



SAFETY DATA SHEET

Revision date 17-Jun-2025

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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

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

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)

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements

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Signal word

Hazard statements

Danger

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 - EU (§28, 1272/2008)

P201 - Obtain special instructions before use
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

56 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
45 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
82 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).

Unknown aquatic toxicity

Contains 0 % of components with unknown hazards to the aquatic environment.

Contains Docetaxel anhydrous

2.3. Other hazards

Other hazards

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

PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

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

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Chemical name	Weight-%	REACH registration number	EC No (EU Index 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 (603-002-00-5)	Flam. Liq. 2 (H225)	Not classified	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 classified	No data available	No data available
Citric acid (CAS #: 77-92-9)	**		201-069-1 (607-750-00-3)	Eye Irrit. 2A (H319)SE 3 (H335)	Not classified	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Polyethylene glycol (CAS #: 25322-68-3)	*		Not Listed	Not classified	Not classified	No data available	No data available
Polysorbate 80 (CAS #: 9005-65-6)	*	-	500-019-9	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	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

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

* Proprietary

** to adjust pH

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards

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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.
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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, CO2, 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 mists) may fuel fires/explosions.
Hazardous combustion products	Formation of toxic gases is possible during heating or fire.
Explosion data	
Sensitivity to mechanical impact	No information available.
Sensitivity to static discharge	No information available.

5.3. Advice for firefighters

Special protective equipment and precautions 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.

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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 dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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

TWA-TMW: 1000 mg/m³; inhalable fraction
STEL-KZGW: 4000 mg/m³ (4 X 15 min); inhalable fraction

Denmark

TWA: 1000 mg/m³;
STEL: 2000 mg/m³;

Germany DFG

TWA-MAK: 250 mg/m³; II(2);inhalable fraction
Peak: 500 mg/m³; inhalable fraction

Germany TRGS

TWA-AGW; 200 mg/m³ (exposure factor 2); inhalable fraction

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Russia	MAC: 10 mg/m ³
Slovakia	TWA: 1000 mg/m ³ ;
Switzerland	TWA-MAK: 500 mg/m ³ ;
Ethyl alcohol (ethanol)	
ACGIH TLV	STEL: 1000 ppm
Austria	TWA-TMW: 1000 ppm;
	TWA-TMW: 1900 mg/m ³ ;
	STEL-KZGW: 2000 ppm (3 X 60 min);
	STEL-KZGW: 3800 mg/m ³ (3 X 60 min);
Bulgaria	TWA: 1000 mg/m ³ ;
Czech Republic	1000 mg/m ³
	Ceiling: 3000 mg/m ³
Denmark	TWA: 1000 ppm;
	TWA: 1900 mg/m ³ ;
	STEL: 2000 ppm;
	STEL: 3800 mg/m ³ ;
Estonia	TWA: 500 ppm;
	TWA: 1000 mg/m ³ ;
	STEL: 1000 ppm;
	STEL: 1900 mg/m ³ ;
Finland	TWA: 1000 ppm;
	TWA: 1900 mg/m ³ ;
	STEL: 1300 ppm;
	STEL: 2500 mg/m ³ ;
France	1900 mg/m ³
Germany DFG	TWA-MAK: 200 ppm; II(4);
	TWA-MAK: 380 mg/m ³ ; II(4);
	Peak: 800 ppm;
	Peak: 1520 mg/m ³ ;
Germany TRGS	TWA-AGW; 200 ppm (exposure factor 4);
	TWA-AGW; 380 mg/m ³ (exposure factor 4);
Hungary	TWA-AK: 1000 ppm;
	TWA-AK: 1900 mg/m ³ ;
	STEL-CK: 2000 ppm;
	STEL-CK: 3800 mg/m ³ ;
Ireland	STEL: 1000 ppm;
Latvia	TWA: 1000 mg/m ³ ;
Netherlands	TWA: 137 ppm;
	TWA: 260 mg/m ³ ;
	STEL: 1000 ppm;
	STEL: 1900 mg/m ³ ;
	Sk
Poland	TWA-NDS: 1900 mg/m ³ ;
Romania	TWA: 1000 ppm;
	TWA: 1900 mg/m ³ ;
	STEL: 5000 ppm;
	STEL: 9500 mg/m ³ ;
Russia	TWA: 1000 mg/m ³
	MAC: 2000 mg/m ³
Slovakia	TWA: 500 ppm;
	TWA: 960 mg/m ³ ;
	Ceiling: 1920 mg/m ³ ;
Spain	STEL (VLA-EC): 1000 ppm;
	STEL (VLA-EC): 1910 mg/m ³ ;
Switzerland	TWA-MAK: 500 ppm;
	TWA-MAK: 960 mg/m ³ ;
	STEL-KZGW: 1000 ppm;
	STEL-KZGW: 1920 mg/m ³ ;

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OSHA PEL

TWA: 1000 ppm
TWA: 1900 mg/m³
(vacated) TWA: 1000 ppm
(vacated) TWA: 1900 mg/m³

United Kingdom

TWA: 1000 ppm;
TWA: 1920 mg/m³;
STEL: 3000 ppm;
STEL: 5760 mg/m³;

Citric acid

Czech Republic
Germany DFG

4 mg/m³
TWA-MAK: 2 mg/m³; I(2);inhalable fraction
Peak: 4 mg/m³; respirable fraction
TWA-AGW; 2 mg/m³ (exposure factor 2); inhalable fraction
MAC: 1 mg/m³
TWA-MAK: 2 mg/m³; inhalable dust
STEL-KZGW: 4 mg/m³; inhalable dust

Germany TRGS
Russia
Switzerland

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.

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.

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.).

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.).

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Thermal hazards No information available.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Solution
Physical state	Liquid
Color	Clear, colorless to pale yellow
Odor	No information available.
Odor threshold	No information available

Property

Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	3.3 (ethanol)
Upper explosion limit	19 (ethanol)
Flash point	16.1
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	4-7
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

Values

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

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 information available.

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10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information 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

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)	-

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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.

100 % of the mixture consists of ingredient(s) of unknown acute toxicity.
56 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
45 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
82 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).

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 has not been classified by this agency. No other components are listed as carcinogens by

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IARC, US OSHA or NTP.

Ethyl alcohol (ethanol)

IARC
NTP

Group 1
Known

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

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.

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

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	Not PBT/vPvB
Ethyl alcohol (ethanol)	Not PBT/vPvB PBT assessment does not apply

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Citric acid	Not PBT/vPvB
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12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects
PMT or vPvM properties

No information available.
Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

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

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
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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
	Developmental
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

National regulations

France

Occupational Illnesses (R-463-3, France)

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

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905

Not applicable

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
Ethyl alcohol (ethanol) 64-17-5	Present	-	Fertility Category 1A Development Category 1A Can be harmful via breastfeeding

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material

Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20

Not applicable

Major Accidents Ordinance SR 814.012

Not applicable

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.

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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	75	-

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Ethyl alcohol (ethanol) 64-17-5	Product-type 1: Human hygiene Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals Product-type 4: Food and feed area
Citric acid 77-92-9	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals Product-type 6: Preservatives for products during storage

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

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 any hazard and/or precautionary statements referred to under Sections 2-15

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.

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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 17-Jun-2025

Prepared By Pfizer Global Environment, Health, and Safety

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