



# SAFETY DATA SHEET

Revision date 26-Mar-2023

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

### 1.1. Product identifier

Product Name	Silvadene Cream (Silver sulfadiazine)
Product Code(s)	PZ02568
Trade Name:	SILVADENE
Item Code	H000015503, H000015504
Chemical Family:	Sulfonamide

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

Recommended Use	Pharmaceutical product used as antimicrobial
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### 1.3. Details of the supplier of the safety data sheet

Pfizer Inc  
66 Hudson Boulevard East  
New York, New York 10001  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

E-mail address	pfizer-MSDS@pfizer.com
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### 1.4. Emergency telephone number

Emergency Telephone	Chemtrec 1-800-424-9300 International Chemtrec (24 hours): +1-703-527-3887
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## 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
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Hazard statements	Not classified in accordance with international standards for workplace safety.
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### 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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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.
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## 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)
White petrolatum (CAS #: 8009-03-8)	*	-	232-373-2	Carc. 1B (H350)	Not Listed	No data available	No data available
Stearyl Alcohol (CAS #: 112-92-5)	*		204-017-6	Not classified as hazardous	Not Listed	No data available	No data available
Propylene glycol (CAS #: 57-55-6)	*		200-338-0	Not classified as hazardous	Not Listed	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)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
PEG-40 Stearate (CAS #: 9004-99-3)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Isopropyl myristate (CAS #: 110-27-0)	*		203-751-4	Not classified as hazardous	Not Listed	No data available	No data available
Sorbitan monooleate (CAS #: 1338-43-8)	*		215-665-4	Not classified as hazardous	Not Listed	No data available	No data available
Silver sulfadiazine (CAS #: 22199-08-2)	1		244-834-5	Not classified as hazardous	Not Listed	No data available	No data available
Methyl-p-hydroxybenzoate (CAS #: 99-76-3)	*		202-785-7	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

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
White petrolatum 8009-03-8	No data available	3600	No data available	No data available	No data available
Stearyl Alcohol 112-92-5	5000	3000	No data available	No data available	No data available
PEG-40 Stearate	52841	No data available	No data available	No data available	No data available

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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
9004-99-3					
Propylene glycol 57-55-6	20000	20800	No data available	No data available	No data available
Isopropyl myristate 110-27-0	10000	5000	No data available	No data available	No data available
Sorbitan monooleate 1338-43-8	39800	No data available	No data available	No data available	No data available
Silver sulfadiazine 22199-08-2	10000	No data available	No data available	No data available	No data available

## Additional information

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

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

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

### 4.2. Most important symptoms and effects, both acute and delayed

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** None.

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO2, alcohol-resistant foam or water spray.

### 5.2. Special hazards arising from the substance or mixture

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

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

### 5.3. Advice for firefighters

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**Special protective equipment 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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.  
**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 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.

#### Silver sulfadiazine

Pfizer OEL TWA-8 Hr: 2000 µg/m<sup>3</sup>

#### Propylene glycol

Ireland

10 mg/m<sup>3</sup>

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Latvia  
Poland  
Russia  
United Kingdom

150 ppm  
470 mg/m<sup>3</sup>  
STEL: 1410 mg/m<sup>3</sup>  
STEL: 30 mg/m<sup>3</sup>  
STEL: 450 ppm  
7 mg/m<sup>3</sup>  
100 mg/m<sup>3</sup>  
MAC: 7 mg/m<sup>3</sup>  
TWA: 150 ppm  
TWA: 474 mg/m<sup>3</sup>  
TWA: 10 mg/m<sup>3</sup>  
STEL: 450 ppm  
STEL: 1422 mg/m<sup>3</sup>  
STEL: 30 mg/m<sup>3</sup>

## Silver sulfadiazine

Germany

0.01 mg/m<sup>3</sup>  
Ceiling / Peak: 0.02 mg/m<sup>3</sup>  
MAC: 1 mg/m<sup>3</sup>  
0.01 mg/m<sup>3</sup>  
STEL: 0.02 mg/m<sup>3</sup>

Russia  
Switzerland

## Methyl-p-hydroxybenzoate

Russia

MAC: 4 mg/m<sup>3</sup>

## 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 aerosols. Keep airborne contamination levels below the exposure limits listed above in this section.

### Environmental exposure controls

No information available.

### 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

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## 9.1. Information on basic physical and chemical properties

Physical state	Cream
Color	White to Off-white
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

### Property

### Values

pH	No data available
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	No data available
Solubility(ies)	No data available
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
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

### 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.

### 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.

### 10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

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## 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

Contact with sulfonamides may cause dermatitis. Allergic skin reaction may occur based on effects of other sulfonamides. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

#### Known Clinical Effects:

As in all sulfonamide therapy, the following reactions may occur including nausea, vomiting, diarrhea, inflammation of the liver and pancreas, blood disorder, drug fever, skin rash, infection of the conjunctiva and sclera, blood in the urine and crystalluria.

