



SAFETY DATA SHEET

Revision date 06-Dec-2021

Version 2.01

Page 1 / 13

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

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification

Serious eye damage/eye irritation Category 2 - (H319)
Germ cell mutagenicity Category 2 - (H341)
Reproductive toxicity Category 1B - (H360D)
Effects on or via lactation Yes - (H362)
Physical Hazards Flammable liquids Category 2 - (H225)

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
H225 - Highly flammable liquid and vapor

Precautionary Statements P201 - Obtain special instructions before use

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 2 / 13
Version 2.01

P202 - Do not handle until all safety precautions have been read and understood
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.
No smoking
P280 - Wear protective gloves/protective clothing/eye protection/face protection
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

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

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Ethyl alcohol (ethanol) (CAS #: 64-17-5)	<20	-	200-578-6	Flam. Liq. 2 (H225)	Not Listed	No data available	No data available
Docetaxel anhydrous (CAS #: 114977-28-5)	1		Not Listed	Repr.1B (H360D) Muta.2 (H341) Eye Irrit.2A (H319) Lact. (H362)	Not Listed	No data available	No data available
Citric acid (CAS #: 77-92-9)	**		201-069-1	Eye Irrit. 2A (H319)SE 3 (H335)	Not Listed	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No.	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
---------------	----------	---------------------------	-------	---	------------------------------------	----------	----------------------

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 3 / 13
Version 2.01

				1272/2008 [CLP]			
Polyethylene glycol (CAS #: 25322-68-3)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Polysorbate 80 (CAS #: 9005-65-6)	*	-	500-019-9	Not classified as hazardous	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Polyethylene glycol 25322-68-3	22000	20000	No data available	No data available	No data available
Polysorbate 80 9005-65-6	34.5 mL/kg	No data available	No data available	No data available	No data available
Ethyl alcohol (ethanol) 64-17-5	7060	No data available	116.9 133.8	No data available	No data available
Docetaxel anhydrous 114977-28-5	> 2000	No data available	No data available	No data available	No data available
Citric acid 77-92-9	5400	>2000	No data available	No data available	No data available

Additional information

* Proprietary

** to adjust pH

Non-hazardous ingredients provided for completeness. 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

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	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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.

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 4 / 13
Version 2.01

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as 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.

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.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

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.

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.

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 5 / 13
Version 2.01

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	250 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: 500 mg/m ³
Germany	200 mg/m ³
Russia	MAC: 10 mg/m ³
Slovakia	1000 mg/m ³
Switzerland	500 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 STEL: 1300 ppm STEL: 2500 mg/m ³
France	1900 mg/m ³
Germany	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: 3800 mg/m ³
Ireland	STEL: 1000 ppm
Latvia	1000 mg/m ³
Netherlands	260 mg/m ³ STEL: 1900 mg/m ³

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 6 / 13
Version 2.01

Poland	H*
Romania	1900 mg/m ³ 1000 ppm 1900 mg/m ³ STEL: 5000 ppm
Russia	STEL: 9500 mg/m ³ TWA: 1000 mg/m ³ MAC: 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	
Czech Republic	4 mg/m ³
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 Occupational Exposure Band (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):

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

8.2. Exposure controls

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 airborne contamination levels below the exposure limits listed above in this section.

Environmental exposure controls

No information available.

Personal protective equipment

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.)

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 7 / 13
Version 2.01

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
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture
Property	Values
pH	4-7
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	16.1
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
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
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available
Upper Explosive Limits (Liquid) (% by Vol.):	19 (ethanol)
Lower Explosive Limits (Liquid) (% by Vol.):	3.3 (ethanol)

9.2. Other information

No information available

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 8 / 13
Version 2.01

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information 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 hazard classes as defined in Regulation (EC) No 1272/2008

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	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

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

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 9 / 13
Version 2.01

Rat Inhalation LC50 10h 20,000 ppm

Docetaxel anhydrous

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

Citric acid

Mouse Oral LD50 5400 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Polyethylene glycol	= 22 g/kg (Rat)	> 20 g/kg (Rabbit)	-
Polysorbate 80	= 34.5mL/kg (Rat)	-	-
Ethyl alcohol (ethanol)	= 7060 mg/kg (Rat)	-	= 116.9 mg/L (Rat) 4 h = 133.8 mg/L (Rat) 4 h
Citric acid	= 3 g/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 LOAEL 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

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 10 / 13
Version 2.01

has not been classified by this agency. No other components are listed as carcinogens by IARC, US OSHA or NTP.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

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) NPDES LC50 96 Hours 12,900 mg/L

Fingerling Trout NPDES LC50 24 Hours 11200 mg/L

Pimephales promelas (Fathead Minnow) NPDES LC50 96 Hours 14200 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)

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

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. Endocrine disrupting properties

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 11 / 13
Version 2.01

Endocrine disrupting properties No information available.

12.7. 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 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.

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
Transport hazard class(es): 3
Packing group: II
Environmental Hazard(s): Not applicable
Special precautions for user: Not applicable

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 7/1/1988 when associated with alcohol abuse carcinogen 4/29/2011 developmental toxicity 10/1/1987
TSCA	Present

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 12 / 13
Version 2.01

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

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Ethyl alcohol (ethanol) 64-17-5	RG 84	-

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Citric acid - 77-92-9	Use restricted. See item 75.	

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

EU - Biocides

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

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

SAFETY DATA SHEET

Product Name Docetaxel Injection, USP (Hospira, Inc.)
Revision date 06-Dec-2021

Page 13 / 13
Version 2.01

Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor. Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation. Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects. Reproductive toxicity-Cat.1B; H360D - May damage the unborn child. Reproductive toxicity, effects on or via lactation; 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. Updated Section 3 - Composition / Information on Ingredients. Updated Section 9 - Physical and Chemical Properties. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

Revision date 06-Dec-2021

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this 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.