


# MATERIAL SAFETY DATA SHEET

(according to Regulation 1272/2008/EC)



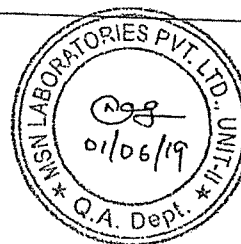
1. IDENTIFICATION OF THE SUBSTANCE AND OF THE SUPPLIER	
Product name	Paclitaxel
Product use	Anti neoplastic agent
Manufacturer's name	MSN Laboratories Limited Unit -II
Address	Sy. No.50, Kardanur (V), Patancheru (M), Medak (Dist), Andhra Pradesh, India. Pin: 502300
Emergency phone no.	+91-9290311494
Fax number	-----

2. HAZARDS IDENTIFICATION	
Classification of the substance : According to Regulation (EC) No1272/2008: Acute toxicity, Oral (Category 3) According to European Directive 67/548/EEC as amended: Toxic if swallowed.	
	
GHS Pictogram:	
Signal Word	Warning
Hazard Statement:	
H301	Harmful if swallowed
H311	Harmful in contact with skin
H331	Toxic if inhaled
H341	Suspected of causing genetic defects
Precautionary Statements:	
P201	Obtain special instructions before use
P202	Do not handle until all safety precautions have been read and understood
P260	Do not breathe dust/fume/gas/mist/vapours/spray
P264	Wash....thoroughly after handling
P270	Do not eat, drink or smoke when using this product
P281	Use personal protective equipment as required

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Other hazards : None

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

Synonyms	5 $\beta$ ,20-Epoxy-1,2 $\alpha$ ,4,7 $\beta$ ,10 $\beta$ ,13 $\alpha$ -hexahydroxytax-11-en-9-one 4,10-diacetate 2-benzoate, 13-ester with (2R,3S)-N-benzoyl-3-phenylisoserine			
Molecular Formula	C <sub>47</sub> H <sub>51</sub> NO <sub>14</sub>			
Molecular Weight	853.9			
CAS. No	EC. No	Index. No	Classification	Concentration
33069-62-4	1272/2008	--	H301, T-Toxic, H341, R46.	98 – 100%

For the full text of the H-Statements and R and S -Phrases mentioned in this Section, see Section 16

## 4. FIRST-AID MEASURES

If Inhaled	Remove to fresh air. If breathing is irregular or stopped, administer artificial respiration. Call a physician immediately
In case of skin contact	Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention. If skin irritation persists, call a physician
In case of eye contact	In case of eye contact, rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention
If swallowed	IF SWALLOWED: Immediately call a POISON CENTRE or doctor /physician. Rinsemouth
Note to Physicians	Material is cytotoxic anticancer drug. This product has been reported to interact with the following medications: cisplatin, other chemotherapy drugs, radiation treatment to the lung. Possible risk of harm to the unborn child. Pregnant or nursing women should avoid exposure

## 5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Carbon dioxide, dry chemical powder. Water spray. Avoid spill into drains, surface and groundwater and soil.
Special protective equipment:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

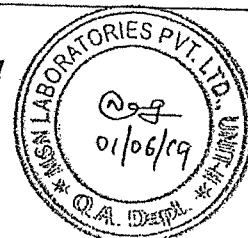
## 6. ACCIDENTAL RELEASE MEASURES

Personal precautions:

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Use personal protective equipment. Examples include tightly fitting safety goggles, disposable lab coat of low permeability with cuffs, double gloves and shoe covers. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.

### **Environmental precautions:**

Prevent further leakage or spillage. Do not let product enter into drains.

### **Methods and materials for containment :**

Wet down any dust to prevent generation of aerosols, if appropriate. Cover with suitable material

### **Cleanup Methods :**

Spill prevention procedures and a spill response procedure should be implemented. Wipe up with absorbent towels or other absorbent material, as appropriate. Place collected material into a suitable container for disposal or reclamation. 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% 1N 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. After spill clean-up and decontamination is complete, flush with water to process sewer, if allowable under national, state or local permits or regulations. Product is classified as hazardous waste. It is recommended that diluted solutions and contaminated material also be treated as a hazardous cytotoxic material.

