

SAFETY DATA SHEET

Docetaxel Injection, USP 20 mg/mL, 80 mg/4 mL and 160 mg/8 mL

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Docetaxel Injection, USP 20 mg/mL, 80 mg/4 mL and 160 mg/8 mL

Trade Name: Docetaxel Injection, USP 20 mg/mL, 80 mg/4 mL and 160 mg/8 mL

Chemical Family: Not determined.

Intended Use: Pharmaceutical product used as Antineoplastic.

Manufacturer Name and Address

Amneal Oncology Pvt. Ltd.,
TSIIC-SEZ, Plot No. S-3, S-4, S-5A,
Polepally (Vil.), Jadcherla (Mdl.),
Mahabubnagar (Dist.),
Telangana, India, Pin - 509301
Emergency Telephone number: +91-8542-302000

2. HAZARDS IDENTIFICATION

Appearance: Pale yellow to brownish - yellow solution

Signal Word: DANGER

Statement of Hazard: May cause harm to breastfed babies.
Suspected of causing genetic defects
Flammable liquid and vapour.
Suspected of damaging the unborn child.

EU Indication of danger: Mutagenic : Category 3
Reproductive Toxicity : Category 1
Irritant

EU Hazard Symbols:



EU Risk Phrases:

R25 - Toxic if swallowed.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.

SAFETY DATA SHEET

Docetaxel Injection, USP 20 mg/mL, 80 mg/4 mL and 160 mg/8 mL

R61 - May cause harm to the unborn child.

POTENTIAL HEALTH HAZARDS

Eye: Irritating to the eyes in the event of an inadvertent splash.

Skin: Not irritating to the skin but may be absorbed and made available systemically.

Ingestion: Moderately toxic if inadvertently ingested.

Inhalation: Compound is supplied in solution and therefore this is not an expected route of exposure under normal conditions.

Chronic Effects: If the compound is bioavailable via the route of exposure and exposure occurs for prolonged periods of time, potential adverse effects include neurotoxicity, myelosuppression, leucopenia, necrosis of the intestinal epithelium, testicular atrophy and lymphoid organ depletion.

The compound was negative in the Ames test but positive in other genotoxicity assays. The Guinea-Pig Anaphylaxis assay was negative.

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	Qty./Unit 20 mg/ml (1 ml fill)	Qty./Unit 20 mg/ml (4 ml fill)	Qty./Unit 20 mg/ml (8 ml fill)
Docetaxel	148408-66-6	Not Listed	Repr.Cat.1; R61 Mut.Cat.3; R68, R64 Xi; R36	20 mg	80 mg	160 mg
Polysorbate 80 NF/Ph. Eur	9005-65-6	-	-	0.54 mg	2.16 mg	4.32 mg
Ethanol absolute (Dehydrate alcohol)	64-17-5	200-578-6	F; R11	0.395g	1.58 g	3.16 g

SAFETY DATA SHEET**Docetaxel Injection, USP 20 mg/mL (1mL fill, 4mL fill, 8mL fill)**

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES**Eye Contact:**

Immediately flush eyes thoroughly with water for at least 15 minutes; Seek immediate medical assistance and notify supervisor.

Skin Contact:

Remove all contaminated clothing and rinse area thoroughly with soap and water for 15 minutes; Seek immediate medical assistance and notify supervisor. Seek medical attention.

Ingestion:

Seek immediate medical assistance. Do not induce vomiting, give liquids, or use any other method to remove poison unless advised by physician or Poison Control.

Inhalation:

Remove from exposure source; notify medical personnel and supervisor if breathing difficulties develop. Administer artificial respiration if necessary.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash Point, 50% ethanol: 75° F (24° C).

Flammable Limits: Lower flammable limit: (pure ethanol) 3.3%

Upper flammable limit: (pure ethanol) 19%

Autoignition Temperature: (pure ethanol) 786° F (419° C).

Hazardous Combustion Products: CO, CO₂ and oxides of nitrogen may be generated in a fire.

Extinguishing Media: Packaging material fires may be extinguished with water, carbon dioxide, or dry chemical.

Firefighting Instructions: Firefighting in confined spaces requires full protective gear and supplied air respiratory protection.

6. ACCIDENTAL RELEASE MEASURES**Health and Safety Precautions:**

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

Measures for Cleaning/Collecting:

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

SAFETY DATA SHEET

Docetaxel Injection, USP 20 mg/mL (1mL fill, 4mL fill, 8mL fill)

Measures for Environmental Protections:

Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:

Flammable liquid and vapour- keep away from ignition sources and clean up spills promptly. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin, and clothing. Use appropriate personal protective equipment. Wash thoroughly after handling. Avoid breathing vapour or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions:

Store between 36 and 77° F (2 and 25°C). Retain in the original package to protect from bright light.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits: An 8-hour TWA exposure limit of 1 mcg/m³ to Docetaxel, For Ethanol, the OSHA 8-hour TWA is 1000 ppm.

Ethyl alcohol (ethanol)

ACGIH Threshold Limit Value (STEL):	1000 ppm
Australia TWA	1000 ppm, 1880 mg/m ³

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use Process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. All operations should be fully enclosed. No air recirculation permitted.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community Environmental legislation.

