



SAFETY DATA SHEET

Revision date 21-May-2023

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

1.1. Product identifier

Product Name Diphenhydramine Hydrochloride Injection, USP (Hospira, Inc.)
Product Code(s) PZ03417
Trade Name: Not applicable
Chemical Family: Not determined

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

Recommended Use Pharmaceutical product used as antihistamine sedative

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.

Specific target organ toxicity (repeated exposure) Category 2 - (H373)

2.2. Label elements

Signal word Warning

Hazard statements H373 - May cause damage to organs through prolonged or repeated exposure; liver

Precautionary Statements
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical attention/advice if you feel unwell
P501 - Dispose of contents/container in accordance with all local and national regulations



2.3. Other hazards

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Other hazards

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

Note:

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

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

| Chemical name | Weight-% | REACH Registration Number | EC No | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|---|----------|---------------------------------|-----------|--|--|----------------------|-------------------------|
| Diphenhydramine hydrochloride (CAS #: 147-24-0) | 5 | | 205-687-2 | Acute Tox.4 (H302) STOT RE.2 (H373) | Not Listed | No data available | No data available |
| Sodium hydroxide (CAS #: 1310-73-2) | ** | - | 215-185-5 | Skin Corr.1A (H314) | Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2% | No data available | No data available |
| + Hydrochloric Acid (CAS #: 7647-01-0) | ** | - | 231-595-7 | Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas | Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10% | No data available | No data available |

NonHazardous

| Chemical name | Weight-% | REACH Registration Number | EC No | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|-----------------------------|----------|---------------------------------|-----------|--|--|----------------------|-------------------------|
| Water (CAS #: 7732-18-5) | 95 | - | 231-791-2 | Not classified as hazardous | Not Listed | No data available | No data available |

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

Acute Toxicity Estimate

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No information available

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4 hour - vapor - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|---|-----------|-------------------|---|---|--------------------------------------|
| Water 7732-18-5 | 89838.9 | No data available | No data available | No data available | No data available |
| Diphenhydramine hydrochloride 147-24-0 | 500 | 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 |

Additional information

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

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

| | |
|---------------------|--|
| Inhalation | Remove to fresh air. If not breathing, give artificial respiration. If discomfort persists, get medical attention. |
| 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 and shoes. Wash skin with soap and water. If skin irritation persists, call a physician. |
| Ingestion | Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. |

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 As for primary cause of fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the Fine particles (such as dust and mists) may fuel fires/explosions.

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chemical

Hazardous combustion products May emit toxic fumes of nitrogen oxides and hydrogen chloride.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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 Keep away from incompatible materials.
Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical active.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Diphenhydramine hydrochloride

Pfizer OEL TWA-8 Hr: 150 µg/m³

Diphenhydramine hydrochloride

Russia

MAC: 0.1 mg/m³

Sodium hydroxide

ACGIH OEL (Ceiling)

2 mg/m³

ACGIH TLV

Ceiling: 2 mg/m³

Austria

2 mg/m³

STEL 4 mg/m³

Bulgaria

2.0 mg/m³

Czech Republic

1 mg/m³

Ceiling: 2 mg/m³

Denmark

Ceiling: 2 mg/m³

Estonia

1 mg/m³

STEL: 2 mg/m³

Finland

Ceiling: 2 mg/m³

France

2 mg/m³

Hungary

1 mg/m³

STEL: 2 mg/m³

Ireland

STEL: 2 mg/m³

Ceiling Limit Value

2 mg/m³

Latvia

0.5 mg/m³

Poland

STEL: 1 mg/m³

0.5 mg/m³

Romania

1 mg/m³

STEL: 3 mg/m³

Slovakia

2 mg/m³

Spain

STEL: 2 mg/m³

Switzerland

2 mg/m³

STEL: 2 mg/m³

OSHA PEL

2 mg/m³

(vacated) Ceiling: 2 mg/m³

United Kingdom

STEL: 2 mg/m³

+ Hydrochloric Acid

ACGIH OEL (Ceiling)

