



SAFETY DATA SHEET

Revision date 10-Jan-2020

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Product Code(s) PZ03238
Trade Name: Taxespira
Chemical Family: Not determined

Contains Docetaxel anhydrous

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Antineoplastic

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address pfizer-MSDS@pfizer.com

Emergency Telephone - Poisons Information Centre: 13 1126

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Serious eye damage/eye irritation
Germ cell mutagenicity
Reproductive toxicity
Effects on or via lactation

Category 2 - (H319)
Category 2 - (H341)
Category 1B - (H360D)
Yes - (H362)

2.2. Label elements

Signal word Danger

Hazard statements
H319 - Causes serious eye irritation
H341 - Suspected of causing genetic defects
H360D - May damage the unborn child
H362 - May cause harm to breast-fed children

Precautionary Statements P280 - Wear protective gloves/protective clothing/eye protection/face protection

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P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P263 - Avoid contact during pregnancy/while nursing



2.3. Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Hazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Polyethylene glycol	Not Listed	25322-68-3	*	Not Listed	
Ethyl alcohol (ethanol)	200-578-6	64-17-5	<20	Flam. Liq. 2 (H225)	
Docetaxel anhydrous	Not Listed	114977-28-5	1	Repr. 1B (H360D) Muta. 2 (H341) Eye Irrit. 2A (H319) Lact. (H362)	
Citric acid	201-069-1	77-92-9	**	Eye Irrit. 2A (H319)	

NonHazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Polysorbate 80	500-019-9	9005-65-6	*	Not Listed	

Full text of H- and EUH-phrases: see section 16

Additional information

* Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

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4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO ₂ , alcohol-resistant foam or water spray.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous combustion products	Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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6.3. Methods and material for containment and cleaning up

Methods for containment	Keep away from incompatible materials.
Methods for cleaning up	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections	See section 8 for more information. See section 13 for more information.
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Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Flammable liquid and vapor- 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 vapor 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 waste water 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.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical product used as. Antineoplastic.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Polyethylene glycol

Austria	1000 mg/m ³ STEL 4000 mg/m ³
Denmark	1000 mg/m ³
Germany	200 mg/m ³ average molecular weight 200-600; because formation of a mist is possible, exposure should be minimized for reasons of occupational safety and hygiene Ceiling / Peak: 400 mg/m ³
Germany	1000 mg/m ³
Russia	MAC: 10 mg/m ³
Slovakia	1000 mg/m ³
Switzerland	1000 mg/m ³

Ethyl alcohol (ethanol)

ACGIH TLV	STEL: 1000 ppm
Austria	1000 ppm 1900 mg/m ³ STEL 2000 ppm STEL 3800 mg/m ³
Bulgaria	1000 mg/m ³
Czech Republic	1000 mg/m ³ Ceiling: 3000 mg/m ³
Denmark	1000 ppm 1900 mg/m ³
Estonia	500 ppm 1000 mg/m ³ STEL: 1000 ppm STEL: 1900 mg/m ³
Finland	1000 ppm 1900 mg/m ³

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France	STEL: 1300 ppm
Germany	STEL: 2500 mg/m ³ 1900 mg/m ³ 200 ppm 380 mg/m ³ Ceiling / Peak: 800 ppm Ceiling / Peak: 1520 mg/m ³
Germany	200 ppm 380 mg/m ³
Hungary	1900 mg/m ³ STEL: 7600 mg/m ³
Ireland	STEL: 1000 ppm
Latvia	1000 mg/m ³
Netherlands	260 mg/m ³ STEL: 1900 mg/m ³ H*
Poland	1900 mg/m ³
Romania	1000 ppm 1900 mg/m ³ STEL: 5000 ppm STEL: 9500 mg/m ³
Russia	TWA: 1000 mg/m ³ STEL: 2000 mg/m ³
Slovakia	500 ppm 960 mg/m ³
Spain	STEL: 1000 ppm STEL: 1910 mg/m ³
Switzerland	500 ppm 960 mg/m ³ STEL: 1000 ppm STEL: 1920 mg/m ³
OSHA PEL	1000 ppm 1900 mg/m ³ (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m ³
United Kingdom	TWA: 1000 ppm TWA: 1920 mg/m ³ STEL: 3000 ppm STEL: 5760 mg/m ³
Citric acid	
Germany	2 mg/m ³ Ceiling / Peak: 4 mg/m ³
Germany	2 mg/m ³
Russia	MAC: 1 mg/m ³
Switzerland	2 mg/m ³ STEL: 4 mg/m ³

Pfizer OEB Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Docetaxel anhydrous
Pfizer Occupational Exposure Band (OEB):
8.2. Exposure controls

OEB 4 (control exposure to the range of 1ug/m³ to <10ug/m³)

Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep

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Environmental exposure controls	airborne contamination levels below the exposure limits listed above in this section.
Personal protective equipment	No information available. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Eye/face protection	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
Hand protection	Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
Skin and body protection	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
Respiratory protection	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solution
Color	Clear, colorless to pale yellow
Molecular formula (MF):	Mixture
Molecular weight	Mixture
Odor	No data available.
Odor threshold	No data available