Page 4 of 9

SAFETY DATA SHEET**Docetaxel Injection, USP 20 mg/mL (1mL fill, 4mL fill, 8mL fill)****Personal Protective Equipment:**

Refer to applicable national standards and regulations in the selection and use of Personal Protective Equipment (PPE).

Hands: Wear impervious, disposable gloves as minimum protection (double recommended).

Eyes: Safety glasses recommended. Full-face protection recommended for spill cleanup if potential exists for splashing.

Skin: Wear impervious disposable protective clothing when handling this compound. Solvex nitrile NBR gloves are recommended if potential exists for significant hand/wrist exposure. Latex gloves will offer temporary protection from small splashes but should be changed immediately if vomiting splash occurs.

Respiratory protection: Whenever excessive air contamination (dust, mist, vapour) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling point: (For pure ethanol) 78.5 C

Vapor Pressure: (For pure ethanol) 40 mm Hg @ 19 C

Vapor Density: (For pure ethanol) 1.59

Specific Gravity: 0.95

pH: Approximately neutral (6.5 at 250 g/l in water)

Odor: Characteristic alcohol odor.

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Incompatibility: Direct light and heat.

Hazardous Polymerization: Will not occur.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Docetaxel: >2000 mg/kg p.o. rat LD50. Moderately toxic by ingestion. Sub-chronic animal bioassays indicate potential for neurotoxicity, myelosuppression, leukopenia, necrosis of the intestinal epithelium, testicular atrophy and lymphoid organ depletion.

SAFETY DATA SHEET

Docetaxel Injection, USP 20 mg/mL (1mL fill, 4mL fill, 8mL fill)

Ethanol: 20,000 ppm/10 hrs inhalation-rat LC50; 2000 mg/kg oral-child LDLo. Slightly toxic by inhalation and ingestion. Central nervous system depressant; hepatotoxin.

Acute Toxicity: (Species, Route, End Point, Dose)

The following data describe the active ingredient,

Docetaxel anhydrous

Rat	Oral	LD50	> 2000 mg/kg
Mouse	IV	LD50	138 mg/kg

Citric acid, anhydrous

Rat	Oral	LD50	3000 mg/kg
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Polysorbate 80

Rat	Intravenous	LD 50	1790 mg/kg
Mouse	Oral	LD 50	25 g/kg

Ethyl alcohol (ethanol)

Mouse	Oral	LD50	3450 mg/kg
Rat	Oral	LD50	7060 mg/kg
Rat	Inhalation	LC50 10h	20,000 ppm

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result):

Docetaxel anhydrous

Daphnia magna (Water Flea)	LC50/ 48 Hours	> 3.3 mg/L
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Ethyl alcohol (ethanol)

Oncorhynchus mykiss (Rainbow Trout)	LC50/ 96h	12,900-15,300 mg/L
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Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable

No data for the finished product. Based upon water solubility and Log P value (octanol/water partition coefficient) of 3.2, the active ingredient docetaxel should partition to the aquatic compartment fairly exclusively.

SAFETY DATA SHEET**Docetaxel Injection, USP 20 mg/mL (1mL fill, 4mL fill, 8mL fill)****13. DISPOSAL CONSIDERATIONS****Waste Treatment Methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. It should be disposed of as a RCRA characteristic waste (D001). Waste must be disposed of in accordance with all federal, state, and local regulations. Incineration is the preferred method

14. TRANSPORT INFORMATION

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

US DOT (49 CFR): UN1170, Ethanol solutions, III

IATA: UN1170, Ethanol solution, 3, III

IMDG: UN1170, Ethanol solution, 3, III

UN proper shipping name: Ethanol solution

Transport hazard class (es): 3

Packing group: III

Flash Point (°C): 24

15. REGULATORY INFORMATION

EU Symbol: T

EU Indication of danger: Toxic to reproduction: Category 1
Mutagenic: Category 3
Irritant

SAFETY DATA SHEET**Docetaxel Injection, USP 20 mg/mL (1mL fill, 4mL fill, 8mL fill)****EU Risk Phrases:**

R10 - Flammable.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.
R64 - May cause harm to breastfed babies

EU Safety Phrases:

S22 - Do not breathe dust.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

DANGER
Flammable liquid and vapour.
Suspected of causing genetic defects.
May damage fertility or the unborn child.
May cause harm to breastfed babies.

Canada - WHMIS: Classifications

WHMIS hazard class: Class D, Division 2, Subdivision A
Class D, Division 2, Subdivision B

16. OTHER INFORMATION**Text of R phrases**

Abbreviations from Sections 2, 3 and 15

R22 - Harmful if swallowed

R36/37/28 - Irritating to eyes, respiratory system and skin

R45 - May cause cancer

R61 - May cause harm to the unborn child.

R64 - May cause harm to breastfed babies.

R68 - Possible risks of irreversible effects.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.**Reasons for Revision:** Updated Section 14 - Transport Information.**Prepared by:** Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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Page 8 of 9

SAFETY DATA SHEET**Docetaxel Injection, USP 20 mg/mL (1mL fill, 4mL fill, 8mL fill)**

Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage, and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Amneal be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential, or exemplary damages, howsoever arising, even if Amneal has been advised of the possibility of such damages.