2 ppm

ACGIH TLV

Ceiling: 2 ppm

Austria

5 ppm

8 mg/m³

STEL 10 ppm

STEL 15 mg/m³

Bulgaria

STEL: 10 ppm

STEL: 15.0 mg/m³

5 ppm

8.0 mg/m³

Czech Republic

8 mg/m³

Ceiling: 15 mg/m³

Estonia

5 ppm

8 mg/m³

STEL: 10 ppm

STEL: 15 mg/m³

European Union

TWA: 5 ppm

TWA: 8 mg/m³

STEL: 10 ppm

STEL: 15 mg/m³

Finland

STEL: 5 ppm

STEL: 7.6 mg/m³

Germany

2 ppm

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| | |
|---|--|
| | 3.0 mg/m ³ |
| | Ceiling / Peak: 4 ppm |
| | Ceiling / Peak: 6 mg/m ³ |
| Germany | 2 ppm |
| | 3 mg/m ³ |
| Hungary | 8 mg/m ³ |
| | STEL: 16 mg/m ³ |
| Ireland | 8 mg/m ³ |
| | 5 ppm |
| | STEL: 10 ppm |
| | STEL: 15 mg/m ³ |
| Italy | 5 ppm |
| | 8 mg/m ³ |
| | STEL: 10 ppm |
| | STEL: 15 mg/m ³ |
| Ceiling Limit Value | 2 ppm |
| | 3.0 mg/m ³ |
| Latvia | 5 ppm |
| | 8 mg/m ³ |
| | STEL: 10 ppm |
| | STEL: 15 mg/m ³ |
| Netherlands | 8 mg/m ³ |
| | STEL: 15 mg/m ³ |
| Poland | STEL: 10 mg/m ³ |
| | 5 mg/m ³ |
| Romania | 5 ppm |
| | 8 mg/m ³ |
| | STEL: 10 ppm |
| | STEL: 15 mg/m ³ |
| Russia | MAC: 5 mg/m ³ |
| Slovakia | 5 ppm |
| | 8.0 mg/m ³ |
| Spain | 5 ppm |
| | 7.6 mg/m ³ |
| | STEL: 10 ppm |
| | STEL: 15 mg/m ³ |
| Switzerland | 2 ppm |
| | 3 mg/m ³ |
| | STEL: 4 ppm |
| | STEL: 6 mg/m ³ |
| U.S. - OSHA - Final PELs - Ceiling Limits | 5 ppm |
| | 7 mg/m ³ |
| OSHA PEL | (vacated) Ceiling: 5 ppm |
| | (vacated) Ceiling: 7 mg/m ³ |
| | Ceiling: 5 ppm |
| | Ceiling: 7 mg/m ³ |
| United Kingdom | TWA: 1 ppm |
| | TWA: 2 mg/m ³ |
| | STEL: 5 ppm |
| | STEL: 8 mg/m ³ |

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental exposure controls

No information available.

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| | |
|---------------------------------------|---|
| 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 | Liquid |
| Color | Colorless |
| Odor | Odorless. |
| Odor threshold | No information available |
| Molecular formula | Mixture |
| Molecular weight | Mixture |
| Property | Values |
| pH | 4-6.5 |
| 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 | Soluble |
| Solubility(ies) | Highly soluble: alcohol |
| Partition coefficient | No data available |
| Autoignition temperature | No data available |
| Decomposition temperature | No data available |
| Kinematic viscosity | No data available |
| Dynamic viscosity | No data available |

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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

Oxidizing properties None

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 of use.

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 Avoid direct sunlight, conditions that might generate heat, and sources of ignition.

10.5. Incompatible materials

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

10.6. Hazardous decomposition products

Hazardous decomposition products Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

Section 11: TOXICOLOGICAL INFORMATION

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

Short term May cause skin irritation. Not an eye irritant. Not a skin sensitizer (based on animal data). May be harmful if swallowed. May cause central nervous system effects. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects: The most common adverse effects seen with the therapeutic use of diphenhydramine HCl include drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance. Higher doses may cause CNS stimulation and/or depression, and impairment of motor and cognitive skills.

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.

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STOT - repeated exposure

Reproductive toxicity

Germ cell mutagenicity

Carcinogenicity

Aspiration hazard

Classification is based on mixture calculation methods based on component data.

