



SAFETY DATA SHEET

Revision date 21-Nov-2022

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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

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/protective clothing/eye protection/face protection
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
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 attention/advice

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



2.3. 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

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) |
|--|----------|---------------------------|-----------|---|---|-------------------|----------------------|
| Tobramycin sulfate (CAS #: 49842-07-1) | <= 4 | | 256-499-2 | Repr. 1A (H360D) Skin Sens. 1 (H317) | Not Listed | No data available | No data available |
| SODIUM CHLORIDE (CAS #: 7647-14-5) | * | - | 231-598-3 | Not classified as hazardous | 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 |
| + Sulfuric acid (CAS #: 7664-93-9) | ** | | 231-639-5 | 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 | 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 :: | No data available | No data available |

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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 carbon dioxide, dry chemical, or water spray.

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.

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 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

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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.

Tobramycin sulfate

Pfizer OEL TWA-8 Hr: 600 µg/m³

SODIUM CHLORIDE

Latvia 5 mg/m³
Russia MAC: 5 mg/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

Edetate disodium

Russia MAC: 2 mg/m³

+ Sulfuric acid

ACGIH TLV 0.2 mg/m³
Austria 0.1 mg/m³
STEL 0.2 mg/m³
Bulgaria 0.05 mg/m³
Czech Republic 1 mg/m³
0.05 mg/m³
Ceiling: 2 mg/m³
Denmark 0.05 mg/m³
Estonia 0.05 mg/m³
European Union TWA: 0.05 mg/m³
Finland 0.05 mg/m³
STEL: 0.1 mg/m³
France 0.05 mg/m³
Germany 0.1 mg/m³
Ceiling / Peak: 0.1 mg/m³
Germany 0.1 mg/m³
Hungary 0.05 mg/m³
Ireland 0.05 ppm

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| | |
|-------------------------|--|
| Italy | STEL: 0.15 ppm |
| Ceiling Limit Value | 0.05 mg/m ³ |
| Latvia | 1 mg/m ³ |
| Netherlands | 0.05 mg/m ³ |
| Poland | 0.05 mg/m ³ |
| Romania | 0.05 mg/m ³ |
| Russia | MAC: 1 mg/m ³ |
| Slovakia | Skin |
| Spain | 0.05 mg/m ³ |
| Switzerland | 0.05 mg/m ³ |
| OSHA PEL | 0.1 mg/m ³ |
| United Kingdom | STEL: 0.2 mg/m ³ |
| | 1 mg/m ³ |
| | (vacated) TWA: 1 mg/m ³ |
| | TWA: 0.05 mg/m ³ |
| | STEL: 0.15 mg/m ³ |
| Sodium hydroxide | |
| ACGIH OEL (Ceiling) | 2 mg/m ³ |
| ACGIH TLV | Ceiling: 2 mg/m ³ |
| Austria | 2 mg/m ³ |
| | STEL 4 mg/m ³ |
| Bulgaria | 2.0 mg/m ³ |
| Czech Republic | 1 mg/m ³ |
| | Ceiling: 2 mg/m ³ |
| Denmark | Ceiling: 2 mg/m ³ |
| Estonia | 1 mg/m ³ |
| | STEL: 2 mg/m ³ |
| Finland | Ceiling: 2 mg/m ³ |
| France | 2 mg/m ³ |
| Hungary | 1 mg/m ³ |
| | STEL: 2 mg/m ³ |
| Ireland | STEL: 2 mg/m ³ |
| Ceiling Limit Value | 2 mg/m ³ |
| Latvia | 0.5 mg/m ³ |
| Poland | STEL: 1 mg/m ³ |
| | 0.5 mg/m ³ |
| Romania | 1 mg/m ³ |
| | STEL: 3 mg/m ³ |
| Slovakia | 2 mg/m ³ |
| Spain | STEL: 2 mg/m ³ |
| Switzerland | 2 mg/m ³ |
| | STEL: 2 mg/m ³ |
| OSHA PEL | 2 mg/m ³ |
| United Kingdom | (vacated) Ceiling: 2 mg/m ³ |
| | STEL: 2 mg/m ³ |

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.

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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. |
| 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 | Sterile solution |
| Color | Clear, 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 |

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| | |
|-----------------------------------|--------------------------|
| 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

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.

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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

| 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 |
| 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

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0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Sodium metabisulfite USP

IARC

Group 3 (Not Classifiable)

+ Sulfuric acid

IARC

Group 1 (Carcinogenic to Humans)

NTP

Known Human Carcinogen

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

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 No information available.

| Chemical name | PBT and vPvB assessment |
|--------------------------|---|
| SODIUM CHLORIDE | The substance is not PBT / vPvB PBT assessment does not apply |
| Sodium metabisulfite USP | The substance is not PBT / vPvB PBT assessment does not apply |
| Edetate disodium | The substance is not PBT / vPvB PBT assessment does not apply |
| + Sulfuric acid | The substance is not PBT / vPvB PBT assessment does not apply |
| Sodium hydroxide | The substance is not PBT / vPvB PBT assessment does not apply |

12.6. Endocrine disrupting properties

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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

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 toxicity 7/1/1990 |
| 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 |

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|---|--------------------------|
| 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 3/14/2003 |
| TSCA | Present |
| 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 |

| Chemical name | French RG number | Title |
|---------------------------------------|------------------|-------|
| SODIUM CHLORIDE 7647-14-5 | RG 78 | - |
| 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. | |
| + Sulfuric acid - 7664-93-9 | Use restricted. See item 75. | |
| Sodium hydroxide - 1310-73-2 | Use restricted. See item 75. | |

Persistent Organic Pollutants

Not applicable

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

Not applicable

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

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

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.

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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.