SAFETY DATA SHEET

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

1.1. Product identifier

Product Name Naloxone Hydrochloride Injection, USP (Hospira Inc.)

Product Code(s) PZ03125
Trade Name: Naloxone Hydrochloride Injection
Chemical Family: Mixture

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
Lake Forest, Illinois 60045
1-800-879-3477

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

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 statements Not 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).

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Methyl-p-hydroxybenzoate 99-76-3	< 1		202-785-7	Aquatic Chronic 2 (H411)	Not Listed	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
Naloxone hydrochloride 357-08-4	0.04		206-611-0	Aquatic Acute 2 (H401) Aquatic Chronic 1 (H410)	Not Listed	No data available	1
Propylparaben 94-13-3	< 1		202-307-7	Aquatic Chronic 3 (H412)	Not Listed	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)
Water 7732-18-5	*		231-791-2	No data available	Not Listed	No data available	No data available
SODIUM CHLORIDE 7647-14-5	*		231-598-3	No data available	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	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
Naloxone hydrochloride 357-08-4	> 1000	No data available	No data available	No data available	No data available

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 Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin contact Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

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 As for primary cause of fire.

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.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

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

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

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

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling
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

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

Naloxone hydrochloride

Pfizer OEL TWA-8 Hr: 200 µg/m³	
Methyl-p-hydroxybenzoate	
Russia	MAC: 4 mg/m³
SODIUM CHLORIDE	
Latvia	5 mg/m³
Russia	MAC: 5 mg/m³
+ 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
Bulgaria	STEL: 10 ppm
	STEL: 15.0 mg/m³
	5 ppm
	8.0 mg/m³
Czech Republic	8 mg/m³
	Ceiling: 15 mg/m³
Denmark	Ceiling: 5 ppm
	Ceiling: 8 mg/m³
Estonia	5 ppm
	8 mg/m³
	STEL: 10 ppm
	STEL: 15 mg/m³
European Union	TWA: 5 ppm
	TWA: 8 mg/m³
	STEL: 10 ppm
	STEL: 15 mg/m³
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
Germany	2 ppm
	3 mg/m³
Hungary	8 mg/m³
	STEL: 16 mg/m³
Ireland	8 mg/m³
	5 ppm
	STEL: 10 ppm
	STEL: 15 mg/m³
Italy	5 ppm
	8 mg/m³
	STEL: 10 ppm
	STEL: 15 mg/m³
Ceiling Limit Value	2 ppm
	3.0 mg/m³
Latvia	5 ppm
	8 mg/m³
	STEL: 10 ppm
	STEL: 15 mg/m³
Netherlands	8 mg/m³
	STEL: 15 mg/m³
Poland	STEL: 10 mg/m³
	5 mg/m³
Romania	5 ppm
	8 mg/m³
	STEL: 10 ppm

	STEL: 15 mg/m³
Russia	MAC: 5 mg/m³
Slovakia	5 ppm
	8.0 mg/m³
Spain	5 ppm
	7.6 mg/m³
	STEL: 10 ppm
	STEL: 15 mg/m³
Switzerland	2 ppm
	3 mg/m³
	STEL: 4 ppm
	STEL: 6 mg/m³
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
	Ceiling: 7 mg/m³
United Kingdom	TWA: 1 ppm
	TWA: 2 mg/m³
	STEL: 5 ppm
	STEL: 8 mg/m³

Propylparaben

Russia	MAC: 10 mg/m³

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.

SODIUM CHLORIDE

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

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental exposure controls No information available.

Personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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.).

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

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solution
Color	Colorless
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

Property	**Values**
pH	3.0-6.5
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	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)
Naloxone hydrochloride
Measured 5 Log P -1.16
Measured 7 Log P 0.628
Measured 9 Log P 1.41

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
Reactivity No data available.
10.2. Chemical stability
Stability Stable under normal conditions.
Explosion data
Sensitivity to Mechanical Impact No data available.
Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions
Possibility of hazardous reactions No information available.
10.4. Conditions to avoid
Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials
Incompatible materials As a precautionary measure, keep away from strong oxidizers.

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

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
Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include headache, sweating, nausea, decrease in blood pressure (hypotension), increase in blood pressure (hypertension), shortness of breath (dyspnea), increased heart rate (tachycardia), irritability, anxiety, inability to concentrate, lack of appetite.

