



SAFETY DATA SHEET

Revision date 15-Jun-2025

Version 3

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

1.1. Product identifier

Product Name Tobramycin Injection (Hospira, Inc.)
Product Code(s) PZ03453
Trade Name: Tobramycin Injection
Chemical Family: Aminoglycoside

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

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

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

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

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Skin sensitization

Category 1 - (H317)

Reproductive toxicity

Category 1A - (H360D)

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



Signal word

Danger

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Hazard statements

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

Precautionary Statements - EU (§28, 1272/2008)

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 should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash it before reuse
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

Note:

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

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH 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)
Tobramycin sulfate (CAS #: 49842-07-1)	<= 4		256-499-2	Repr. 1A (H360D) Skin Sens. 1 (H317)	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
Sodium metabisulfite USP (CAS #: 7681-57-4)	<1.0		231-673-0 (016-063-00-2)	Acute Tox. 4 (H302) Eye Dam. 1 (H318)	Not classified	No data available	No data available

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+ Sulfuric acid (CAS #: 7664-93-9)	**		231-639-5 (016-020-00-8)	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 5%≤C<15% Skin Corr. 1A :: C≥15% Skin Irrit. 2 :: 5%≤C<15%	No data available	No data available
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

NonHazardous

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
Edetate disodium (CAS #: 139-33-3)	*		205-358-3	Not classified	Not classified	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 mg/kg	Dermal 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
Tobramycin sulfate 49842-07-1	>7500	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 metabisulfite USP 7681-57-4	1310	2000	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
+ Sulfuric acid 7664-93-9	2140	No data available	0.375	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available

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

Additional information

* Proprietary

** to adjust pH

+ Substance with a Union workplace exposure limit

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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.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO2 or water spray.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous combustion products	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-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.
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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.
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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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.
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 dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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.

Tobramycin sulfate

Pfizer OEL TWA-8 Hr: 600 µg/m³

SODIUM CHLORIDE

Latvia

TWA: 5 mg/m³;

Russia

MAC: 5 mg/m³

Sodium metabisulfite USP

ACGIH TLV

TWA: 5 mg/m³

Denmark

TWA: 5 mg/m³;

France

STEL: 10 mg/m³;

Ireland

5 mg/m³

TWA: 5 mg/m³;

STEL: 15 mg/m³ (calculated; thoracic fraction);

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Spain
Switzerland
OSHA PEL
United Kingdom

TWA-(VLA-ED): 5 mg/m³;
TWA-MAK: 5 mg/m³; inhalable dust
(vacated) TWA: 5 mg/m³
TWA: 5 mg/m³;
STEL: 15 mg/m³;

Edetate disodium

Russia

MAC: 2 mg/m³

+ Sulfuric acid

ACGIH TLV
Austria

TWA: 0.2 mg/m³ thoracic particulate matter
TWA-TMW: 0.1 mg/m³; inhalable fraction
STEL-KZGW: 0.2 mg/m³ (); inhalable fraction
TWA: 0.05 mg/m³; respirable aerosol
1 mg/m³

Bulgaria
Czech Republic

0.05 mg/m³

Denmark

Ceiling: 2 mg/m³

Estonia
European Union
Finland

TWA: 0.05 mg/m³; mist

STEL: 0.1 mg/m³; mist

TWA: 0.05 mg/m³; particles that reach the upper respiratory tract

TWA: 0.05 mg/m³; mist (thoracic fraction)

TWA: 0.05 mg/m³; thoracic fraction

STEL: 0.1 mg/m³; thoracic fraction

France
Germany DFG

0.05 mg/m³

TWA-MAK: 0.1 mg/m³; I(1);inhalable fraction

Peak: 0.1 mg/m³; inhalable fraction

Germany TRGS
Hungary
Ireland

TWA-AGW; 0.1 mg/m³ (exposure factor 1); inhalable fraction

TWA-AK: 0.05 mg/m³;

TWA: 0.05 ppm;

STEL: 0.15 ppm (calculated);

Italy MDLPS
Ceiling Limit Value

TWA: 0.05 mg/m³; thoracic fraction, mist

1 mg/m³

Latvia
Netherlands

TWA: 0.05 mg/m³; fog, which is defined as the thoracic fraction

TWA: 0.05 mg/m³; mist, thoracic fraction

Poland

TWA-NDS: 0.05 mg/m³; thoracic fraction

Romania

TWA: 0.05 mg/m³; thoracic fraction

Russia

MAC: 1 mg/m³

Skin

Slovakia

TWA: 0.05 mg/m³;

Spain

TWA-(VLA-ED): 0.05 mg/m³; mist

Switzerland

TWA-MAK: 0.1 mg/m³; inhalable dust

STEL-KZGW: 0.2 mg/m³; inhalable dust

OSHA PEL

TWA: 1 mg/m³

(vacated) TWA: 1 mg/m³

United Kingdom

TWA: 0.05 mg/m³; mist

STEL: 0.15 mg/m³; mist

Sodium hydroxide

ACGIH OEL (Ceiling)

2 mg/m³

ACGIH TLV

Ceiling: 2 mg/m³

Austria

TWA-TMW: 2 mg/m³; inhalable fraction

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

Bulgaria

TWA: 2.0 mg/m³; alkaline aerosols

Czech Republic

1 mg/m³

Ceiling: 2 mg/m³

Denmark

Ceiling: 2 mg/m³;

