



SAFETY DATA SHEET

Revision date 18-Jun-2025

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

1.1. Product identifier

Product Name Bupivacaine Hydrochloride and Epinephrine Injection, USP (Hospira, Inc.)
Product Code(s) PZ03150
Trade Name: MARCAINE WITH EPINEPHRINE
Chemical Family: Not determined

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

Recommended Use Pharmaceutical product used as anesthetic agent

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

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

Acute toxicity - Oral

Category 4

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

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Signal word

Hazard statements

Warning

H302 - Harmful if swallowed

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

P264 - Wash hands thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

P330 - Rinse mouth

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

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)
Bupivacaine Hydrochloride (CAS #: 14252-80-3)	</=0.75		Not Listed	Acute Tox. 2 (H300)	Not classified	No data available	No data available
Sodium metabisulfite USP	<0.1		231-673-0 (016-063-00-2)	Acute Tox. 4 (H302)	Not classified	No data available	No data available

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(CAS #: 7681-57-4)				Eye Dam. 1 (H318)			
Epinephrine bitartrate (CAS #: 51-42-3)	<0.1		200-097-1	Acute Tox. 2 (H300) Acute Tox. 2 (H310)	Not classified	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
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (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
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available
Monothioglycerol (CAS #: 96-27-5)	*	-	202-495-0	Not classified	Not classified	No data available	No data available
Edetate calcium disodium (CAS #: 62-33-9)	*		200-529-9	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate

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
Bupivacaine Hydrochloride 14252-80-3	18	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

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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
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
Monothioglycerol 96-27-5	No data available	673	No data available	No data available	No data available
Edetate calcium disodium 62-33-9	10000	No data available	1.9775	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

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

Additional information

+ Substance with a Union workplace exposure limit

* Proprietary

** to adjust pH

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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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, alcohol-resistant foam or water spray.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the	Not flammable.
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chemical

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

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.

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 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.

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Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Bupivacaine Hydrochloride

Pfizer OEL TWA-8 Hr: 20 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;

STEL: 10 mg/m³;

5 mg/m³

France

TWA: 5 mg/m³;

Ireland

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

Spain

TWA-(VLA-ED): 5 mg/m³;

Switzerland

TWA-MAK: 5 mg/m³; inhalable dust

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

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;

STEL-CK: 2 mg/m³;

Ireland

STEL: 2 mg/m³;

Ceiling Limit Value

2 mg/m³

Latvia

TWA: 0.5 mg/m³;

Poland

TWA-NDS: 0.5 mg/m³;

STEL-NDSch: 1 mg/m³;

Romania

TWA: 1 mg/m³;

STEL: 3 mg/m³;

Slovakia

TWA: 2 mg/m³;

Spain

STEL (VLA-EC): 2 mg/m³;

Switzerland

TWA-MAK: 2 mg/m³; inhalable dust

STEL-KZGW: 2 mg/m³; inhalable dust

OSHA PEL

TWA: 2 mg/m³

(vacated) Ceiling: 2 mg/m³

United Kingdom

STEL: 2 mg/m³;

+ Hydrochloric Acid

ACGIH OEL (Ceiling)

2 ppm

ACGIH TLV

Ceiling: 2 ppm

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Austria	TWA-TMW: 5 ppm; TWA-TMW: 8 mg/m ³ ; STEL-KZGW: 10 ppm (8 X 5 min); STEL-KZGW: 15 mg/m ³ (8 X 5 min);
Bulgaria	TWA: 5 ppm; TWA: 8.0 mg/m ³ ; STEL: 10 ppm; STEL: 15.0 mg/m ³ ;
Czech Republic	8 mg/m ³ Ceiling: 15 mg/m ³
Denmark	STEL: 5 ppm; STEL: 8 mg/m ³ ;
Estonia	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
European Union	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Finland	STEL: 5 ppm; STEL: 7.6 mg/m ³ ;
Germany DFG	TWA-MAK: 2 ppm; I(2); TWA-MAK: 3.0 mg/m ³ ; I(2); Peak: 4 ppm; Peak: 6 mg/m ³ ;
Germany TRGS	TWA-AGW; 2 ppm (exposure factor 2); TWA-AGW; 3 mg/m ³ (exposure factor 2);
Hungary	TWA-AK: 8 mg/m ³ ; TWA-AK: 5 ppm; STEL-CK: 165 mg/m ³ ; STEL-CK: 10 ppm;
Ireland	TWA: 8 mg/m ³ ; TWA: 5 ppm; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Italy MDLPS	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Ceiling Limit Value	2 ppm 3.0 mg/m ³
Latvia	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Netherlands	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Poland	TWA-NDS: 5 mg/m ³ ; STEL-NDSch: 10 mg/m ³ ;
Romania	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Russia	MAC: 5 mg/m ³

