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Pfizer Ireland Pharmaceuticals

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

### 1.1. Product identifier

Product Name Succinylcholine Chloride Injection, USP (Hospira Inc.)

Product Code(s) PZ03128

Trade Name: QUELICIN; Ethicholine

Item CodeH000012095Chemical Family:Not determined

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

Recommended Use Pharmaceutical product

#### 1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company

275 North Field Drive OSG Building Lake Forest, Illinois 60045 Ringaskiddy, Co. Cork.

1-800-879-3477 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: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Acute toxicity - Oral Category 4 - (H302)

#### **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 Warning

H302 - Harmful if swallowed

Precautionary Statements - EU (§28, P264 - Wash hands thoroughly after handling

1272/2008)

P270 - Do not eat, drink or smoke when using this product

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel

unwell

P330 - Rinse mouth

P501 - Dispose of contents/container in accordance with local, regional, national, and

international regulations as applicable

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.

1	Chemical name	EU - REACH (1907/2006) - Article 59(1)	EU - REACH (1907/2006) - Endocrine
		- Candidate List of Substances of Very	Disruptor Assessment List of
		High Concern (SVHC) for Authorisation	Substances
	Propylparaben	-	Endocrine disrupting properties

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 (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Succinylcholine Chloride	2-10		200-747-4	Acute Tox 3 (H301)	Not classified	No data available	No data available

(CAS #: 71-27-2)							
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available
NonHazardous	144 1 1 1 24		I = 0 11 /=··		1 6 1/1		
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)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available
Methyl-p-hydroxyben zoate (CAS #: 99-76-3)	*		202-785-7	Not classified	Not classified	No data available	No data available
Propylparaben (CAS #: 94-13-3)	*		202-307-7	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		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Succinylcholine Chloride 71-27-2	100	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

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

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#### Additional information

- \* Proprietary
- \*\* to adjust pH
- + Substance with a Union workplace exposure limit

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. Non-hazardous ingredients provided for completeness.

# 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.

**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.

#### 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

Not applicable.

Hazardous combustion products Formation of toxic gases is possible during heating or fire. May emit toxic fumes of carbon

monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing

compounds.

**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

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#### 6.1. Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Personal precautions

Section 8). Minimize exposure.

Use personal protection recommended in Section 8. For emergency responders

6.2. Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be **Environmental precautions** 

taken to avoid environmental release.

# 6.3. Methods and material for containment and cleaning up

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

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.

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 thoroughly after handling. 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)

Pharmaceutical drug product. Specific use(s)

# Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

**Exposure Limits** 

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

**SODIUM CHLORIDE** 

Latvia TWA: 5 mg/m<sup>3</sup>; Russia MAC: 5 mg/m<sup>3</sup>

Methyl-p-hydroxybenzoate

Russia MAC: 4 mg/m<sup>3</sup>

Sodium hydroxide

ACGIH OEL (Ceiling) 2 mg/m<sup>3</sup>

**ACGIH TLV** Ceiling: 2 mg/m<sup>3</sup>

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

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

Finland Ceiling: 2 mg/m<sup>3</sup>; 2 mg/m<sup>3</sup> France

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

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

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

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/m3; 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;

+ Hydrochloric Acid

ACGIH OEL (Ceiling) 2 ppm Ceiling: 2 ppm **ACGIH TLV** Austria TWA-TMW: 5 ppm;

TWA-TMW: 8 mg/m<sup>3</sup>;

STEL-KZGW: 10 ppm (8 X 5 min); STEL-KZGW: 15 mg/m3 (8 X 5 min); Bulgaria

TWA: 5 ppm; TWA: 8.0 mg/m<sup>3</sup>; STEL: 10 ppm; STEL: 15.0 mg/m3;

Czech Republic 8 mg/m<sup>3</sup>

Ceiling: 15 mg/m<sup>3</sup> Denmark STEL: 5 ppm; STEL: 8 mg/m3;

Estonia TWA: 5 ppm; TWA: 8 mg/m<sup>3</sup>; STEL: 10 ppm;

STEL: 15 mg/m<sup>3</sup>; TWA: 5 ppm; TWA: 8 mg/m<sup>3</sup>; STEL: 10 ppm; STEL: 15 mg/m<sup>3</sup>;

Finland STEL: 5 ppm; STEL: 7.6 mg/m3; Germany DFG TWA-MAK: 2 ppm; I(2);

TWA-MAK: 3.0 mg/m<sup>3</sup>; I(2); Peak: 4 ppm; Peak: 6 mg/m3;

Germany TRGS TWA-AGW; 2 ppm (exposure factor 2); TWA-AGW; 3 mg/m³ (exposure factor 2);

