



## MATERIAL SAFETY DATA SHEET

**Product Name: Docetaxel Hospira 10 mg/ml Concentrate for Solution for Infusion**

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

<b>Manufacturer Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Zybus Hospira Oncology Private Limited Plot-3, Pharmez "Special Economic Zone" Sarkhej - Bawla highway (NH No 8A) Ahmedabad - 382 213 Gujarat, India
<b>Emergency Telephone Hospira, Inc., Non-Emergency</b>	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887 224 212-2055	
<b>Product Name</b>	Docetaxel Hospira 10 mg/ml Concentrate for Solution for Infusion	
<b>Synonyms</b>	(2R,3S)-N-carboxy-3-phenylisoserine,N- <i>tert</i> -butyl ester, 13-ester with 5b-20-epoxy-1,2a,4,7b,10b,13a-hexahydroxytax-11-en-9-one 4-acetate 2-benzoate, trihydrate; Taxotere <sup>®</sup> .	

### 2. HAZARD INFORMATION / CLASSIFICATION

<b>Emergency Overview</b>	Docetaxel Hospira 10 mg/ml Concentrate for Solution for Infusion is a solution containing docetaxel, a semisynthetic taxane similar to paclitaxel. Docetaxel induces microtubule formation and stabilization of microtubules, thereby disrupting normal cell division in the G <sub>2</sub> and M phases of the cell cycle. Clinically, docetaxel is used to treat some types of cancers. It is cytotoxic and neurotoxic. The formulated product is a flammable liquid. In the workplace, this product also should be considered a potential occupational reproductive hazard, harmful to the fetus, and a potential human carcinogen. Following an accidental over-exposure, possible target organs may include the bone marrow, gastrointestinal system, peripheral nervous system, cardiovascular system, liver, testes, skin and the fetus.		
<b>Occupational Exposure Potential</b>	Information on the absorption of this product via inhalation or skin contact is not available. 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. Avoid liquid aerosol generation and skin contact. Avoid sparks, flames, and other sources of ignition when working with open containers.		
<b>Signs and Symptoms</b>	During occupational use, this material should be considered irritating to the skin, eyes and respiratory tract. In clinical use, adverse effects have included myelosuppression, fever, edema, fatigue, nausea, vomiting and diarrhea, hypotension and abnormal ECG, hepatotoxicity, peripheral neuropathy, hair loss, skin reactions, joint and muscle pain, and hypersensitivity reactions.		
<b>Medical Conditions Aggravated by Exposure</b>	Pre-existing hypersensitivity to docetaxel or other taxanes. Pre-existing bone marrow, blood, gastrointestinal, cardiovascular, peripheral nervous system, liver, testes, or skin ailments; or pregnancy.		
<b>Carcinogen Lists:</b>	<b>IARC:</b> Not listed	<b>NTP:</b> Not listed	<b>OSHA:</b> Not listed

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Ingredient Name** Docetaxel Anhydrous  
**Chemical Formula** C<sub>43</sub>H<sub>53</sub>NO<sub>14</sub>

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Docetaxel Anhydrous	1	114977-28-5	DA4172750
Ethyl Alcohol	18	64-17-5	KQ6300000
PEG 300	55	25322-68-3	TQ3630000
Polysorbate 80	26	9005-65-6	WG2932500

Hazardous ingredients present at less than 1% include citric acid.

### 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.

### 5. FIRE FIGHTING MEASURES

**Flammability** Flashpoint 61°F.

**Fire & Explosion Hazard** Flammable liquid and vapor. Keep away from flames, sparks, and other sources of ignition. This product will burn in a fire. Vapors may form an explosive mixture with air. In the event of a large spill, the vapors are heavier than air, and may travel along the ground or be moved by ventilation and ignited by heat or other flames/ignition. Containers may explode in the heat of a fire.

**Extinguishing Media** As with any fire, use extinguishing media appropriate for primary cause of fire. For small fires, use water fog or fire extinguishing media suitable for Class B fires (e.g. dry chemical, carbon dioxide or foam). For large fires, apply water from as far away as possible; use very large quantities of water applied as a mist or spray.

