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

#### 1.1. Product identifier

Product Name Oxaliplatin Injection (Solution for Intravenous Use) (Hospira Inc.)

Product Code(s) PZ02902
Trade Name: Not applicable
Chemical Family: Not determined

Contains Oxaliplatin

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

Recommended Use Pharmaceutical product used as Antineoplastic

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Cake 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

**Germ cell mutagenicity Reproductive toxicity**Category 1B - (H340)

Category 1B - (H360D)

**OSHA Classification** 

Hazards not otherwise classified (HNOC)

Not applicable

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

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Not applicable

2.2. Label elements



Signal word Dang

Hazard statements
H340 - May cause genetic defects
H360D - May damage the unborn child

Precautionary Statements - EU (§28, P321 - Specific treatment (see .? on this label)

1272/2008)

P201 - Obtain special instructions before use

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

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P308 + P313 - IF exposed or concerned: Get medical advice/attention

P202 - Do not handle until all safety precautions have been read and understood

2.5 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

2.5 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

2.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

2.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).

2.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).

#### Unknown aquatic toxicity

Contains 2.5 % of components with unknown hazards to the aquatic environment.

Contains Oxaliplatin

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients

(see Section 8).

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

Chemical name	Weight-%	REACH	EC No (EU	Classification	Specific	M-Factor	M-Factor
		registration	Index No)	according to	concentration		(long-term)
		number		Regulation	limit (SCL)		

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				(EC) No.			
				1272/2008			
				[CLP]			
Sodium hydroxide	<0.5	-	215-185-5	Skin Corr.1A	Eye Irrit. 2 ::	No data	No data
(CAS #: 1310-73-2)			(011-002-00-6)	(H314)	0.5%<=C<2%	available	available
					Skin Corr. 1A ::		
					C>=5%		
					Skin Corr. 1B :: 2%<=C<5%		
					2%<=C<5%     Skin Irrit. 2 ::		
					0.5%<=C<2%		
Oxaliplatin	0.5		(607-007-00-3)	Eye Irrit 2A	Not classified	No data	No data
(CAS #:	0.0		(667 667 66 6)	(H319)	1 tot olabbilloa	available	available
61825-94-3)				Repr.1B		a vaa	
·				(H360D)			
				Muta.1B			
				(H340)			
NonHazardous							
Chemical name	Weight-%	REACH	EC No (EU	Classification	Specific	M-Factor	M-Factor
		registration	Index No)	according to	concentration		(long-term)
		number		Regulation	limit (SCL)		
				(EC) No.			
				1272/2008			
Water	*		231-791-2	[CLP] Not classified	Not classified	No data	No data
(CAS #: 7732-18-5)		-	231-791-2	INOL CIASSIIIEO	Not classified	available	available
Tartaric acid	*		201-766-0	Not classified	Not classified	No data	No data
(CAS #: 87-69-4)			201-700-0	INULUIASSIIIEU	INOL CIASSIIIEU	available	available
(CAS #. 61-69-4)						available	available

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

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapor - mg/L	hour - gas - ppm
Water	89838.9	No data available	No data available	No data available	No data available
7732-18-5					
Tartaric acid	No data	2000	No data available	No data available	No data available
87-69-4	available				
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available

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

### **Additional information**

\* Proprietary

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

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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.

**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

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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.

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.

**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.

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.

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** Prevent further leakage or spillage if safe to do so.

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean Methods for cleaning up

spill area thoroughly.

Clean contaminated objects and areas thoroughly observing environmental regulations. Prevention of secondary hazards

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

Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. Advice on safe handling

> When handling, use appropriate personal protective equipment (see Section 8). 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.

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

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.

Tartaric acid

Germany DFG TWA-MAK: 2 mg/m<sup>3</sup>; I(2);inhalable fraction

Peak: 4 mg/m³; inhalable fraction

Germany TRGS TWA-AGW; 2 mg/m³ (exposure factor 2); inhalable fraction Switzerland

TWA-MAK: 2 mg/m<sup>3</sup>; inhalable dust

STEL-KZGW: 4 mg/m3; inhalable dust

Sodium hydroxide

Denmark

ACGIH OEL (Ceiling) 2 ma/m3 **ACGIH TLV** Ceiling: 2 mg/m3

Austria TWA-TMW: 2 mg/m<sup>3</sup>; inhalable fraction

STEL-KZGW: 4 mg/m3 (8 X 5 min); inhalable fraction

TWA: 2.0 mg/m<sup>3</sup>; alkaline aerosols Bulgaria

Czech Republic 1 mg/m<sup>3</sup>

> Ceiling: 2 mg/m3 Ceiling: 2 mg/m3; TWA: 1 mg/m<sup>3</sup>;

Estonia STEL: 2 mg/m3; Finland Ceiling: 2 mg/m3;

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France 2 mg/m<sup>3</sup>

TWA-AK: 1 mg/m<sup>3</sup>; Hungary STEL-CK: 2 mg/m3;

Ireland STEL: 2 mg/m<sup>3</sup>; Ceiling Limit Value 2 mg/m<sup>3</sup>

Latvia TWA: 0.5 mg/m<sup>3</sup>; Poland TWA-NDS: 0.5 mg/m<sup>3</sup>; STEL-NDSCh: 1 mg/m3;

Romania TWA: 1 mg/m<sup>3</sup>; STEL: 3 mg/m3;

Slovakia TWA: 2 mg/m<sup>3</sup>;

Spain STEL (VLA-EC): 2 mg/m3;

Switzerland TWA-MAK: 2 mg/m3; inhalable dust STEL-KZGW: 2 mg/m<sup>3</sup>; inhalable dust

**OSHA PEL** TWA: 2 mg/m<sup>3</sup>

(vacated) Ceiling: 2 mg/m<sup>3</sup>

United Kingdom STEL: 2 mg/m3; Oxaliplatin

Austria TWA-TMW: 0.002 mg/m3; inhalable fraction

DS RS

0.001 mg/m<sup>3</sup> Czech Republic

Ceiling: 0.002 mg/m<sup>3</sup> Finland TWA: 1 mg/m<sup>3</sup>;

STEL: 3 mg/m3; pSk

Germany DFG DS RS

Slovakia TWA: 0.001 mg/m<sup>3</sup>;

Ceiling: 0.002 mg/m3; TWA-MAK: 0.002 mg/m3;

S

**Pfizer Occupational Exposure Band** 

(OEB) Statement:

Switzerland

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

Personal protective equipment

Engineering controls should be used as the primary means to control exposures. General **Engineering controls** 

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.