PZ03128

**European Union** 

Hungary TWA-AK: 8 mg/m³; TWA-AK: 5 ppm;

STEL-CK: 165 mg/m³;
STEL-CK: 10 ppm;
Ireland TWA: 8 mg/m³;
TWA: 5 ppm;

STEL: 10 ppm; STEL: 15 mg/m<sup>3</sup>; TWA: 5 ppm;

TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;

Ceiling Limit Value 2 ppm 3.0 mg/m³

Latvia TWA: 5 ppm;
TWA: 8 mg/m³;
STEL: 10 ppm;

STEL: 15 mg/m³;
Netherlands
TWA: 5 ppm;
TWA: 8 mg/m³;
STEL: 10 ppm;
STEL: 15 mg/m³;

Poland TWA-NDS: 5 mg/m³;

STEL-NDSCh: 10 mg/m³; Romania TWA: 5 ppm;

TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;

Russia MAC: 5 mg/m³
Slovakia TWA: 5 ppm;
TWA: 8.0 mg/m³;

Ceiling: 15 mg/m³; TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m³; STEL (VLA-EC): 10 ppm;

STEL (VLA-EC): 15 mg/m³;
Switzerland
TWA-MAK: 2 ppm;
TWA-MAK: 3 mg/m³;

STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m<sup>3</sup>;

U.S. - OSHA - Final PELs - Ceiling Limits 5 ppm 7 mg/m³

OSHA PEL Ceiling: 5 ppm
Ceiling: 7 mg/m³

(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m³

United Kingdom TWA: 1 ppm; gas and aerosol mist

TWA: 2 mg/m³; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m³; gas and aerosol mist

Propylparaben

Spain

Italy MDLPS

Russia MAC: 10 mg/m<sup>3</sup>

**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

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revision when new information becomes available.

Succinylcholine Chloride

Pfizer Occupational Exposure

Band (OEB):

OEB 3 (control exposure to the range of 10ug/m3 to < 100ug/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.

Personal protective equipment 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. Refer to applicable national standards and regulations in the

selection and use of personal protective equipment (PPE).

**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 gloves (e.g. Nitrile, etc.) are 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 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 half mask, P3 filter).

(Respirators must meet the standards in accordance with EN140, 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

Physical state Liquid Color Colourless

Odor No information available.
Odor threshold No information available

Property Values

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

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Lower and upper explosion limit/flammability limit

Lower explosion limit No data available No data available Upper explosion limit No data available Flash point **Autoignition temperature** No data available

**Decomposition temperature** 

SADT (°C) No data available

3.0 - 4.5

pH (as aqueous solution) No data available Kinematic viscosity No data available Dynamic viscosity No data available

No data available Soluble Solubility

Vapor pressure No data available Density and/or relative density No data available **Bulk density** No data available **Liquid Density** No data available No data available Vapor density

Particle characteristics

**Particle Size** No information available **Particle Size Distribution** No information available

9.2. Other information

Molecular formula Mixture Mixture Molecular weight

9.2.1. Information with regard to physical hazard classes

**Oxidizing properties** None

9.2.2. Other safety characteristics

No information available

# Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stable under normal conditions. Stability

**Explosion data** 

Sensitivity to mechanical impact No information available. Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

No information available. Possibility of hazardous reactions

10.4. Conditions to avoid

Conditions to avoid None known.

10.5. Incompatible materials

Incompatible materials None known.

10.6. Hazardous decomposition products

Hazardous decomposition products Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

# Section 11: TOXICOLOGICAL INFORMATION

Product Name Succinylcholine Chloride Injection, USP (Hospira Inc.)

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#### 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

**Known Clinical Effects:** The most common adverse effects seen during clinical use of this drug include increase in

> blood pressure (hypertension), decrease in blood pressure (hypotension), respiratory arrest, troubled breathing, irregular heartbeat (cardiac arrhythmia), slow heart rate (bradycardia),

increased heart rate (tachycardia), malignant hyperthermia.

Harmful if swallowed. Classification is based on mixture calculation methods based on **Acute toxicity** 

component data.

Serious eye damage/eye irritation

Skin corrosion/irritation Respiratory or skin sensitization STOT - single exposure STOT - repeated exposure Reproductive toxicity

Germ cell mutagenicity Carcinogenicity **Aspiration hazard** 

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. 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.

