SAFETY DATA SHEET

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

1.1. Product identifier

Product Name Gentamicin Sulfate Injection, USP 80 mg/2 mL (40 mg/mL as Gentamicin) (Hospira, Inc.)

Product Code(s) PZ03380
Trade Name: Not applicable
Chemical Family: Not determined

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

Recommended Use Pharmaceutical product used as antibiotic 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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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.

Skin sensitization Category 1 - (H317)
Reproductive toxicity Category 1A - (H360D)

2.2. Label elements

Signal word Danger

Hazard statements
H317 - May cause an allergic skin reaction
H360D - May damage the unborn child

Precautionary Statements
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves and protective clothing
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P363 - Wash contaminated clothing before reuse

P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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)
Gentamicin sulfate (CAS #: 1405-41-0)	4		215-778-9	Repr. Cat.1A (H360D) Skin Sens. 1 (H317)	Not Listed	No data available	No data available
Sodium metabisulfite USP (CAS #: 7681-57-4)	<1.0		231-673-0	Acute Tox. 4 (H302) Eye Dam. 1 (H318)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 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 (CAS #: 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%	No data available	No data available

					STOT SE 3 :: C>=10%		

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)
Propylparaben (CAS #: 94-13-3)	<1.0		202-307-7	Not classified as hazardous	Not Listed	No data available	No data available
Methyl-p-hydroxybenzoate (CAS #: 99-76-3)	<1.0		202-785-7	Not classified as hazardous	Not Listed	No data available	No data available
Edetate disodium (CAS #: 139-33-3)	*		205-358-3	Not classified as hazardous	Not Listed	No data available	No data available

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

Acute Toxicity Estimate
No information available

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
Gentamicin sulfate 1405-41-0	5000	No data available	No data available	No data available	No data available
Sodium metabisulfite USP 7681-57-4	1310	2000	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
Edetate disodium 139-33-3	2000	No data available	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

* 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	Use extinguishing agent suitable for type of surrounding fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Not applicable.
Hazardous combustion products	Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

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.

Gentamicin sulfate
Pfizer OEL TWA-8 Hr: 100 µg/m³

Sodium metabisulfite USP

ACGIH TLV	5 mg/m³
Denmark	5 mg/m³
France	5 mg/m³
Ireland	5 mg/m³ STEL: 15 mg/m³
Spain	5 mg/m³
Switzerland	5 mg/m³
OSHA PEL	(vacated) TWA: 5 mg/m³
United Kingdom	TWA: 5 mg/m³ STEL: 15 mg/m³

Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m³
ACGIH TLV	Ceiling: 2 mg/m³
Austria	2 mg/m³ STEL 4 mg/m³
Bulgaria	2.0 mg/m³
Czech Republic	1 mg/m³ Ceiling: 2 mg/m³
Denmark	Ceiling: 2 mg/m³
Estonia	1 mg/m³ STEL: 2 mg/m³
Finland	Ceiling: 2 mg/m³
France	2 mg/m³
Hungary	1 mg/m³ STEL: 2 mg/m³
Ireland	STEL: 2 mg/m³
Ceiling Limit Value	2 mg/m³
Latvia	0.5 mg/m³
Poland	STEL: 1 mg/m³ 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
Propylparaben	
Russia	MAC: 10 mg/m³
Methyl-p-hydroxybenzoate	
Russia	MAC: 4 mg/m³
Edetate disodium	
Russia	MAC: 2 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
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

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Impervious 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	No information available
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

Property	**Values**
pH	No data available
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

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.
Hazardous polymerization Will not occur.

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

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

10.6. Hazardous decomposition products
Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Short term Accidental ingestion may cause effects similar to those seen in clinical use.
Known Clinical Effects: Adverse effects associated with therapeutic use include effects on hearing, kidney effects, blood cell changes, fever, chills, allergic skin rash. Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.
Acute toxicity Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation Based on available data, the classification criteria are not met.
Skin corrosion/irritation Based on available data, the classification criteria are not met.
Respiratory or skin sensitization Classification is based on mixture calculation methods based on component data.
STOT - single exposure Based on available data, the classification criteria are not met.
STOT - repeated exposure Based on available data, the classification criteria are not met.
Reproductive toxicity Classification is based on mixture calculation methods based on component data.
Germ cell mutagenicity Based on available data, the classification criteria are not met.
Carcinogenicity Based on available data, the classification criteria are not met.
Aspiration hazard Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)
Gentamicin sulfate
Rat Oral LD50 > 5000 mg/kg
Rat Para-periosteal LD50 96 mg/kg
Rat Intramuscular LD50 384 mg/kg

Propylparaben
Mouse Oral LD 50 6332 mg/kg
Mouse Sub-tenon injection (eye) LD 50 200 mg/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
Edetate disodium
Rat Oral LD50 2000-2200 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Gentamicin sulfate	> 5 g/kg (Rat)	-	-
Sodium metabisulfite USP	= 1310 mg/kg (Rat)	> 2000 mg/kg (Rat)	-

Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
Edetate disodium	= 2 g/kg (Rat)	-	-
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

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)
+ Hydrochloric Acid
Skin irritation Severe
Eye irritation Severe
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

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
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
Methyl-p-hydroxybenzoate
28 Day(s) Rat Oral 250 mg/kg/day NOAEL Gastrointestinal System, Spleen, Thymus

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Gentamicin sulfate
Embryo / Fetal Development Rat Intraperitoneal 375 mg/kg/day LOAEL Developmental toxicity
Prenatal & Postnatal Development Rat Subcutaneous 660 mg/kg/day LOAEL Developmental toxicity
Prenatal & Postnatal Development Rat Subcutaneous 660 mg/kg/day LOAEL Neonatal toxicity,

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)
Gentamicin sulfate
DNA Binding Assay *E. coli* Negative
+ Hydrochloric Acid
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative
Methyl-p-hydroxybenzoate
In Vivo Dominant Lethal Assay Rat Negative

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

Sodium metabisulfite USP
IARC Group 3 (Not Classifiable)
+ 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 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 metabisulfite USP	The substance is not PBT / vPvB PBT assessment does not apply
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
Propylparaben	The substance is not PBT / vPvB
Methyl-p-hydroxybenzoate	The substance is not PBT / vPvB
Edetate disodium	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

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:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable
Special precautions for user:	Not applicable

Section 15: REGULATORY INFORMATION

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

Gentamicin sulfate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	215-778-9

Sodium metabisulfite USP

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-673-0
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5

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 Poisons (SUSMP)	Schedule 5 Schedule 6

Propylparaben

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

Edetate disodium

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	205-358-3
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

Chemical name	French RG number	Title
Sodium metabisulfite USP 7681-57-4	RG 66	-

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 does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium metabisulfite USP - 7681-57-4	Use restricted. See item 75.	
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

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

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.1A; H314 - Causes severe skin burns and eye damage Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage Reproductive toxicity-Cat.1A; H360D - May damage the unborn child Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

Data Sources:	Publicly available toxicity information. Safety data sheets for individual ingredients.
Reason for revision	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.
Revision date	19-Aug-2023
Prepared By	Pfizer Global Environment, Health, and Safety

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