Estonia

TWA: 1 mg/m³;

STEL: 2 mg/m³;

Finland

Ceiling: 2 mg/m³;

France

2 mg/m³

Hungary

TWA-AK: 1 mg/m³;

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Ireland
Ceiling Limit Value
Latvia
Poland

Romania

Slovakia
Spain
Switzerland

OSHA PEL

United Kingdom

STEL-CK: 2 mg/m³;
STEL: 2 mg/m³;
2 mg/m³
TWA: 0.5 mg/m³;
TWA-NDS: 0.5 mg/m³;
STEL-NDSch: 1 mg/m³;
TWA: 1 mg/m³;
STEL: 3 mg/m³;
TWA: 2 mg/m³;
STEL (VLA-EC): 2 mg/m³;
TWA-MAK: 2 mg/m³; inhalable dust
STEL-KZGW: 2 mg/m³; inhalable dust
TWA: 2 mg/m³
(vacated) Ceiling: 2 mg/m³
STEL: 2 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.

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

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.).

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Thermal hazards No information available.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Sterile solution
Physical state	Liquid
Color	Clear, colorless
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
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	3.0-6.5
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

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Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

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

General Information:

The information included in this section describes the potential hazards of the individual ingredients

Short term

May cause eye and skin irritation (based on components)

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on kidneys

Known Clinical Effects:

May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Adverse effects most commonly reported in clinical use include effects on hearing, nausea, vomiting, and vertigo (vestibular ototoxicity), nervous system/brain toxicity (neurotoxicity) and kidney toxicity (nephrotoxicity). May cause adverse effects on the developing fetus. Serious allergic reactions, including anaphylaxis, have been reported.

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)

Tobramycin sulfate

Rat Oral LD50 > 7500 mg/kg

Rat Para-periosteal LD50 133 mg/kg

SODIUM CHLORIDE

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

Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 4 g/kg

Rabbit Dermal LD 50 > 10 g/kg

+ Sulfuric acid

Rat Oral LD50 2140 mg/kg

Edetate disodium

Rat Oral LD50 2000-2200 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

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Chemical name	Oral LD50	Dermal 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 metabisulfite USP	= 1310 mg/kg (Rat)	> 2000 mg/kg (Rat)	-
Edetate disodium	= 2 g/kg (Rat)	-	-
+ Sulfuric acid	= 2140 mg/kg (Rat)	-	= 0.375 mg/L (Rat) 4 h
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-

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

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

Tobramycin sulfate

Eye Irritation Rabbit Slight

Skin Irritation Rabbit Slight

SODIUM CHLORIDE

Skin irritation Rabbit Mild

Eye irritation Rabbit Mild

+ Sulfuric acid

Eye Irritation Rabbit Severe

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

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

Tobramycin sulfate

Reproductive & Fertility Rat Subcutaneous 100 mg/kg/day NOAEL No effects at maximum dose

Embryo / Fetal Development Rat Subcutaneous 100 mg/kg/day NOAEL No effects at maximum dose

Embryo / Fetal Development Rabbit Subcutaneous 20 mg/kg/day LOAEL Maternal Toxicity, Fetal mortality

Carcinogenicity

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Sodium metabisulfite USP

IARC

Group 3

+ Sulfuric acid

IARC

Group 1

NTP

Known

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.

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Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply
Sodium metabisulfite USP	Not PBT/vPvB PBT assessment does not apply
+ Sulfuric acid	Not PBT/vPvB PBT assessment does not apply
Edetate disodium	Not PBT/vPvB PBT assessment does not apply
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review 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.

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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

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

Tobramycin sulfate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Developmental
EINECS	256-499-2

SODIUM CHLORIDE

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-598-3
AICS	Present

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

Edetate disodium

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

+ Sulfuric acid

CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	1000 lb
California Proposition 65	Carcinogen
TSCA	Present

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EINECS	231-639-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 6
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

National regulations

Chemical name	French RG number
SODIUM CHLORIDE 7647-14-5	RG 78
Sodium metabisulfite USP 7681-57-4	RG 66

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905

Not applicable

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
+ Sulfuric acid 7664-93-9	Present	-	-

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable

Major Accidents Ordinance SR 814.012 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 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	75	-
+ Sulfuric acid 7664-93-9	75	-
Sodium hydroxide 1310-73-2	75	-

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Persistent Organic Pollutants

Not applicable

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

Not applicable.

Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE 7647-14-5	Plant protection agent

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE 7647-14-5	Product-type 1: Human hygiene
Sodium metabisulfite USP 7681-57-4	Product-type 9: Fiber, leather, rubber and polymerized materials preservatives

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Chemical name	Limit value	Upper limit value for the purpose of licensing under article 5(3)	Reportable explosives precursors
+ Sulfuric acid 7664-93-9	15 %w/w	40 %w/w	-

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

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

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

H314 - Causes severe skin burns and eye damage H317 - May cause an allergic skin reaction H360D - May damage the unborn child H302 - Harmful if swallowed H318 - Causes serious eye damage

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

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 6 - Accidental Release Measures. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

Revision date 15-Jun-2025

Prepared By Pfizer Global Environment, Health, and Safety

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