Acute Toxicity: (Species, Route, End Point, Dose)
Methyl-p-hydroxybenzoate
Mouse Oral LD50 > 8 g/kg
Rat Oral LD 50 2100 mg/kg

SODIUM CHLORIDE
Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m^3
Rat Oral LD 50 3 g/kg
Mouse Oral LD 50 4 g/kg
Rabbit Dermal LD 50 > 10 g/kg
Naloxone hydrochloride
Rat Oral LD50 > 1000 mg/kg
Mouse Oral LD50 > 1000 mg/kg
Rat Intravenous LD50 107 mg/kg
Mouse Intravenous LD50 90 mg/kg
Propylparaben
Mouse Oral LD 50 6332 mg/kg
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
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

Naloxone hydrochloride	> 1 g/kg (Rat)	-	-

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)
Methyl-p-hydroxybenzoate
Skin irritation Rabbit Non-irritating
Eye irritation Rabbit Slight
Skin Sensitization Guinea Pig Negative

+ Hydrochloric Acid
Skin irritation Severe
Eye irritation Severe
SODIUM CHLORIDE
Skin irritation Rabbit Mild
Eye irritation Rabbit Mild

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
Naloxone hydrochloride
3 Month(s) Rat Oral 2.13 mg/kg/day NOAEL None identified
3 Month(s) Dog Oral 0.68 mg/kg/day NOAEL None identified
9 Month(s) Dog Oral 75 mg/kg/day NOAEL Brain, Pituitary, Thymus, Central Nervous System
30 Day(s) Monkey Subcutaneous 60 mg/kg/day LOAEL Central Nervous System
2 Year(s) Rat Oral 4 mg/kg/day LOAEL Gastrointestinal system, Female reproductive system
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
Naloxone hydrochloride
Embryo / Fetal Development Rat No route specified 8 times human dose NOAEL Not teratogenic
Embryo / Fetal Development Mouse No route specified 4 times human dose NOAEL Not Teratogenic
Fertility and Embryonic Development Rat Oral 200 mg/kg/day NOAEL Paternal toxicity
Fertility and Embryonic Development Rat Oral 200 mg/kg/day NOAEL Fetotoxicity
Embryo / Fetal Development Rat Oral 800 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Oral 400 mg/kg/day NOAEL No effects at maximum dose
Peri-/Postnatal Development Rat Oral 200 mg/kg/day NOAEL Fetotoxicity

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
Naloxone hydrochloride
Bacterial Mutagenicity (Ames) Positive
In Vitro Chromosome Aberration Human Lymphocytes Positive
Mammalian Cell Mutagenicity HGPRT Hamster Negative
In Vivo Chromosome Aberration Rat Bone Marrow Negative
In Vivo Micronucleus Mouse Bone Marrow Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Naloxone hydrochloride
26 Week(s) Mouse Oral 200 mg/kg/day NOAEL Not carcinogenic

52 Week(s) Rat Oral 25 mg/kg/day LOAEL Not carcinogenic
2 Year(s) Rat Oral 100 mg/kg/day NOAEL Not carcinogenic

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

+ Hydrochloric Acid

IARC Group 3 (Not Classifiable)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

12.1. Toxicity

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

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

Naloxone hydrochloride

Pseudokirchneriella subcapitata (Green Alga) OECD ErC50 72 hours > 36 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD NOEC 72 hours 5.5 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Naloxone hydrochloride

Activated sludge OECD EC50 > 1000 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Naloxone hydrochloride

Daphnia magna (Water Flea) OECD 21 Day(s) NOEC 0.96 mg/L Reproduction
Daphnia magna (Water Flea) OECD 21 Day(s) EC50 > 0.96 mg/L Reproduction
Pimephales promelas (Fathead Minnow) OECD 34 Day(s) NOEC 0.061 mg/L Growth

12.2. Persistence and degradability

Persistence and degradability

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

Methyl-p-hydroxybenzoate

OECD Activated sludge Ultimate (CO_2 Evolution) 89 % After 28 Day(s) Ready

Naloxone hydrochloride

OECD Water - Sediment (various) Mineralization 10.2 & 6.3 % in 103 Day(s) N/A
OECD Water - Sediment (various) Total System DT50 28 & 103 Day(s) N/A

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

Naloxone hydrochloride

Measured 5 Log P -1.16
Measured 7 Log P 0.628
Measured 9 Log P 1.41

12.4. Mobility in soil

Mobility in soil

Sorption:
Naloxone hydrochloride (357-08-4)

Method	Inoculum	End Point	Result
OECD	Soil (various)	Kd (Geometric mean)	12
OECD	Soil (various)	Koc (Geometric mean)	3
OECD	Sediment (various)	Kd (Geometric mean)	53
OECD	Sediment (various)	Koc (Geometric mean)	2
OECD	Activated sludge	Kd	7.76
OECD	Activated sludge	Koc	1.34

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Methyl-p-hydroxybenzoate	The substance is not PBT / vPvB
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
Propylparaben	The substance is not PBT / vPvB

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

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

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 CHLORIDE
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **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 Poisons (SUSMP)** Schedule 5 / Schedule 6

Naloxone hydrochloride
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **EINECS** 206-611-0

Propylparaben
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **TSCA** Present
- **EINECS** 202-307-7
- **AICS** Present

France

Occupational Illnesses (R-463-3, France)

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

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
+ 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 requirements (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
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage. Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation. Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects. Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects. Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life. Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects.

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 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.

Revision date 14-Feb-2022

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.