**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.

### 6. ACCIDENTAL RELEASE MEASURES

**Spill Cleanup and Disposal** Isolate the area around spill and remove all sources of ignition. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable inert 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 docetaxel. Use care to avoid splashing when applying the bleach solution. Absorb the liquid with an inert absorbent material (e.g. absorbent pad). Clean again with soap and water. Dispose of spill materials according to applicable federal, state, or local regulations.

**7. HANDLING AND STORAGE**

**Handling** Docetaxel is a cytotoxic anti-neoplastic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic anti-neoplastics agents to minimize potential exposures. Several guidelines on handling cytotoxic anti-neoplastic 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. When handling, precautions may include the use of a containment cabinet during the weighing, reconstitution and/or solubilization of this anti-neoplastic agent. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials is recommended 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 anti-neoplastic agents. For product protection, follow temperature storage recommendations noted on the product case label, the primary container label, or the product insert. Do not freeze and protect from light (keep in original outer carton).

**Special Precautions** Persons with known hypersensitivities to docetaxel or other taxanes, women who are pregnant, or women who want to become pregnant, should consult a health and/or safety professional prior to handling open containers of this material.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Exposure Guidelines**

Component	Exposure limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Docetaxel	8-hr TWA: Not established	8-hr TWA: Not established	8-hr TWA: Not Established	8-hr TWA: Not Established
Ethyl Alcohol	8 hr TWA: 1000 ppm; 1900 mg/m3	8 hr TWA: 1000 ppm	8-hr TWA: Not Established	8-hr TWA: Not Established
Polysorbate 80	8 hr TWA: Not established	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established
PEG 300	8 hr TWA: Not established	8 hr TWA: Not Established	8 hr TWA: 10 mg/m3	8 hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
 EEL: Employee Exposure Limit.  
 TWA: 8-hour Time Weighted Average.  
 STEL: 15-minute Short Term Exposure Limit.

**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.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION: continued**

<b>Eye Protection</b>	As a minimum, the use of chemical safety goggles is recommended when handling this material.
<b>Engineering Controls</b>	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 also recommended.

**9. PHYSICAL/CHEMICAL PROPERTIES**

<b>Appearance/Physical State</b>	Docetaxel is white to almost-white powder. Docetaxel Hospira 10 mg/ml Concentrate for Solution for Infusion is a clear colorless to pale yellow solution, practically free from visible particles.
<b>Odor</b>	NA
<b>Odor Threshold:</b>	NA
<b>pH:</b>	NA
<b>Melting point/Freezing point:</b>	NA
<b>Initial Boiling Point/Boiling Point Range</b>	NA
<b>Flash Point:</b>	NA
<b>Evaporation Rate:</b>	NA
<b>Flammability (solid, gas):</b>	NA
<b>Upper/Lower Flammability or Explosive Limits:</b>	LEL: 3.3% based on ethanol UEL: 19% based on ethanol
<b>Vapor Pressure</b>	NA
<b>Vapor Density (Air =1)</b>	NA
<b>Evaporation Rate</b>	NA
<b>Specific Gravity</b>	NA
<b>Solubility</b>	Soluble in water at approximately 0.1 mg/ml.
<b>Partition coefficient: n-octanol/water:</b>	NA
<b>Auto-ignition temperature</b>	NA
<b>Decomposition temperature</b>	NA

**10. STABILITY AND REACTIVITY**

<b>Reactivity</b>	NA
<b>Chemical Stability</b>	Consult package insert for product stability information.
<b>Hazardous Reactions</b>	NA
<b>Conditions to avoid</b>	Heat, flames, sparks or other sources of ignition.
<b>Incompatibilities</b>	Not determined
<b>Hazardous Decomposition Products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).
<b>Hazardous Polymerization</b>	Not anticipated to occur with this material.