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Slovakia	TWA: 5 ppm; TWA: 8.0 mg/m ³ ; Ceiling: 15 mg/m ³ ;
Spain	TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m ³ ; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m ³ ;
Switzerland	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m ³ ; STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m ³ ;
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m ³
OSHA PEL	Ceiling: 5 ppm Ceiling: 7 mg/m ³ (vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m ³
United Kingdom	TWA: 1 ppm; gas and aerosol mist TWA: 2 mg/m ³ ; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m ³ ; gas and aerosol mist

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)

Epinephrine bitartrate

Pfizer Occupational Exposure Band (OEB):

OEB 4 - Skin (control exposure to the range of 1ug/m³ to <10ug/m³, provide additional precautions to protect from skin contact)

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 disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with

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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

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.

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: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients

Short term May cause mild eye irritation. May cause slight skin irritation. (based on components).

Anesthetic drug: may cause central nervous system and cardiovascular system effects.

Known Clinical Effects: Adverse effects associated with therapeutic use include dizziness, nervousness, agitation, drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.

Acute toxicity 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 Based on available data, the classification criteria are not met.

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

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)

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Rabbit Oral LD50 18 mg/kg
Rat Para-periosteal LD50 6 mg/kg
Rat Subcutaneous LD50 43 mg/kg
Mouse Intravenous LD50 6.1 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

Epinephrine bitartrate

Mouse Oral LD50 4 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	= 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)	-
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
Monothioglycerol		= 673 mg/kg (Rabbit)	-
Edetate calcium disodium	= 10 g/kg (Rat)	-	> 1.13 mg/L (Rat) 7 h
+ 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)

SODIUM CHLORIDE

Skin irritation Rabbit Mild
Eye irritation Rabbit Mild

+ Hydrochloric Acid

Skin irritation Severe
Eye irritation Severe

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Bupivacaine Hydrochloride

1 Month(s) Rabbit Subcutaneous 9 mg/kg LOAEL Central nervous system
1 Month(s) Dog Subcutaneous 9 mg/kg NOAEL None identified

Repeated Dose Toxicity Comments: Bupivacaine Hydrochloride: * Doses were administered twice a week.2

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

Bupivacaine Hydrochloride

Prenatal & Postnatal Development Intravenous 0.6 mg/kg LOAEL Neonatal toxicity
Embryo / Fetal Development Rat Subcutaneous 13.3 mg/kg/day NOAEL Maternal Toxicity
Embryo / Fetal Development Rat Subcutaneous 40 mg/kg/day NOAEL Developmental toxicity
Embryo / Fetal Development Rabbit Subcutaneous 22.2 mg/kg/day NOAEL Maternal Toxicity
Embryo / Fetal Development Rabbit Subcutaneous 5.8 mg/kg/day NOAEL Developmental toxicity
Peri-/Postnatal Development Rat Subcutaneous 13.3 mg/kg/day NOAEL Fetotoxicity

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

Bupivacaine Hydrochloride

Mammalian Cell Mutagenicity Negative

+ Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vivo Micronucleus Rat Negative

Carcinogenicity

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

Sodium metabisulfite USP

IARC

Group 3

+ Hydrochloric Acid

IARC

Group 3

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.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview:

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

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability

No information available.

12.3. Bioaccumulative potential

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 CHLORIDE	Not PBT/vPvB PBT assessment does not apply
Sodium metabisulfite USP	Not PBT/vPvB PBT assessment does not apply

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+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply
Monothioglycerol	Not PBT/vPvB
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.

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

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CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
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
Epinephrine bitartrate	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	200-097-1
AICS	Present
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
Monothioglycerol	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-495-0
AICS	Present
Edetate calcium disodium	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-529-9
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

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
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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

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 contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium metabisulfite USP 7681-57-4	75	-
Sodium hydroxide 1310-73-2	75	-
+ Hydrochloric Acid 7647-01-0	75	-

Persistent Organic Pollutants

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

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

Not applicable.

EU - Plant Protection Products (1107/2009/EC)

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

Biocidal Products Regulation (EU) No 528/2012 (BPR)

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

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7681-57-4	materials preservatives
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - 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

H300 - Fatal if swallowed H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage H331 - Toxic if inhaled

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

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 16 - Other Information.

Revision date 18-Jun-2025

Prepared By Pfizer Global Environment, Health, and Safety

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