<u>Property</u>	<u>Values</u>
Melting point / freezing point	4-7
Boiling point / boiling range	No data available
Flash point	No data available
Evaporation rate	16.1
Flammability (solid, gas)	No data available
Flammability Limit in Air	No data available
Upper flammability limit:	No data available
Lower flammability limit:	No data available

Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Explosive properties	No information available
Upper Explosive Limits (Liquid) (% by Vol.):	19 (ethanol)
Lower Explosive Limits (Liquid) (% by Vol.):	3.3 (ethanol)

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Oxidizing properties No information available

9.2. Other information

Liquid Density No data available

Bulk density No data available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

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

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

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

Short term May cause eye irritation (based on components)

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on central nervous system, gastrointestinal system, blood and blood forming organs, and testes.

Known Clinical Effects: Common adverse effects include blood cell changes, nervous system/brain toxicity (neurotoxicity). Serious allergic reactions, including anaphylaxis, have been reported.

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

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

Docetaxel anhydrous

Rat Oral LD50 > 2000 mg/kg

Mouse IV LD50 138 mg/kg

Citric acid

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Rat Oral LD50 3000 mg/kg

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Polyethylene glycol	= 22 g/kg (Rat) = 28 g/kg (Rat)	> 20 g/kg (Rabbit)	-
Polysorbate 80	= 34500 µL/kg (Rat)	-	-
Ethyl alcohol (ethanol)	= 7060 mg/kg (Rat)	-	= 124.7 mg/L (Rat) 4 h
Citric acid	= 3 g/kg (Rat) = 3000 mg/kg (Rat)	> 2000 mg/kg (Rat)	-

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Polyethylene glycol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Docetaxel anhydrous

Eye Irritation Rabbit Irritant
Skin Irritation Rabbit Non-irritating
Skin Sensitization Negative

Citric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Docetaxel anhydrous

28-31 Day(s) Rat Intravenous 0.3 mg/m2/day NOEL Blood forming organs, Male reproductive system
6 Month(s) Rat Intravenous 0.2 mg/kg/day NOEL Blood forming organs, Male reproductive system
6 Month(s) Dog Intravenous 0.375 mg/kg/day LOAEL Male reproductive system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Docetaxel anhydrous

Reproductive & Fertility Rat Intravenous 0.3 mg/kg/day LOAEL Paternal toxicity
Embryo / Fetal Development Rat Intravenous 0.3 mg/kg/day LOAEL Maternal Toxicity, Embryotoxicity, Fetotoxicity, Not Teratogenic
Embryo / Fetal Development Rabbit Intravenous 0.03 mg/kg/day Embryotoxicity, Fetotoxicity, Maternal Toxicity, Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Docetaxel anhydrous

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vivo Micronucleus Mouse Positive
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive

Carcinogenicity

Carcinogenicity of the mixture has not been determined. Consumption of alcoholic beverages is considered carcinogenic to humans (Group 1) by IARC, though ethanol itself has not been classified by this agency. No other components are listed as carcinogens by IARC, US OSHA or NTP.

Ethyl alcohol (ethanol)

IARC Group 1 (Carcinogenic to Humans)

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NTP

Known Human Carcinogen

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

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

Ethyl alcohol (ethanol)

Oncorhynchus mykiss (Rainbow Trout) LC50/96h 12,900-15,300 mg/L

Docetaxel anhydrous

Daphnia magna (Water Flea) LC50 48 hours > 3.3 mg/l

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.

12.2. Persistence and degradability

Persistence and degradability

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Ethyl alcohol (ethanol)

Not Ready

12.3. Bioaccumulative potential

Bioaccumulation

No information available.

12.4. Mobility in soil

Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

No information available.

Chemical Name	PBT and vPvB assessment
Polyethylene glycol	The substance is not PBT / vPvB
Ethyl alcohol (ethanol)	The substance is not PBT / vPvB PBT assessment does not apply
Citric acid	The substance is not PBT / vPvB

12.6. Other adverse effects

Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review

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and implement appropriate technical and procedural waste water 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.

Section 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
UN proper shipping name: Ethanol solution
TDG 3
Packing group: II

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Polyethylene glycol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	Not Listed
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 3 Schedule 2

Polysorbate 80

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	Not Listed
AICS	Present

Ethyl alcohol (ethanol)

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	carcinogen 4/29/2011 in alcoholic beverages carcinogen 7/1/1988 when associated with alcohol abuse developmental toxicity 10/1/1987 in alcoholic beverages
TSCA	Present
EINECS	200-578-6
AICS	Present

Docetaxel anhydrous

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

Citric acid

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	201-069-1
AICS	Present

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15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H225 - Highly flammable liquid and vapor, H319 - Causes serious eye irritation, H341 - Suspected of causing genetic defects, H360D - May damage the unborn child, H362 - May cause harm to breast-fed children

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reason for revision Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification.

Revision date 10-Jan-2020

Prepared By Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.