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

Succinylcholine Chloride

Mouse Oral LD50 125 mg/kg Mouse IV LD50 0.43 mg/kg Rabbit IV LD50 0.24 mg/kg

**SODIUM CHLORIDE** 

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>

Rat Oral LD 50 3 g/kg Mouse Oral LD 50 4 g/kg Rabbit Dermal LD 50 > 10 g/kg

Methyl-p-hydroxybenzoate

Mouse Oral LD50 > 8 g/kg Rat Oral LD 50 2100 mg/kg

# Sodium hydroxide

Mouse IP LD50 40 mg/kg

Propylparaben

Mouse Oral LD 50 6332 mg/kg

Mouse Sub-tenon injection (eye) LD 50 mg/kg

Chemical name	Chemical name Oral LD50		Inhalation LC50 -	
Water > 90 mL/kg (Rat)		-		
SODIUM CHLORIDE = 3550 mg/kg ( Rat )		> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat)1 h	
Sodium hydroxide = 325 mg/kg ( Rat )		= 1350 mg/kg ( Rabbit )	-	
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat)1 h	

A greater than symbol (>) indicates that the toxicity endpoint being tested was not **Acute Toxicity Comments:** 

achievable at the highest dose used in the test.

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

SODIUM CHLORIDE

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Skin irritation Rabbit Mild Eye irritation Rabbit Mild Methyl-p-hydroxybenzoate

Skin irritation Rabbit Non-irritating

Eye irritation Rabbit Slight

Skin Sensitization Guinea Pig Negative

Sodium hydroxide

Eye Irritation Rabbit Severe Skin Irritation Rabbit Severe

+ Hydrochloric Acid

Skin irritation Severe Eye irritation Severe

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

Methyl-p-hydroxybenzoate

28 Day(s) Rat Oral 250 mg/kg/day NOAEL Gastrointestinal System, Spleen, Thymus

Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system

4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

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

Methyl-p-hydroxybenzoate

Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOEL Maternal toxicity, Developmental toxicity

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

Methyl-p-hydroxybenzoate

In Vivo Dominant Lethal Assay Rat Negative

+ Hydrochloric Acid

Bacterial Mutagenicity (Ames) Salmonella Negative

In Vivo Micronucleus Rat Negative

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

OSHA.

+ Hydrochloric Acid

IARC Group 3

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.

12.1. Toxicity

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

Methyl-p-hydroxybenzoate

Oryzias latipes (Japanese Rice Fish) OECD LC50 96 hours 59.5 mg/L

Daphnia magna (Water Flea) ISO EC50 48 hours 11.2 mg/L

#### 12.2. Persistence and degradability

Persistence and degradability

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

Methyl-p-hydroxybenzoate

OECD Activated sludge Ultimate (CO2 Evolution) 89 % After 28 Day(s) 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

Chemical name	PBT and vPvB assessment	
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply	
Methyl-p-hydroxybenzoate	Not PBT/vPvB	
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply	
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply	
Propylparaben	Not PBT/vPvB	

### 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 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:
Not applicable
Not applicable
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
Succinylcholine Chloride	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	200-747-4
SODIUM CHLORIDE	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-598-3
AICS	Present
Methyl-p-hydroxybenzoate	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-785-7
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
+ Hydrochloric Acid	
CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
AICS	Present

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Standard for Uniform Scheduling of Medicines and

Poisons (SUSMP)

Schedule 5 Schedule 6

Propylparaben

Not Listed

CERCLA/SARA Section 313 de minimus % California Proposition 65

Not Listed Present

TSCA EINECS

**AICS** 

202-307-7 Present

#### **National regulations**

**France** 

Occupational Illnesses (R-463-3, France)

<u> </u>	
Chemical name	French RG number
SODIUM CHLORIDE	RG 78
7647-14-5	

# **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	-
+ Hydrochloric Acid 7647-01-0	75	-

# **Persistent Organic Pollutants**

Not applicable

Named dangerous substances per Seveso Directive (2012/18/EU)

Upper-tier requirements (tons)
250

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

Not applicable.

# EU - Plant Protection Products (1107/2009/EC)

Product Name Succinylcholine Chloride Injection, USP (Hospira Inc.)

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SODIUM CHLORIDE	Plant protection agent
7647-14-5	

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

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE	Product-type 1: Human hygiene
7647-14-5	
+ Hydrochloric Acid	Product-type 2: Disinfectants and algaecides not intended
7647-01-0	for direct application to humans or animals

### **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

# 15.2. Chemical safety assessment

No information available **Chemical Safety Report** 

# 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

H301 - Toxic if swallowed H314 - Causes severe skin burns and eye damage H331 - Toxic if inhaled

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

Updated Section 1 - Identification of the Substance/Preparation and the Reason for revision

Company/Undertaking. Updated Section 11 - Toxicology Information.

**Revision date** 13-Jun-2025

**Prepared By** Pfizer Global Environment, Health, and Safety

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