## 11. TOXICOLOGICAL INFORMATION

### Acute Toxicity

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
*Taxotere for Injection	4	LD50	Oral	>2000	mg/kg	Rat
Docetaxel (anhydrous)	100	LD50	Intravenous	156	mg/kg	Mouse
Docetaxel (anhydrous)	100	LDLo	Intravenous	> 20	mg/kg	Rat
Docetaxel (anhydrous)	100	LD50	Intravenous	2.5	mg/kg	Dog
PEG 300	100	LD50	Oral	27,500, 31,000 17,300 19,600	mg/kg mg/kg mg/kg	Rat Rabbit Guinea Pig
PEG 300	100	LD50	Dermal	>20,000	mg/kg	Rabbit
Polysorbate 80	100	LD50	Oral	~36,570 25,000	mg/kg mg/kg	Rat Mouse
Polysorbate 80	100	LD50	Intravenous	1790 1790	mg/kg mg/kg	Rat 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

LD50 is the dosage producing 50% mortality.

\*Sanofi Aventis MSDS

- 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. However, inadvertent skin contact with this product may produce mild irritation with redness and discomfort. Ethanol may produce mild skin irritation with redness and dryness.
- Ocular Irritation/Corrosion** None anticipated from normal handling of this product. However, inadvertent eye contact of this product with eyes may produce irritation with stinging with redness, watering, and discomfort. Exposure to ethanol has produced severe eye irritation in studies in animals.
- Dermal or Respiratory Sensitization** None anticipated from normal handling of this product. However, in clinical use, severe hypersensitivity reactions, characterized by hypotension and/or bronchospasm, or generalized rash/erythema, have occurred in about 2% of pre-medicated patients. The incidence of hypersensitivity reactions is higher in patients without pre-medication.
- Reproductive Effects** \*Docetaxel did not impair fertility in rats when administered in multiple intravenous dosages of up to 0.3 mg/kg, but decreased testicular weights were reported. Similarly, in a 10-cycle toxicity study in rats and dogs (dosing once every 21 days for 6 months), testicular atrophy or degeneration were observed at intravenous dosages of 5 mg/kg in rats and 0.375 mg/kg in dogs.
- In other studies in both rats and rabbits, administration of docetaxel at dosages  $\geq 0.3$  and 0.03 mg/kg/day, respectively, during the period of organogenesis, produced embryotoxicity and fetotoxicity (as characterized by intrauterine mortality, increased resorption, reduced fetal weight, and fetal ossification delay). These dosages also caused maternal toxicity.

Chronic prenatal exposure to ethanol has been associated with a distinct pattern of congenital malformations that have collectively been termed the "fetal alcohol syndrome".

## 11. TOXICOLOGICAL INFORMATION:continued

<b>Mutagenicity</b>	*Docetaxel was clastogenic in an <i>in vitro</i> chromosome aberration assay in CHO-K <sub>1</sub> cells, and in an <i>in vivo</i> micronucleus test in the mouse, but it did not induce mutagenicity in the Ames test or the CHO/HGPRT gene mutation assays.
<b>Carcinogenicity</b>	*Long term studies in animals to assess the carcinogenic potential of docetaxel have not been conducted.
<b>Target Organ Effects</b>	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, testes and the fetus.

\*Abstracted from the Taxotere® Package Insert

## 12. ECOLOGICAL INFORMATION

<b>Aquatic Toxicity</b>	Not determined for product  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
<b>Persistence/ Biodegradability</b>	Not determined for product.  Ethanol was reported to be degraded between 45% and 74% in five days in two aqueous biodegradation assays.
<b>Bioaccumulation</b>	Not determined for product.  Because of its low octanol:water partition coefficient, ethanol is not anticipated to bioaccumulate.
<b>Mobility in Soil</b>	Not determined for product.

Notes:

1. LC50: Concentration in water that produces 50% mortality.
2. EC50: Concentration in water that produces 50% inhibition of growth in algae.

## 13. DISPOSAL CONSIDERATIONS

<b>Waste Disposal</b>	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 ignitability.
<b>Container Handling and Disposal</b>	Dispose of containers and unused contents in accordance with federal, state and local regulations.