#### 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)

#### PEG-40 Stearate

Rat Oral LD50 > 20,000 mg/kg

#### Propylene glycol

Rat Oral LD 50 22,000 mg/kg

Mouse Oral LD 50 24,900 mg/kg

Rabbit Dermal LD 50 20,800 mg/kg

#### Isopropyl myristate

Mouse Oral LD50 49,700 mg/kg

Rabbit Dermal LD50 5000 mg/kg

#### Silver sulfadiazine

Rat Oral LD50 > 10 g/kg

#### Methyl-p-hydroxybenzoate

Mouse Oral LD50 > 8 g/kg

Rat Oral LD 50 2100 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
White petrolatum		= 3600 mg/kg ( Rabbit )	-
Stearyl Alcohol	> 5 g/kg ( Rat )	> 3 g/kg ( Rabbit )	-
PEG-40 Stearate	= 53 mL/kg ( Rat )	-	-
Propylene glycol	= 20 g/kg ( Rat )	= 20800 mg/kg ( Rabbit )	-
Isopropyl myristate	> 10000 mg/kg ( Rat )	= 5 g/kg ( Rabbit )	> 41 mg/L ( Rat ) 1 h

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Sorbitan monooleate	> 39800 mg/kg ( Rat )	-	-
Silver sulfadiazine	> 10 g/kg ( Rat )	-	-

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

### **Stearyl Alcohol**

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

### **Propylene glycol**

Skin irritation Rabbit Mild

Eye irritation Rabbit Mild

### **Methyl-p-hydroxybenzoate**

Skin irritation Rabbit Non-irritating

Eye irritation Rabbit Slight

Skin Sensitization Guinea Pig Negative

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

### **Methyl-p-hydroxybenzoate**

28 Day(s) Rat Oral 250 mg/kg/day NOAEL Gastrointestinal System, Spleen, Thymus

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

### **Silver sulfadiazine**

Embryo / Fetal Development Rabbit Oral Dose not specified NOAEL Not teratogenic

### **Methyl-p-hydroxybenzoate**

Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOEL Maternal toxicity, Developmental toxicity

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

### **Silver sulfadiazine**

Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative

### **Methyl-p-hydroxybenzoate**

*In Vivo* Dominant Lethal Assay Rat Negative

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

### **Silver sulfadiazine**

24 Month(s) Rat Dermal NOAEL Not carcinogenic

18 Month(s) Mouse Dermal NOAEL Not carcinogenic

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

## **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 of the formulation have not been investigated. Releases to the environment should be avoided.



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## 12.1. Toxicity

### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

#### Methyl-p-hydroxybenzoate

*Oryzias latipes* (Japanese Rice Fish) OECD LC50 96 hours 59.5 mg/L

*Daphnia magna* (Water Flea) ISO EC50 48 hours 11.2 mg/L

## 12.2. Persistence and degradability

### Persistence and degradability

### Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

#### Methyl-p-hydroxybenzoate

OECD Activated sludge Ultimate (CO2 Evolution) 89 % After 28 Day(s) Ready

## 12.3. Bioaccumulative potential

### Bioaccumulation

No information available.

## 12.4. Mobility in soil

### Mobility in soil

No information available.

## 12.5. Results of PBT and vPvB assessment

### PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
White petrolatum	The substance is not PBT / vPvB PBT assessment does not apply
Stearyl Alcohol	The substance is not PBT / vPvB PBT assessment does not apply
Propylene glycol	The substance is not PBT / vPvB PBT assessment does not apply
Isopropyl myristate	The substance is not PBT / vPvB
Methyl-p-hydroxybenzoate	The substance is not PBT / vPvB

## 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.

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## 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

#### White petrolatum

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	232-373-2
AICS	Present

#### Stearyl Alcohol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	204-017-6
AICS	Present

#### PEG-40 Stearate

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

#### Propylene glycol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-338-0
AICS	Present

#### Isopropyl myristate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	203-751-4
AICS	Present

#### Sorbitan monooleate

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<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-665-4
<b>AICS</b>	Present
Silver sulfadiazine	
<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	244-834-5
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4
Methyl-p-hydroxybenzoate	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	202-785-7
<b>AICS</b>	Present

Chemical name	French RG number	Title
White petrolatum 8009-03-8	RG 36	-
Propylene glycol 57-55-6	RG 84	-

## 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
White petrolatum - 8009-03-8	Use restricted. See item 28. Use restricted. See item 75.	

## Persistent Organic Pollutants

Not applicable

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

Not applicable

### 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

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

<b>Data Sources:</b>	Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.
<b>Reason for revision</b>	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.
<b>Revision date</b>	26-Mar-2023
<b>Prepared By</b>	Pfizer Global Environment, Health, and Safety

**Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.**