



SAFETY DATA SHEET

Revision date 16-Jun-2025

Version 4

Page 1 / 15

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

1.1. Product identifier

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Product Code(s) PZ03031
Trade Name: Not applicable
Chemical Family: Mixture

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

Recommended Use Pharmaceutical product used as Analgesic 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

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

SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 2 / 15
Version 4

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

Supplemental Hazard Compound, not fully tested, additional hazards may exist.

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)
Fentanyl Citrate (CAS #: 990-73-8)	<0.1		213-588-0	Acute Tox.2 (H300) Repr.2 (H361fd)	Not classified	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH	EC No (EU	Classification	Specific	M-Factor	M-Factor
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SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 3 / 15
Version 4

		registration number	Index No)	according to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)		(long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
Fentanyl Citrate 990-73-8	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 $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

+ Substance with a Union workplace exposure limit

* Proprietary

** to adjust pH

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

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

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

SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 4 / 15
Version 4

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 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

SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 5 / 15
Version 4

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)

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.

Fentanyl Citrate

Pfizer OEL TWA-8 Hr: 0.3 TWA, 2 STEL $\mu\text{g}/\text{m}^3$, Skin

SODIUM CHLORIDE

Latvia

TWA: 5 mg/m^3 ;

Russia

MAC: 5 mg/m^3

Fentanyl Citrate

ACGIH - Skin Absorbers

Skin - potential significant contribution to overall exposure by the cutaneous route

ACGIH TLV

SL: 1 $\mu\text{g}/100\text{ cm}^2$

TWA: 0.1 $\mu\text{g}/\text{m}^3$ inhalable particulate matter

STEL: 0.2 $\mu\text{g}/\text{m}^3$ inhalable particulate matter

pSk

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 ;

SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 6 / 15
Version 4

Slovakia	STEL: 3 mg/m ³ ;
Spain	TWA: 2 mg/m ³ ;
Switzerland	STEL (VLA-EC): 2 mg/m ³ ;
	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 ;
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;

SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 7 / 15
Version 4

	TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ; TWA-NDS: 5 mg/m ³ ; STEL-NDSch: 10 mg/m ³ ;
Poland	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Romania	MAC: 5 mg/m ³ TWA: 5 ppm; TWA: 8.0 mg/m ³ ; Ceiling: 15 mg/m ³ ;
Russia	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 ;
Slovakia	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m ³ ; STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m ³ ;
Spain	5 ppm 7 mg/m ³
Switzerland	Ceiling: 5 ppm Ceiling: 7 mg/m ³ (vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m ³
U.S. - OSHA - Final PELs - Ceiling Limits	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
OSHA PEL	
United Kingdom	

SODIUM CHLORIDE

Pfizer Occupational Exposure
Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

8.2. Exposure controls

Engineering controls

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

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet

SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 8 / 15
Version 4

the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (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

Appearance	Solution
Physical state	Liquid
Color	No information available
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

SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 9 / 15
Version 4

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 be absorbed through the skin and cause systemic effects. May be fatal if swallowed (based on components) Use of this drug is habit forming. Addiction may occur.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Animal studies indicate that this material may cause adverse effects on the reproductive system

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

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 CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

Rat Oral LD 50 3 g/kg

SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 10 / 15
Version 4

Mouse Oral LD50 4 g/kg
Rabbit Dermal LD50 > 10 g/kg

Fentanyl Citrate

Rat Oral LD50 18 mg/kg
Rat Para-periosteal LD50 990 ug/kg
Rat Intraperitoneal LD50 2070 ug/kg
Mouse Oral LD50 368 mg/kg
Mouse Intravenous LD50 10100 ug/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
SODIUM CHLORIDE	= 3550 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
Fentanyl Citrate	= 18 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)

SODIUM CHLORIDE

Skin irritation Rabbit Mild
Eye irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

+ Hydrochloric Acid

Skin irritation Severe
Eye irritation Severe

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

Fentanyl Citrate

Reproductive & Fertility Rat Subcutaneous 1.25 mg/kg/day LOAEL Fertility
Reproductive & Fertility Rat Intravenous 30 ug/kg LOAEL Fertility, Embryotoxicity
Reproductive & Fertility Rat Subcutaneous 160 ug/kg LOAEL Fertility, Embryotoxicity
Embryo / Fetal Development Rat Oral 500 ug/kg NOAEL Not Teratogenic

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

Fentanyl Citrate

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Negative
In Vivo Micronucleus Mouse 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

SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 11 / 15
Version 4

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: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated. Based on available data, the classification criteria are not met.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply
Sodium 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

SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 12 / 15
Version 4

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 CHLORIDE

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-598-3
AICS	Present

Fentanyl Citrate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	213-588-0
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 8

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

SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 13 / 15
Version 4

CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
SODIUM CHLORIDE 7647-14-5	RG 78

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905

Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable

Major Accidents Ordinance SR 814.012 Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

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

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

Persistent Organic Pollutants

Not applicable

Named dangerous substances per Seveso Directive (2012/18/EU)

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

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

Not applicable.

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

Chemical name	EU - Plant Protection Products (1107/2009/EC)
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SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 14 / 15
Version 4

SODIUM CHLORIDE 7647-14-5	Plant protection agent
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Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE 7647-14-5	Product-type 1: Human hygiene
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H300 - Fatal if swallowed. H314 - Causes severe skin burns and eye damage. H335 - May cause respiratory irritation. H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

Data Sources: Publicly available toxicity information.

Reason for revision Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

Revision date 16-Jun-2025

Prepared By Pfizer Global Environment, Health, and Safety

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SAFETY DATA SHEET

Product Name Fentanyl Citrate Injection (Hospira Inc.)
Revision date 16-Jun-2025

Page 15 / 15
Version 4

is no known information at this time.