#### 14. TRANSPORTATION INFORMATION

**DOT STATUS:** Regulated  
**Proper Shipping Name:** Ethanol solution  
**Hazard Class:** 3  
**UN Number:** UN 1170  
**Packing Group:** II  
**Reportable Quantity:** NA

**ICAO/IATA STATUS:** Regulated  
**Proper Shipping Name:** Ethanol solution  
**Hazard Class:** 3  
**UN Number:** UN 1170  
**Packing Group:** II  
**Reportable Quantity:** NA

**IMDG STATUS:** Regulated  
**Proper Shipping Name:** Ethanol solution  
**Hazard Class:** 3  
**UN Number:** UN 1170  
**Packing Group:** II  
**Reportable Quantity:** NA

Notes: DOT – US Department of Transportation Regulations

#### 15. REGULATORY INFORMATION

**U.S. TSCA Status** Exempt. However, Polysorbate 80 is listed on the TSCA inventory.  
**U.S. CERCLA Status** Not listed  
**U.S. SARA 302 Status** Not listed  
**U.S. SARA 313 Status** Not listed  
**U.S. RCRA Status** Classified as D001 hazardous waste based on ignitability  
**U.S. PROP 65 (Calif.)** Not listed







Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

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

**15. REGULATORY INFORMATION: continued**

**GHS Classification**

\*Where medicinal products are not exempt, the recommended GHS workplace classification for this product is as follows:

Hazard Class	Flammable Liquid	Acute Oral Toxicity	Eye Irritation	Skin Irritation	Toxic to Reproduction	Mutagenicity	Target Organ Toxicity
Hazard Category	2	Unknown	2A	2	2	2	2
Hazard Symbol		NA					
Signal Word	Danger	NA	Warning	Warning	Warning	Warning	Warning
Hazard Statement	Highly flammable liquid and vapor	NA	Causes serious eye irritation	Causes skin irritation	Suspected of damaging fertility or the unborn child	Suspected of causing genetic defects	May cause damage to the bone marrow, peripheral nervous system, cardiovascular system, gastrointestinal system, liver, testes and skin through prolonged or repeated exposure.

**GHS Precautionary Statements:**

**Prevention:**

Keep container tightly closed  
 Keep away from ignitions sources such as heat/sparks/open flame – No smoking  
 Take precautionary measures against static discharge.  
 Obtain special instructions before use.  
 Do not handle until all safety precautions have been read and understood.  
 Use personal protective equipment as required.  
 Avoid breathing vapors or spray.  
 In case of inadequate ventilation wear respiratory protection.  
 Wear protective gloves.  
 Contaminated work clothing should not be allowed out of the workplace.  
 Do not eat, drink or smoke when using this product.  
 Wash hands thoroughly after handling.

**Response:**

IF SWALLOWED: Immediately call a POISON CENTER or doctor. Rinse mouth.

IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms call a POISON CENTER or a doctor.

IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs, seek medical attention. Take off contaminated clothing and wash before reuse.





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.

If exposed or concerned, get medical attention.

**15. REGULATORY INFORMATION: continued**

**EU Classification\***

\*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance docetaxel.

<b>Classification(s):</b>	Irritant	Toxic to Reproduction Category 2	Carcinogen Category 3	Mutagen Category 2
<b>Symbol:</b>				
<b>Indication of Danger:</b>	Xi	T	Xn	T
<b>Risk Phrases:</b>	R22 – Harmful if swallowed R36/37/38 - Irritating to eyes, respiratory system, and skin R40 - Limited evidence of a carcinogenic effect R46 - May cause heritable genetic damage R60 - May impair fertility R61 - May cause harm to the unborn child R64 - May cause harm to breastfed babies			
<b>Safety Phrases:</b>	S23: Do not breathe vapor or spray S24: Avoid contact with the skin S25: Avoid contact with eyes S36/37/39 Wear suitable protective clothing, gloves and eye/face protection. S60: This material and its container must be disposed of as hazardous waste			

**16. OTHER INFORMATION**

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD <sub>50</sub>	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Global Occupational Toxicology  
 Date Prepared: November 24, 2009  
 Date(s) Revised: April 9, 2010  
 November 19, 2010

**Disclaimer:**

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