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.

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**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

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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 Band (OEB) is

exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (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.).

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** No information available

Odorless.

Odor threshold No information available

<u>Property</u> <u>Values</u>

Melting point / freezing point No data available

Boiling point or initial boiling point and boiling range 100

Flammability (solid, gas)

No data available

Lower and upper explosion limit/flammability limit

Lower explosion limit
Upper explosion limit
No data available
No data available
No data available
Autoignition temperature
No data available

Autoignition temperature No data available

Decomposition temperature

SADT (°C) No data available

pH 4.8-7

pH (as aqueous solution) 4.0-7
No data available

Kinematic viscosity
Dynamic viscosity
No data available
No data available
No data available
Vapor pressure
No data available
No data available
Pulls density
No data available

Bulk density

Liquid Density

Vapor density

No data available

No data available

No data available

No data available

**Particle characteristics** 

Particle Size No information available Particle Size Distribution No information available

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9.2. Other information

Mixture Molecular formula 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

No information available. Reactivity

10.2. Chemical stability

Stable up to .?°C. Stability

**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 mists) may fuel fires/explosions. As a precautionary measure, keep

away from heat sources and electrostatic discharge.

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 active

ingredient

Short term Individuals sensitive to this chemical or other materials in its chemical class may develop

allergic reactions. In the workplace, platinum compounds have been reported to cause

allergic skin and respiratory reactions.

May cause effects on blood and blood forming organs Repeat-dose studies in animals have Long Term:

shown a potential to cause adverse effects on testes and the developing fetus.

**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include vomiting, diarrhea, bone

marrow suppression, decreased red blood cell count (anemia), decreased white blood cells (leukopenia), decrease in platelets and red/white blood cells (pancytopenia), nervous system/brain toxicity (neurotoxicity), and skin and acute mucous membrane irritation.

**Acute toxicity** 

Serious eye damage/eye irritation

Skin corrosion/irritation

Respiratory or skin sensitization

STOT - single exposure

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

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

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

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STOT - repeated exposure
Reproductive toxicity
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
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Based on available data, the classification criteria are not met.

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

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Oxaliplatin

Rat Oral LD50 > 100 mg/kg Rat IP LD 50 14.3 mg/kg

Mouse Intraperitoneal LD 50 19.8 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Tartaric acid		> 2000 mg/kg (Rat)	•
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
·			

#### **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.

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- 2.5 % of the mixture consists of ingredient(s) of unknown acute toxicity.
- 2.5 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
- 2.5 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
- 2.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).
- 2.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
- 2.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).

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

Sodium hydroxide

Eye Irritation Rabbit Severe Skin Irritation Rabbit Severe

Oxaliplatin

Eye Irritation (In vitro, BCOP) Irritant Skin Irritation (In vitro, RhE) Negative

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

Oxaliplatin

Fertility and Embryonic Development Rat No route specified 1 mg/kg/day NOAEL Fetotoxicity

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

<u>Oxaliplatin</u>

Bacterial Mutagenicity (Ames) Salmonella Negative

In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Positive

In Vitro Chromosome Aberration Human Lymphocytes Positive

In Vivo Micronucleus Mouse Bone Marrow Positive

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or

OSHA.

#### 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.

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11.2.2. Other information

Other adverse effects No information available.

#### Section 12: ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases

to the environment should be avoided.

Unknown aquatic toxicity

12.1. Toxicity

Contains 2.5 % of components with unknown hazards to the aquatic environment.

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No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

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	
Tartaric acid	Not PBT/vPvB	
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply	

#### 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 No information available.

**PMT or vPvM properties**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

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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.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
Not applicable

### Section 15: REGULATORY INFORMATION

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

Water	
-------	--

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 231-791-2
AICS Present

Tartaric acid

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 201-766-0
AICS Present

Sodium hydroxide

CERCLA/SARA Section 313 de minimus % Not Listed **Hazardous Substances RQs** 1000 lb California Proposition 65 Not Listed **TSCA** Present **EINECS** 215-185-5 **AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 5 Poisons (SUSMP) Schedule 6

Oxaliplatin

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

Poisons (SUSMP)

#### National regulations

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#### Germany

# **Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

TRGS 905 Not applicable

#### Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018

Storage of Hazardous Material

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

Major Accidents Ordinance SR 814.012

Not applicable

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.

#### Authorizations and/or restrictions on use:

This product contains one or more substance(s) 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
Sodium hydroxide 1310-73-2	75	-

#### **Persistent Organic Pollutants**

Not applicable

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

Not applicable.

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Tartaric acid	Simplified procedure - Category 1
87-69-4	

#### Explosives Precursors Marketing and Use (2019/1148)

Not applicable

#### Legend:

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

**DSL/NDSL** - 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

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

H314 - Causes severe skin burns and eye damage. H340 - May cause genetic defects. H360D - May damage the unborn child.

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

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 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

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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.

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