## **7. HANDLING AND STORAGE**

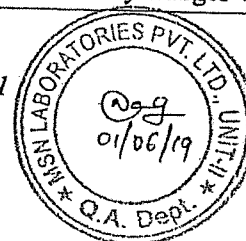
### **Precautions for safe handling:**

Highly potent material. Avoid formation of dust and aerosols. Avoid exposure obtain special instructions before use. Use of inert gas should be considered for process conditions to minimize the risk of ignition. Keep away from heat and sources of ignition. Prevent release to drains and waterways. Minimize dust generation and accumulation. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when

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subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

### **Container requirements:**

Store in polyethylene-lined metallic containers Provide anti-static bags where drum liners are used. Store in airtight containers.

### **Conditions for safe storage:**

Preserve in tight, light-resistant containers. Store at controlled room temperature.

## **8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

### **Personal protective equipment:**

Glasses, Gloves, Respirator, Particulate etc

### **Respiratory protection:**

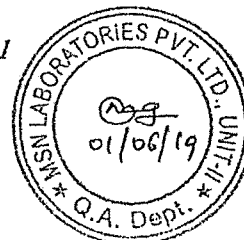
Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient to control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges when exposures are up to 10 times the exposure control guideline. Wear a loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator (PAPR) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters when exposures are 25-50 times the exposure control guideline. Wear a tight-fitting, full facepiece HEPA PAPR when exposures are 50-100 times the exposure control guideline. Wear a hoodshroud HEPA PAPR or full facepiece supplied air respirator operated in a pressure demand or other positive pressure mode when exposures are 100-1000 times the exposure control guideline..

### **Hand protection:**

Wear gloves at all times when handling containers, including when unpacking, inspecting or transporting within a facility. When handling >25 grams wear double gloves (EN 420, EN 374).

### **Eye protection:**

Safety glasses with side-shields are recommended (EN 166). Face shields or chemical safety goggles



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(EN 166) may be required if splash potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected..

### **Skin and body protection:**

Wear a laboratory coat(EN 340) when handling quantities up to 25 grams. For quantities from 25- 100 grams: wear disposable labcoat or coverall of low permeability (EN 1149-1); disposable wrist gauntlets/sleeves unless working in glove box. For quantities over 100 grams and manufacturing operations, wear disposable coverall of low permeability; disposable shoe covers; and, disposable wrist gauntlets/sleeves unless working in glove box. For quantities over 100 grams and manufacturing operations, gloves and booties should be taped to protective clothing to prevent gaps in PPE and air supplied full-body suits (EN 1073) may be required as associated with advanced respiratory protection. For manufacturing operations, air supplied full-body suits may be required as associated with advanced respiratory protection.

### **Hygiene measures:**

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

<b>Appearance:</b>	White to almost white crystalline powder
<b>pH:</b>	No Data available
<b>Melting point:</b>	---
<b>Boiling point:</b>	No Data available
<b>Flash point:</b>	No Data available
<b>Ignition temperature:</b>	No Data available
<b>Lower explosion limit:</b>	No Data available
<b>Upper explosion limit:</b>	No Data available
<b>Water solubility:</b>	Practically insoluble in water

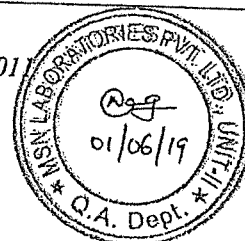
## **10. STABILITY AND REACTIVITY**

<b>Chemical stability:</b>	Stable under recommended storage conditions
<b>Conditions to avoid:</b>	No data available

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Materials to avoid:	Oxidizing agents, acids and bases. Do not use with PVC materials
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions. Carbon oxides, nitrogen oxides (NOx)

### 11. TOXICOLOGICAL INFORMATION

**Acute toxicity:**

LD50 Oral - rat – 400 mg/kg

**Skin corrosion/irritation:**

Mildly irritating to skin

**Serious eye damage/eye irritation:**

Mildly irritating to eyes

**Respiratory or skin sensitization:**

Mildly irritating to respiratory tract

**Sensitization:**

Not a dermal sensitizer.

