SAFETY DATA SHEET

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

1.1. Product identifier

Product Name Bupivacaine Hydrochloride Injection (Hospira, Inc.)

Product Code(s) PZ03230
Synonyms Bupivacaine Spinal (Bupivacine in Dextrose, USP)
Trade Name: MARCAINE; MARCAINE SPINAL
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

Signal word Warning
Hazard statements 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 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 ::	No data available	No data available

					10%<=C<25% STOT SE 3 :: C>=10%		

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)
Methyl-p-hydroxybenzoate (CAS #: 99-76-3)	*		202-785-7	Not classified	Not classified	No data available	No data available
Dextrose (CAS #: 14431-43-7)	*		Not Listed	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
Bupivacaine Hydrochloride 14252-80-3	18	No data available	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
+ 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 >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information
* Proprietary
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 Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Not flammable.

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.

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

Methyl-p-hydroxybenzoate

Russia	MAC: 4 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
Austria	TWA-TMW: 5 ppm; TWA-TMW: 8 mg/m³; STEL-KZGW: 10 ppm (8 X 5 min); STEL-KZGW: 15 mg/m³ (8 X 5 min);
Bulgaria	TWA: 5 ppm; TWA: 8.0 mg/m³; STEL: 10 ppm; STEL: 15.0 mg/m³;
Czech Republic	8 mg/m³ Ceiling: 15 mg/m³
Denmark	STEL: 5 ppm; STEL: 8 mg/m³;
Estonia	TWA: 5 ppm; TWA: 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 DFG	TWA-MAK: 2 ppm; I(2); TWA-MAK: 3.0 mg/m³; I(2); Peak: 4 ppm; Peak: 6 mg/m³;
Germany TRGS	TWA-AGW; 2 ppm (exposure factor 2); TWA-AGW; 3 mg/m³ (exposure factor 2);
Hungary	TWA-AK: 8 mg/m³; TWA-AK: 5 ppm; STEL-CK: 165 mg/m³; STEL-CK: 10 ppm;
Ireland	TWA: 8 mg/m³; TWA: 5 ppm; STEL: 10 ppm; STEL: 15 mg/m³;
Italy MDLPS	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Ceiling Limit Value	2 ppm 3.0 mg/m³
Latvia	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Netherlands	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Poland	TWA-NDS: 5 mg/m³; STEL-NDSCh: 10 mg/m³;

Romania	TWA: 5 ppm; TWA: 8 mg/m^3; STEL: 10 ppm; STEL: 15 mg/m^3;
Russia	MAC: 5 mg/m^3
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

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.).

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	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	No data available
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
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: 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)
Bupivacaine Hydrochloride
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
Methyl-p-hydroxybenzoate

Mouse Oral LD50 > 8 g/kg
Rat Oral LD 50 2100 mg/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
+ 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
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
+ Hydrochloric Acid
Skin irritation Severe
Eye irritation 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
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))
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
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)
Bupivacaine Hydrochloride
Mammalian Cell Mutagenicity Negative
Methyl-p-hydroxybenzoate
In Vivo Dominant Lethal Assay Rat 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.

+ 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

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 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
Methyl-p-hydroxybenzoate	Not PBT/vPvB
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply
+ Hydrochloric Acid	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

Bupivacaine Hydrochloride
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **EINECS** Not Listed

Methyl-p-hydroxybenzoate
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **TSCA** Present
- **EINECS** 202-785-7
- **AICS** Present

Sodium 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

Dextrose

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
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

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 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 hydroxide 1310-73-2	75	-
+ Hydrochloric Acid 7647-01-0	75	-

Persistent Organic Pollutants
Not applicable

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.

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algaecides 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/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
H300 - Fatal if swallowed H314 - Causes severe skin burns and 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 3 - Composition / Information on Ingredients. Updated Section 6 - Accidental Release Measures. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

Revision date 13-Jun-2025

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.