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

1.1. Product identifier

Product Name Lidocaine Hydrochloride Injection (Hospira, Inc.)

Product Code(s) PZ03337 Synonyms Lidocaine

Trade Name: Lignocaine Injection Chemical Family: Not determined

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

Recommended Use Pharmaceutical product anesthetic agent

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

OSG Building Ringaskiddy, Co. Cork. Ireland

+353 21 4378701

Pfizer Ireland Pharmaceuticals

1.4. Emergency telephone number

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

E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

2.2. Label elements

Signal word Not Classified

Hazard statementsNot classified in accordance with international standards for workplace safety.

2.3. Other hazards

Other hazards

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

(see Section 8).

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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.

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Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH	EC No	Classification	Specific	M-Factor	M-Factor
S.Iomod name	TVOIGHT 70	Registration Number	20110	according to Regulation (EC) No. 1272/2008	concentration limit (SCL)	W F GOLO	(long-term)
				[CLP]			
Lidocaine Hydrochloride 73-78-9	1-2		200-803-8	Acute Tox.4 (H302)	Not Listed	No data available	No data available
Sodium hydroxide 1310-73-2	**		215-185-5	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 7647-01-0	**		231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	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							
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)
101		1		: . :			

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

Acute Toxicity Estimate

Water

7732-18-5

SODIUM CHLORIDE

7647-14-5

231-791-2

231-598-3

No data

available

No data

available

Not Listed

Not Listed

No data

available

No data

available

No data

available

No data

available

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Product Name Lidocaine Hydrochloride Injection (Hospira, Inc.) Revision date 10-Feb-2022

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
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Lidocaine Hydrochloride 73-78-9	317	No data available	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
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

Additional information + Substance with a Union workplace exposure limit

* 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.

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

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Specific hazards arising from the

chemical

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

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

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gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

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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.

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 Contain the source of the spill or leak if it is safe to do so. Collect spill with a

non-combustible absorbent material and transfer to labeled container for disposal.

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

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. 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 drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

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Exposure Limits

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

Lidocaine Hydrochloride

Pfizer OEL TWA-8 Hr: 300 STEL 2500 µg/m³, Skin

Sodium hydroxide

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

STEL 4 mg/m³ 2.0 mg/m³ Bulgaria

1 mg/m³ Czech Republic Ceiling: 2 mg/m³

Ceiling: 2 mg/m³ Denmark Estonia 1 mg/m³

STEL: 2 mg/m3 Finland Ceiling: 2 mg/m³ France 2 mg/m³

Hungary 1 ma/m³ STEL: 2 mg/m³ STEL: 2 mg/m3 Ireland Ceiling Limit Value 2 mg/m³

0.5 mg/m³ Latvia STEL: 1 mg/m³ Poland 0.5 mg/m³

Romania 1 mg/m³ STEL: 3 mg/m³ Slovakia 2 mg/m³

Spain STEL: 2 mg/m³ Switzerland 2 mg/m³ STEL: 2 mg/m3 **OSHA PEL** 2 mg/m³

(vacated) Ceiling: 2 mg/m3

United Kingdom STEL: 2 mg/m3

SODIUM CHLORIDE

Latvia 5 mg/m³ Russia MAC: 5 mg/m³

Czech Republic

European Union

+ Hydrochloric Acid ACGIH OEL (Ceiling) 2 ppm

ACGIH TLV Ceiling: 2 ppm Austria 5 ppm

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

Bulgaria STEL: 15.0 mg/m3

> 5 ppm 8.0 mg/m³ 8 mg/m³

Ceiling: 15 mg/m³ Ceiling: 5 ppm

Denmark Ceiling: 8 mg/m³

Estonia 5 ppm 8 mg/m³

STEL: 10 ppm STEL: 15 mg/m³ TWA: 5 ppm

TWA: 8 mg/m³

STEL: 10 ppm STEL: 15 mg/m³

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Finland STEL: 5 ppm STEL: 7.6 mg/m³

Germany 2 ppm 3.0 mg/m³

Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m³ Page 6/13

Germany 2 ppm

Hungary 3 mg/m³ 8 mg/m³

STEL: 16 mg/m³ lreland 8 mg/m³

5 ng/m

STEL: 10 ppm STEL: 15 mg/m³

 $\begin{array}{ccc} \text{Italy} & & 5 \text{ ppm} \\ & & 8 \text{ mg/m}^3 \end{array}$

