SAFETY DATA SHEET

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

1.1. Product identifier

Product Name: Nalbuphine Hydrochloride Injection (Hospira Inc.)

Product Code(s): PZ03107

Trade Name: Nalbuphine Hydrochloride Injection

Chemical Family: Mixture

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

Recommended Use: Pharmaceutical product used as Analgesic

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

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: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

2.2. Label elements

Signal word: Not Classified

Hazard statements: Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Weight-%</th>
<th>REACH Registration Number</th>
<th>EC No</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
<th>Specific concentration limit (SCL)</th>
<th>M-Factor</th>
<th>M-Factor (long-term)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nalbuphine Hydrochloride (CAS #: 23277-43-2)</td>
<td>1-2</td>
<td>245-549-9</td>
<td>Acute Tox 4 (H302)</td>
<td>Not Listed</td>
<td>No data available</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide (CAS #: 1310-73-2)</td>
<td>**</td>
<td>-</td>
<td>215-185-5</td>
<td>Skin Corr.1A (H314)</td>
<td>Eye Irrit. 2 :: 0.5%&lt;=C&lt;2% Skin Corr. 1A :: C&gt;=5% Skin Corr. 1B :: 2%&lt;=C&lt;5% Skin Irrit. 2 :: 0.5%&lt;=C&lt;2%</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>+ Hydrochloric Acid (CAS #: 7647-01-0)</td>
<td>**</td>
<td>-</td>
<td>231-595-7</td>
<td>Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas</td>
<td>Eye Irrit. 2 :: 10%&lt;=C&lt;25% Skin Corr. 1B :: C&gt;=25% Skin Irrit. 2 :: 10%&lt;=C&lt;25% STOT SE 3 :: C&gt;=10%</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Weight-%</th>
<th>REACH Registration Number</th>
<th>EC No</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
<th>Specific concentration limit (SCL)</th>
<th>M-Factor</th>
<th>M-Factor (long-term)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water (CAS #: 7732-18-5)</td>
<td>*</td>
<td>-</td>
<td>231-791-2</td>
<td>Not classified as hazardous</td>
<td>Not Listed</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Citric acid (CAS #: 77-92-9)</td>
<td>*</td>
<td>-</td>
<td>201-069-1</td>
<td>Eye Irrit. 2A (H319)SE 3 (H335)</td>
<td>Not Listed</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Sodium Citrate (CAS #: 6132-04-3)</td>
<td>*</td>
<td>-</td>
<td>612-118-5</td>
<td>Not classified as hazardous</td>
<td>Not Listed</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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

**Acute Toxicity Estimate**

No information available

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50 - 4 hour - dust/mist - mg/L</th>
<th>Inhalation LC50 - 4 hour - vapor - mg/L</th>
<th>Inhalation LC50 - 4 hour - gas - ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>89838.9</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Product Name  Nalbuphine Hydrochloride Injection (Hospira Inc.)

Revision date  19-Dec-2022

Table:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50 - 4 hour - dust/mist - mg/L</th>
<th>Inhalation LC50 - 4 hour - vapor - mg/L</th>
<th>Inhalation LC50 - 4 hour - gas - ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>7732-18-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nalbuphine Hydrochloride 23277-43-2</td>
<td>1100</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Sodium hydroxide 1310-73-2</td>
<td>325</td>
<td>1350</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>+ Hydrochloric Acid 7647-01-0</td>
<td>238</td>
<td>5010</td>
<td>No data available</td>
<td>No data available</td>
<td>563.3022</td>
</tr>
<tr>
<td>Citric acid 77-92-9</td>
<td>5400</td>
<td>&gt;2000</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Additional information

* Proprietary
** 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. Seek immediate medical attention/advice.

**Eye contact**
Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

**Skin contact**
Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

**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 As for primary cause of fire.

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
Formation of toxic gases is possible during heating or fire.
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 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.

Nalbuphine Hydrochloride
Pfizer OEL TWA-8 Hr: 10 µg/m³
## Sodium hydroxide

<table>
<thead>
<tr>
<th>Country</th>
<th>Ceiling Limit Value</th>
<th>STEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>2 mg/m³</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>2.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Czech Republic</td>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Denmark</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia</td>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Finland</td>
<td>Ceiling: 2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Hungary</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>Ceiling: 2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Latvia</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td>STEL: 1 mg/m³</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>Romania</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovakia</td>
<td>STEL: 3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>STEL: 2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>STEL: 2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>European Union</td>
<td>TWA: 5 ppm</td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>STEL: 10 ppm</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>2 ppm</td>
<td>Ceiling: 4 ppm</td>
</tr>
<tr>
<td>Hungary</td>
<td>3 mg/m³</td>
<td>Ceiling: 6 mg/m³</td>
</tr>
</tbody>
</table>

## Hydrochloric Acid

<table>
<thead>
<tr>
<th>Country</th>
<th>Ceiling Limit Value</th>
<th>STEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>8 mg/m³</td>
<td>10 ppm</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>STEL: 10 ppm</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td>European Union</td>
<td>TWA: 8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>STEL: 10 ppm</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>2 ppm</td>
<td>Ceiling: 4 ppm</td>
</tr>
<tr>
<td>Hungary</td>
<td>8 mg/m³</td>
<td>STEL: 16 mg/m³</td>
</tr>
</tbody>
</table>
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.
Personal protective equipment

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. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solution</td>
</tr>
<tr>
<td>Color</td>
<td>Colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>No information available.</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>Molecular formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>pH</td>
<td>3.0-4.5</td>
</tr>
<tr>
<td>Melting point / freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No information available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper flammability limit:</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower flammability limit:</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Kinematic viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Dynamic viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td></td>
</tr>
</tbody>
</table>

