SAFETY DATA SHEET

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

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

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).

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)
White petrolatum (CAS #: 8009-03-8)	*	-	232-373-2 (649-254-00-X)	Carc. 1B (H350)	Not classified	No data available	No data available
Stearyl Alcohol (CAS #: 112-92-5)	*		204-017-6	Not classified	Not classified	No data available	No data available
Propylene glycol (CAS #: 57-55-6)	*		200-338-0	Not classified	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
PEG-40 Stearate (CAS #: 9004-99-3)	*		Not Listed	Not classified	Not classified	No data available	No data available
Isopropyl myristate (CAS #: 110-27-0)	*		203-751-4	Not classified	Not classified	No data available	No data available
Sorbitan monooleate (CAS #: 1338-43-8)	*		215-665-4	Not classified	Not classified	No data available	No data available
Silver sulfadiazine (CAS #: 22199-08-2)	1		244-834-5	Not classified	Not classified	No data available	No data available
Methyl-p-hydroxybenzoate (CAS #: 99-76-3)	*		202-785-7	Not classified	Not classified	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 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
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 9004-99-3	52841	No data available	No data available	No data available	No data available
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

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

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.

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 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 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.

Silver sulfadiazine

Pfizer OEL TWA-8 Hr: 2000 µg/m³

Propylene glycol

Ireland	TWA: 10 mg/m³; particulate TWA: 150 ppm; total vapour and particulates TWA: 470 mg/m³; total vapour and particulates STEL: 1410 mg/m³ (calculated); particulates STEL: 30 mg/m³ (calculated); STEL: 450 ppm (calculated); total vapor and particulates
Latvia	TWA: 7 mg/m³;
Poland	TWA-NDS: 100 mg/m³; vapor and inhalable fraction
Russia	MAC: 7 mg/m³
United Kingdom	TWA: 150 ppm; total vapour and particulate TWA: 474 mg/m³; total vapour and particulate TWA: 10 mg/m³; particulate STEL: 450 ppm; total vapour and particulate STEL: 1422 mg/m³; total vapour and particulate STEL: 30 mg/m³; particulate

Silver sulfadiazine

Germany DFG	TWA-MAK: 0.01 mg/m³; I(2);inhalable fraction Peak: 0.02 mg/m³; inhalable fraction
Germany TRGS	DS RS
Russia	MAC: 1 mg/m³
Switzerland	TWA-MAK: 0.01 mg/m³; inhalable dust STEL-KZGW: 0.02 mg/m³; inhalable dust

Methyl-p-hydroxybenzoate

Russia	MAC: 4 mg/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 aerosols. 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 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.).

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	Cream/ Lotion
Color	White to Off-white
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

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

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 (CO_2 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	Not PBT/vPvB PBT assessment does not apply
Stearyl Alcohol	Not PBT/vPvB PBT assessment does not apply
Propylene glycol	Not PBT/vPvB PBT assessment does not apply
Isopropyl myristate	Not PBT/vPvB
Methyl-p-hydroxybenzoate	Not PBT/vPvB

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
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

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

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-665-4
AICS	Present

Silver sulfadiazine

CERCLA/SARA Section 313 de minimus %	1.0 %
California Proposition 65	Not Listed
EINECS	244-834-5
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

Methyl-p-hydroxybenzoate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-785-7
AICS	Present

National regulations

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

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
White petrolatum 8009-03-8	28 75	-

Persistent Organic Pollutants
Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590
Not applicable.

Explosives Precursors Marketing and Use (2019/1148)
Not applicable

Legend:

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

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.
Reason for revision	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.
Revision date	18-Jun-2025
Prepared By	Pfizer Global Environment, Health, and Safety

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