STEL: 10 ppm STEL: 15 mg/m³

Ceiling Limit Value STEL: 15 mg/m

3.0 mg/m³ 5 ppm 8 mg/m³ STEL: 10 ppm

Netherlands 8 mg/m³

STEL: 15 mg/m³

STEL: 15 mg/m³

Poland STEL: 10 mg/m³ 5 mg/m³

5 ppm 8 mg/m³ STEL: 10 ppm STEL: 15 mg/n

 Russia
 MAC: 5 mg/m³

 Slovakia
 5 ppm

 8.0 mg/m³
 8.0 mg/m³

 Spain
 5 ppm

 7.6 mg/m³
 STEL: 10 ppm

STEL: 10 ppm STEL: 15 mg/m³ 2 ppm

Switzerland 2 ppm 3 mg/m³ STEL: 4 ppr

STEL: 4 ppm STEL: 6 mg/m³ 5 ppm

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

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

Ceiling: 5 ppm

United Kingdom Ceiling: 7 mg/m³ TWA: 1 ppm

TWA: 2 mg/m³ STEL: 5 ppm STEL: 8 mg/m³

SODIUM CHLORIDE

Latvia

Romania

Pfizer Occupational Exposure OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Band (OEB):

8.2. Exposure controls

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

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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.

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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.

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the Eye/face protection

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.).

Impervious protective clothing is recommended if skin contact with drug product is possible Skin and body protection

and for bulk processing operations. (Protective clothing must meet the standards in

accordance with EN13982, ANSI 103 or international equivalent.).

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is Respiratory protection

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.).

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

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state Solution Color Clear, colorless

Odor No information available. **Odor threshold** No information available

Molecular formula Mixture Molecular weight Mixture

Property Values pН

Melting point / freezing point

No data available Boiling point / boiling range

Flash point No information available **Evaporation rate** No data available

Flammability (solid, gas) No data available

Flammability Limit in Air No data available Upper flammability limit:

Lower flammability limit: No data available

Vapor pressure No data available Vapor density No data available Relative density No data available No data available Water solubility Solubility(ies) No data available No data available Partition coefficient

SAFFTY DATA SHEFT

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No data available Autoignition temperature **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

9.2. Other information

No information available

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 data available. Reactivity

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

No information available. Possibility of hazardous reactions

10.4. Conditions to avoid

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

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

There are no data for this formulation. The information included in this section describes the **General Information:**

potential hazards of the individual ingredients

Short term Harmful if swallowed May cause mild eye irritation. May cause slight skin irritation. (based

on components) Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from

exposure.

Adverse effects associated with the rapeutic use include dizziness, nervousness, agitation. **Known Clinical Effects:**

drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are

cardiovascular collapse, central nervous system depression, and/or hypotension.

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

Lidocaine Hydrochloride

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Rat Oral LD50 317 mg/kg

Rat Para-periosteal LD50 25 mg/kg Rat Intraperitoneal LD50 133 mg/kg

Mouse Oral LD50 292 mg/kg

Mouse Intravenous LD50 19.5 mg/kg

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

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

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
SODIUM CHLORIDE	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat)1 h
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

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

Lidocaine Hydrochloride

Eye Irritation Rabbit Mild Skin Irritation Rabbit Mild

+ Hydrochloric Acid

Skin irritation Severe

Eye irritation Severe

SODIUM CHLORIDE

Skin irritation Rabbit Mild

Eye irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

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

Lidocaine Hydrochloride

Embryo / Fetal Development Rat Subcutaneous 30 mg/kg NOAEL Not teratogenic Embryo / Fetal Development Rat Intraperitoneal 56 mg/kg NOAEL Not Teratogenic

Embryo / Fetal Development Rat Intraperitoneal 72 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Rat Intravenous 500 mg/kg/day LOAEL Fetotoxicity

Embryo / Fetal Development Rat Intraperitoneal 6 mg/kg LOAEL Developmental toxicity

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

Lidocaine Hydrochloride

Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative

In Vitro Chromosome Aberration Human Lymphocytes Negative

In Vivo Micronucleus Mouse 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

Group 3 (Not Classifiable) IARC

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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

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

<u>Bioaccumulation</u> 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 hydroxide	The substance is not PBT / vPvB PBT assessment does
	not apply
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does
	not apply
+ Hydrochloric Acid	The substance is not PBT / vPvB PBT assessment does
	not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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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.

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
Lidocaine Hydrochloride	Nat Lista d
CERCLA/SARA Section 313 de minimus %	Not Listed Not Listed
California Proposition 65 TSCA	Present
EINECS	200-803-8
Sodium hydroxide	200 000 0
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
SODIUM CHLORIDE CERCLA/SARA Section 313 de minimus %	Nat Lista d
	Not Listed Not Listed
California Proposition 65 TSCA	Present
EINECS	231-598-3
AICS	Present
+ 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
Standard for Uniform Scheduling of Medicines and	Schedule 5
Poisons (SUSMP)	Schedule 6

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France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
SODIUM CHLORIDE	RG 78	-
7647-14-5		

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	Use restricted. See item 75.	
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

Persistent Organic Pollutants

Not applicable

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

Not applicable

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

Chemical name	Lower-tier requirer	ments (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid - 7647-01-0	25		250

Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

EU - Biocides

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources:Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

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

Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. 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.