PZ03107
SAFETY DATA SHEET

Product Name  Nalbuphine Hydrochloride Injection (Hospira Inc.)
Revision date  19-Dec-2022

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
10.2. Chemical stability
Stability
Explosion data
Sensitivity to Mechanical Impact
Sensitivity to Static Discharge

10.3. Possibility of hazardous reactions
Possibility of hazardous reactions
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
Use of this drug is habit forming. Addiction may occur.
Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include dizziness, dry mouth, vertigo, sedation, headache, sweating, nausea, vomiting, respiratory depression, symptoms of dependence/withdrawal.
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)
Nalbuphine Hydrochloride

PZ03107
SAFETY DATA SHEET

Product Name  Nalbuphine Hydrochloride Injection (Hospira Inc.)
Revision date  19-Dec-2022

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>&gt; 90 mL/kg (Rat)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>= 325 mg/kg (Rat)</td>
<td>= 1350 mg/kg (Rabbit)</td>
<td>-</td>
</tr>
<tr>
<td>+ Hydrochloric Acid</td>
<td>238 - 277 mg/kg (Rat)</td>
<td>&gt; 5010 mg/kg (Rabbit)</td>
<td>= 1.68 mg/L (Rat) 1 h</td>
</tr>
<tr>
<td>Citric acid</td>
<td>= 3 g/kg (Rat)</td>
<td>&gt; 2000 mg/kg (Rat)</td>
<td>-</td>
</tr>
</tbody>
</table>

Irritation / Sensitization: (Study Type, Species, Severity)
- **Hydrochloric Acid**
  - Skin irritation: Severe
  - Eye irritation: Severe
- **Sodium hydroxide**
  - Eye Irritation: Rabbit, Severe
  - Skin Irritation: Rabbit, Severe
- **Citric acid**
  - Eye Irritation: Rabbit, Severe
  - Skin Irritation: Rabbit, Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
- **Nalbuphine Hydrochloride**
  - 6 Month(s) Rat Subcutaneous 7 mg/kg/day LOAEL Blood
  - 6 Month(s) Dog Subcutaneous 4 mg/kg/day LOAEL None identified

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
- **Nalbuphine Hydrochloride**
  - Reproductive & Fertility Rat Subcutaneous 56 mg/kg/day NOAEL No effects at maximum dose
  - Embryo / Fetal Development Rat Subcutaneous 100 mg/kg/day NOAEL Not Teratogenic
  - Embryo / Fetal Development Rabbit Subcutaneous 32 mg/kg/day NOAEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
- **Nalbuphine Hydrochloride**
  - Bacterial Mutagenicity (Ames) Bacteria Negative
  - HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative
  - Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative
  - Mammalian Cell Mutagenicity Mouse Lymphoma Positive
  - *In Vivo* Micronucleus Mouse Negative
  - **Hydrochloric Acid**
    - Bacterial Mutagenicity (Ames) *Salmonella* Negative
    - *In Vivo* Micronucleus Rat Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
- **Nalbuphine Hydrochloride**
  - 24 Month(s) Rat Oral 200 mg/kg/day NOAEL Not carcinogenic
  - 19 Month(s) Mouse Oral 200 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: 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.

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>PBT and vPvB assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>The substance is not PBT / vPvB PBT assessment does not apply</td>
</tr>
<tr>
<td>+ Hydrochloric Acid</td>
<td>The substance is not PBT / vPvB PBT assessment does not apply</td>
</tr>
<tr>
<td>Citric acid</td>
<td>The substance is not PBT / vPvB</td>
</tr>
<tr>
<td>Sodium Citrate</td>
<td>The substance is not PBT / vPvB PBT assessment does not apply</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>UN number:</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name:</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Transport hazard class(es):</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Packing group:</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Environmental Hazard(s):</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Special precautions for user:</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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

Nalbuphine Hydrochloride
- CERCLA/SARA Section 313 de minimus %: Not Listed
- California Proposition 65: Not Listed
- EINECS: 245-549-9

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
- 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

Citric acid
- CERCLA/SARA Section 313 de minimus %: Not Listed
California Proposition 65  Not Listed
TSCA  Present
EINECS  201-069-1
AICS  Present

Sodium Citrate
CERCLA/SARA Section 313 de minimus %  Not Listed
California Proposition 65  Not Listed
EINECS  Not Listed
AICS  Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)  Schedule 5

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)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Restricted substance per REACH Annex XVII</th>
<th>Substance subject to authorization per REACH Annex XIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide - 1310-73-2</td>
<td>Use restricted. See item 75.</td>
<td></td>
</tr>
<tr>
<td>+ Hydrochloric Acid - 7647-01-0</td>
<td>Use restricted. See item 75.</td>
<td></td>
</tr>
<tr>
<td>Citric acid - 77-92-9</td>
<td>Use restricted. See item 75.</td>
<td></td>
</tr>
</tbody>
</table>

Persistent Organic Pollutants
Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Not applicable

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Lower-tier requirements (tons)</th>
<th>Upper-tier requirements (tons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ Hydrochloric Acid - 7647-01-0</td>
<td>25</td>
<td>250</td>
</tr>
</tbody>
</table>

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
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage Acute toxicity, inhalation-Cat.3; 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 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information. Added Pfizer OEL (Section 8).

Revision date 19-Dec-2022

Prepared By Pfizer Global Environment, Health, and Safety

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