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

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

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

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

Acute Toxicity: (Species, Route, End Point, Dose)

Diphenhydramine hydrochloride

Rat Oral LD50 500 mg/kg

Mouse Oral LD50 114 mg/kg

Guinea Pig Oral LD50 284 mg/kg

Human Oral LDmin. 10.1 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|-------------------------------|-------------------------|-------------------------|-------------------------|
| Water | > 90 mL/kg (Rat) | - | - |
| Diphenhydramine hydrochloride | = 500 mg/kg (Rat) | - | - |
| 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 |

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

Diphenhydramine hydrochloride

Eye Irritation Rabbit Non-irritating

Skin Sensitization - Beuhler Guinea Pig Negative

Skin Sensitization - LLNA Mouse Negative

+ Hydrochloric Acid

Skin irritation Severe

Eye irritation Severe

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Skin Irritation / Sensitization

Skin irritation has been reported in clinical use.

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

Diphenhydramine hydrochloride

13 Week(s) Rat Oral 310 mg/kg/day LOAEL Liver

2 Year(s) Rat Oral 15 mg/kg/day NOAEL Liver

2 Year(s) Mouse Oral 21 mg/kg/day NOAEL Liver

Chronic Effects/Carcinogenicity

Liver toxicity was seen in a two-year oral study in rats treated with diphenhydramine. A No-Observed-Adverse- Effect-Level (NOAEL) of 15 mg/kg/day was obtained for female animals. There was equivocal evidence of carcinogenic activity in male and female rats. No evidence of carcinogenic activity was observed in male or female mice.

Subchronic Effects

In a 13-week oral study, dose-related liver toxicity was seen in rats at doses of >13 mg/kg/day in males and > 15 mg/kg/day in females. The NOAEL in this study was ~6.5 mg/kg/day (males) and 7 mg/kg/day (females) There were no compound-related histological effects observed in mice.

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

Diphenhydramine hydrochloride

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Not teratogenic, Maternal toxicity, Fetotoxicity

Embryo / Fetal Development Mouse Oral 80 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity, Fetotoxicity

Embryo / Fetal Development Rat Oral 50 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity, Fetotoxicity

Reproductive Effects

No evidence of impaired fertility was seen in studies performed in rats and rabbits at doses up to 5 times the human dose of diphenhydramine hydrochloride.

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Teratogenicity No evidence of harm to the fetus was seen in studies performed in rats and rabbits at doses up to 5 times the human dose of diphenhydramine hydrochloride.

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

Diphenhydramine hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Negative

In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive without activation Negative with activation

In Vitro Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative

In Vitro Unscheduled DNA Synthesis Rat Hepatocyte Negative

+ Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vivo Micronucleus Rat Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Diphenhydramine hydrochloride

2 Year(s) Rat Oral 15 mg/kg/day NOAEL Not carcinogenic

2 Year(s) Mouse Oral 46 mg/kg/day NOAEL Not carcinogenic

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

+ Hydrochloric Acid

IARC

Group 3 (Not Classifiable)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. 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

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PBT and vPvB assessment

| Chemical name | PBT and vPvB assessment |
|---------------------|---|
| Sodium hydroxide | The substance is not PBT / vPvB PBT assessment does not apply |
| + Hydrochloric Acid | The substance is not PBT / vPvB PBT assessment does not apply |

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

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

Water

| | |
|---|------------|
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| TSCA | Present |
| EINECS | 231-791-2 |
| AICS | Present |

Diphenhydramine hydrochloride

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

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| EINECS | 205-687-2 |
| 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 |
| + Hydrochloric Acid | Schedule 6 |
| 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 |

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 | Use restricted. See item 75. | |
| + Hydrochloric Acid - 7647-01-0 | Use restricted. See item 75. | |

Persistent Organic Pollutants

Not applicable

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

Not applicable

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

| Chemical name | EU - Biocides |
|---------------------------------|--|
| + Hydrochloric Acid - 7647-01-0 | Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals |

Legend:

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

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

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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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure Acute toxicity, inhalation-Cat.2; H331 - Toxic if inhaled

| | |
|----------------------------|--|
| Data Sources: | Pfizer proprietary drug development information. Publicly available toxicity information. |
| Reason for revision | Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. |
| Revision date | 21-May-2023 |
| Prepared By | Pfizer Global Environment, Health, and Safety |

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