



SAFETY DATA SHEET

Revision date 17-Jun-2025

Version 3

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

1.1. Product identifier

Product Name Sufentanil Citrate Injection, USP CII (Hospira Inc.)
Product Code(s) PZ03109
Trade Name: Sufentanil Citrate Injection, USP CII
Chemical Family: Not determined

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

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

GHS - Classification: This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

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 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).

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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) |
|----------------------------------------|----------|---------------------------|-----------------------------------------|-----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|-------------------|----------------------|
| 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 |
| Sufentanil Citrate (CAS #: 60561-17-3) | 0.005 | | 262-295-4 | Acute Tox 2 (H300)2 (H361d) | Not classified | 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 |

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

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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 |
|----------------------------------|-----------------|-------------------|---------------------------------------------|-----------------------------------------|--------------------------------------|
| Water 7732-18-5 | 89838.9 | 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 |
| Sufentanil Citrate 60561-17-3 | 5 | No data available | No data available | No data available | No data available |

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

* 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 | 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 | Use extinguishing agent suitable for type of surrounding fire. |
|-------------------------------------|----------------------------------------------------------------|

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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.

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 Restrict access to work area. 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)

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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.

Sodium hydroxide

| | |
|---------------------|----------------------------------------------------------------|
| ACGIH OEL (Ceiling) | 2 mg/m ³ |
| ACGIH TLV | Ceiling: 2 mg/m ³ |
| Austria | TWA-TMW: 2 mg/m ³ ; inhalable fraction |
| | STEL-KZGW: 4 mg/m ³ (8 X 5 min); inhalable fraction |
| Bulgaria | TWA: 2.0 mg/m ³ ; alkaline aerosols |
| Czech Republic | 1 mg/m ³ |
| | Ceiling: 2 mg/m ³ |
| Denmark | Ceiling: 2 mg/m ³ ; |
| Estonia | TWA: 1 mg/m ³ ; |
| | STEL: 2 mg/m ³ ; |
| Finland | Ceiling: 2 mg/m ³ ; |
| France | 2 mg/m ³ |
| Hungary | TWA-AK: 1 mg/m ³ ; |
| | STEL-CK: 2 mg/m ³ ; |
| Ireland | STEL: 2 mg/m ³ ; |
| Ceiling Limit Value | 2 mg/m ³ |
| Latvia | TWA: 0.5 mg/m ³ ; |
| Poland | TWA-NDS: 0.5 mg/m ³ ; |
| | STEL-NDSch: 1 mg/m ³ ; |
| Romania | TWA: 1 mg/m ³ ; |
| | STEL: 3 mg/m ³ ; |
| Slovakia | TWA: 2 mg/m ³ ; |
| Spain | STEL (VLA-EC): 2 mg/m ³ ; |
| Switzerland | TWA-MAK: 2 mg/m ³ ; inhalable dust |
| | STEL-KZGW: 2 mg/m ³ ; inhalable dust |
| OSHA PEL | TWA: 2 mg/m ³ |
| | (vacated) Ceiling: 2 mg/m ³ |
| United Kingdom | STEL: 2 mg/m ³ ; |

+ Hydrochloric Acid

| | |
|---------------------|----------------------------------------------|
| ACGIH OEL (Ceiling) | 2 ppm |
| ACGIH TLV | Ceiling: 2 ppm |
| 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 ; |

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

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United Kingdom

TWA: 1 ppm; gas and aerosol mist
TWA: 2 mg/m³; gas and aerosol mist
STEL: 5 ppm; gas and aerosol mist
STEL: 8 mg/m³; 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.

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. It is recommended that all operations be fully enclosed and no air recirculated.

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 disposable gloves (e.g. Nitrile, etc.) (double 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 disposable 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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, 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

Physical state

Liquid

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Color Colorless
Odor No information available.
Odor threshold No information available

Property

Melting point / freezing point
Boiling point or initial boiling point and boiling range
Flammability (solid, gas)
Lower and upper explosion limit/flammability limit
 Lower explosion limit
 Upper explosion limit
Flash point
Autoignition temperature
Decomposition temperature
 SADT (°C)
pH
 pH (as aqueous solution)
Kinematic viscosity
 Dynamic viscosity
Solubility
Vapor pressure
Density and/or relative density
 Bulk density
 Liquid Density
Vapor density
Particle characteristics
 Particle Size
 Particle Size Distribution

Values

No data available
No data available
No data available
No data available
No data available
No data available
No data available
No data available
No data available
No data available
No data available
3.5-6
No data available
No data available
No data available
No data available
Soluble
No data available
No data available
No data available
No data available
No data available
No data available
No data available
No information available
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.

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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 |
| Long Term: | Animal studies have shown a potential to cause adverse effects on the fetus. |
| Known Clinical Effects: | The most common adverse effects seen during clinical use of this drug include drowsiness, nausea, decrease in blood pressure (hypotension), increase in blood pressure (hypertension), respiratory depression, musculoskeletal system rigidity; decreased heart rate (bradycardia). |
| 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)

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Sufentanil Citrate

Rat IV LD50 17.9 mg/kg

Mouse IV LD50 18.7 mg/kg

Dog IV LD50 10.1-19.5 mg/kg

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---------------------|-------------------------|-------------------------|-------------------------|
| Water | > 90 mL/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)

+ Hydrochloric Acid

Skin irritation Severe

Eye irritation Severe

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

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

Sufentanil Citrate

Embryo / Fetal Development Rat No route specified 2.5 times human dose LOAEL Embryotoxicity

Embryo / Fetal Development Rabbit No route specified 2.5 times human dose LOAEL Embryotoxicity

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

+ 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 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

| Chemical name | PBT and vPvB assessment |
|---------------------|--------------------------------------------|
| + Hydrochloric Acid | Not PBT/vPvB PBT assessment does not apply |
| 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.

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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 |

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 |

+ Hydrochloric Acid

| | |
|--------------------------------------|-------|
| CERCLA/SARA Section 313 de minimus % | 1.0 % |
|--------------------------------------|-------|

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Hazardous Substances RQs

California Proposition 65

TSCA

EINECS

AICS

Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)

Sufentanil Citrate

CERCLA/SARA Section 313 de minimus %

California Proposition 65

EINECS

5000 lb

Not Listed

Present

231-595-7

Present

Schedule 5

Schedule 6

Not Listed

Not Listed

262-295-4

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 algacides not intended for direct application to humans or animals |

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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 H314 - Causes severe skin burns and eye damage H361d - Suspected of damaging the unborn child
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 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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