**Carcinogenicity:**

Not available

**Mutagenicity and clastogenicity:**

Paclitaxel can cause for chromosome damage in vivo and in vitro. Paclitaxel has been shown to be clastogenic *in vitro* (chromosome aberrations in human lymphocytes) and *in vivo*.

**Reproductive toxicology & Teratology:**

Paclitaxel is caused to reduce the fertility and reproductive indices, and increased embryo and fetotoxicity. Therefore, Paclitaxel is a teratogenic substance.

**Specific target organ toxicity - single exposure:**

No Data available

**Specific target organ toxicity - repeated exposure:**

bone marrow, cardiovascular system, peripheral nervous system, gastrointestinal tract, skin, male reproductive organs.

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**Aspiration hazard:**  
No data available

**Potential health effects:**  
**Inhalation:** Toxic if inhaled. causes mild respiratory tract irritation.  
**Ingestion:** Toxic if swallowed  
**Skin:** Toxic absorbed through skin. Causes mild skin irritation.  
**Eyes:** causes mild eye irritation.

**Additional Information**  
RTECS: WX1272100

**12. ECOLOGICAL INFORMATION**

**Toxicity**  
Acute Toxicity to Aquatic Invertebrates and toxic to microorganisms

**Persistence and degradability**  
Ready biodegradation (28 Days) : Readily biodegradable - rapidly biodegradable in the environment

**Bio accumulative potential**  
No data available

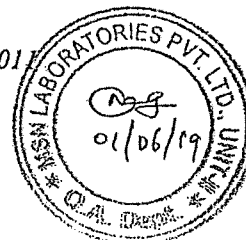
**Mobility in soil**  
No data available

**PBT and vPvB assessment**  
No data available

**Other adverse effects**  
No data available

**13. DISPOSAL CONSIDERATIONS**

**Product:**  
Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent



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and burn in a chemical incinerator equipped with an afterburner and scrubber.  
Contaminated packaging: Dispose of as unused product.

**14. TRANSPORT INFORMATION**

NOT REGULATED AS PER IATA

**15. REGULATORY INFORMATION**

This safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008.

**16. OTHER INFORMATION**

**Text of H-code(s) and R-phrase(s) mentioned in Section 3**

H301 : Toxic if swallowed

H311 : Toxic in contact with skin

H331 : Toxic if inhaled

H341 : Suspected of causing genetic defects

H360 : May damage fertility or the unborn child

H370 : Causes damage to organs

R23/24/25: Toxic by inhalation, in contact with skin and if swallowed

R46 : May cause heritable genetic damage.

R48 : Danger of serious damage to health by prolonged exposure.

R60 : May impair fertility.

R61 : May cause harm to the unborn child.

S22: Do not breathe dust.

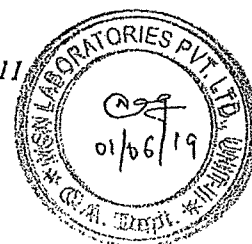
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

S38: In case of insufficient ventilation, wear suitable respiratory equipment.

S45: In case of accident or if you feel unwell, seek medical advice immediately

S53: Avoid exposure - obtain special instructions before use.

S60: This material and its container must be disposed of as hazardous waste.





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**Notice:** The information and recommendations in this safety data sheet are to the best of our knowledge, accurate at the date of issue. Nothing herein shall be deemed to create any warranty expressed or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material for any particular purpose.

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