & Mandal

Ranga Reddy Dist

Telangana State, India.

PIN 509228

Phone: +91 40 3044 9200

2. Hazards Identification

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 2

Reproductive Toxicity: Category 1B

Flammable liquids- Category 2

Label Elements

Signal Word: 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

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P405 - Store locked up

P501 - Dispose of contents/container in accordance with all local and national regulations

CLP/GHS hazard pictogram

Other Hazards No data available



Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. Composition/Information on Ingredients

C.A.S. No : 33069-62-4

Molecular Formula : C₄₇H₅₁NO₁₄

Molecular Weight : 853.9

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

Ingredient	CAS Number	EU EINECS	GHS Classification
Paclitaxel	33069-62-4	Not listed	Repr. 1B (H360FD) Mut. 2 (H341)
Dehydrated alcohol	64-17-5	200-578-6	Flam. Liq. 2 (H225)
Citric acid, anhydrous	77-92-9	201-069-1	Not listed
Polyoxyl 35 castor oil (Kolliphor®ELP)	61791-12-6	Not listed	Not listed

4. First Aid Measures

Immediate Medical Attention Needed : Yes

Eye contact

- If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water

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for at least 15 minutes.

If irritation occurs or persists, notify medical personnel and supervisor.

Skin contact

- Wash exposed area with soap and water and remove contaminated clothing/shoes.

If irritation occurs or persists, notify medical personnel and supervisor.

Inhalation

- Immediately move exposed subject to fresh air. If not breathing, give artificial respiration.

If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

Ingestion

- Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel.

Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

5. Fire Fighting Measures

Extinguishing media : Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

Specific hazards arising from the substance or mixture : No information identified. May emit toxic fumes of carbon monoxide, carbon dioxide, and oxides of nitrogen.

Flammability/Explosivity : Not considered to be a fire hazard. No explosivity data available. High concentrations of finely divided airborne organic particles can potentially explode if ignited.

Advice for firefighters : Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

6. Accidental Release Measures

Personal precautions - If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe dust

Environmental protection - Do not empty into drains. Avoid release to the environment.

Methods for cleaning up - DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations. Decontaminate the area twice.

7. Handling and Storage

Precautions for safe handling ; Follow recommendations for handling potent cytotoxic pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid breathing dust. Wash thoroughly after handling

Storage : As per pack insert.

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8. Exposure Controls/Personal Protection

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.

Personal Protective Equipment: Hands: Rubber gloves

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit

Hygiene measures: Wash skin thoroughly with soap and water.

9. Physical and Chemical Properties

Color: A clear colorless to slightly yellow viscous solution free from visible particulate matter

10. Stability and Reactivity

Reactivity : No information identified.

Chemical stability : Rapid decomposition in neutral or alkaline solutions; pharmacological stability not guaranteed beyond expiration date imprinted on package.

Possibility of hazardous reactions : Not expected to occur.

Conditions to avoid : Avoid extreme temperatures. Avoid direct sunlight.

Incompatible materials : No information identified.

Hazardous decomposition products : No information identified

11. Toxicological Information

COMPONENT	TYPE	ROUTE	SPECIES	DOSAGE
Paclitaxel	LD50	Intravenous	Mouse	12 mg/kg
Paclitaxel	LD50	Intraperitoneal	Mouse	128 mg/kg

Germ cell mutagenicity

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

no data available

Teratogenicity

no data available

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Specific target organ toxicity - single exposure (Globally Harmonized System)

no data available

Specific target organ toxicity - repeated exposure (Globally Harmonized System)

no data available

Aspiration hazard

no data available

Potential health effects

Inhalation May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion May be harmful if swallowed.

Skin May be harmful if absorbed through skin. May cause skin irritation.

Eyes May cause eye irritation.

Synergistic effects

no data available

Additional Information

RTECS: Not available

12. Ecological Information

[Aquatic Toxicity]

No information is available about the potential of this product to produce adverse environmental effects.

Results of PBT and vPvB assessment

Not performed.

13. Disposal Considerations

Waste from residues

- Observe local/national regulations regarding waste disposal
- Incinerate in qualified installation with flue gas scrubbing
- DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

14. Transport Information

Hazard Class : Not regulated.

UN Number : Not assigned.

15. Regulatory Information

Hazard Class: N/A

Identification Number: N/A

Packing Group: N/A

Label: N/A

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Emergency Response Guide Book: N/A

Special precautions for users: N/D

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.