



SAFETY DATA SHEET

Revision date: 23-Oct-2018

Version: 3.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Cortisporin (neomycin and polymyxin B sulfates and hydrocortisone acetate) Cream

Trade Name: CORTISPORIN

Chemical Family: Not applicable

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

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Pfizer Pharmaceuticals Group
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International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2

Label Elements

Signal Word: Warning

Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



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Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Hydrocortisone acetate	50-03-3	200-004-4	Not Listed	0.5
Mineral oil	8012-95-1	232-384-2	Not Listed	*
Neomycin Sulfate	1405-10-3	215-773-1	Resp. Sens. 1 (H334) Skin Sens.1(H317) Repro. 2 (H361d) Aq. Acute 3 (H402) Aq. Chronic 3 (H412)	0.7
Polymyxin B sulfate	1405-20-5	215-774-7	Acute Tox.4 (H302) Skin Sens.1 (H317) Resp Sens.1 (H334)	0.2
White petrolatum	8009-03-8	232-373-2	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water, purified	7732-18-5	231-791-2	Not Listed	*
Poloxamer 188	106392-12-5	Not Listed	Not Listed	*
Emulsifying wax	8014-38-8	Not Listed	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*

Additional Information: * Proprietary
 Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** If irritation occurs or persists, get medical attention. Remove clothing and wash affected skin with soap and water.
- 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.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

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Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Use adequate ventilation. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Antibiotic agent

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Mineral oil

ACGIH Threshold Limit Value (TWA)	5 mg/m ³
Australia TWA	5 mg/m ³
Belgium OEL - TWA	5 mg/m ³
Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	5 mg/m ³
Denmark OEL - TWA	1 mg/m ³
Finland OEL - TWA	5 mg/m ³
Greece OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	1 mg/m ³
Netherlands OEL - TWA	5 mg/m ³
OSHA - Final PELs - TWAs:	5 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 mg/m ³
Romania OEL - TWA	5 mg/m ³
Slovakia OEL - TWA	5 ppm 1 mg/m ³ 5 mg/m ³
Spain OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³

Neomycin Sulfate

Pfizer OEL TWA-8 Hr: 100 µg/m³, Sensitizer

White petrolatum

ACGIH Threshold Limit Value (TWA) 5 mg/m³ (oil mist, mineral)
ACGIH Threshold Limit Value (STEL) 10 mg/m³ (oil mist, mineral)

Propylene glycol

Australia TWA 150 ppm
474 mg/m³
10 mg/m³

Ireland OEL - TWAs 150 ppm
470 mg/m³
10 mg/m³

Latvia OEL - TWA 7 mg/m³
Lithuania OEL - TWA 7 mg/m³

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.

Hydrocortisone acetate

Pfizer Occupational Exposure Band (OEB): OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Polymyxin B sulfate

Pfizer Occupational Exposure Band (OEB): OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

Engineering Controls:	General room ventilation is adequate unless the process generates dust, mist or fumes. Local and general ventilation should be used as necessary, when handling this material in bulk.
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.
Hands:	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.)
Eyes:	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.)
Skin:	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.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Cream	Color:	White
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Hydrocortisone acetate

No data available

Neomycin Sulfate

Predicted 7.4 Log D 1.20

Polymyxin B sulfate

No data available

Emulsifying wax

No data available

Methylparaben

No data available

Poloxamer 188

No data available

Water, purified

No data available

White petrolatum

No data available

Mineral oil

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9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Propylene glycol

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

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

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May be harmful if swallowed. May cause allergic reaction (based on components) .

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus (based on components) .

Acute Toxicity: (Species, Route, End Point, Dose)

Hydrocortisone acetate

Mouse IP LD50 2300 mg/kg

Rat SC LD50 449mg/kg

Neomycin Sulfate

Rat Oral LD 50 2750 mg/kg

Mouse Oral LD 50 2880mg/kg

Mouse Intraperitoneal LD 50 116mg/kg

Rat Subcutaneous LD 50 633mg/kg

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11. TOXICOLOGICAL INFORMATION

Mouse Subcutaneous LD 50 275mg/kg

Polymyxin B sulfate

Mouse Oral LD50 790 mg/kg
Rat SC LD50 50mg/kg
Rat IV LD50 3.98mg/kg

Emulsifying wax

Mouse Oral 15,000 mg/kg

Propylene glycol

Rat Oral LD 50 22,000 mg/kg
Mouse Oral LD 50 24,900mg/kg
Rabbit Dermal LD 50 20,800mg/kg

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)

Neomycin Sulfate

Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Minimal
Skin Sensitization Positive

Mineral oil

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

Neomycin Sulfate

6 Week(s) Dog Oral 100 mg/kg/day NOAEL No effects at maximum dose
3 Month(s) Guinea Pig Oral 10 mg/kg/day NOAEL No effects at maximum dose
3 Month(s) Dog Subcutaneous 20 mg/kg/day LOAEL Kidney
12 Month(s) Cat Oral 12 mg/kg/day NOAEL Blood forming organs
3 Month(s) Guinea Pig Subcutaneous 10 mg/kg/day LOAEL Kidney

Polymyxin B sulfate

9 Day(s) Mouse Subcutaneous 284 mg/kg LOAEL Skin

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Neomycin Sulfate

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11. TOXICOLOGICAL INFORMATION

Reproductive & Fertility	Mouse	Oral	4000 mg/L	NOAEL	No effects at maximum dose
2 Generation Reproductive Toxicity	Rat	Oral	25 mg/kg/day	NOAEL	Fetotoxicity
Reproductive & Fertility	Rat	Oral	25 mg/kg/day	NOAEL	No effects at maximum dose
Prenatal & Postnatal Development	Rat	Subcutaneous	6 mg/kg/day	LOAEL	Developmental toxicity,

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

Neomycin Sulfate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vivo</i> Cytogenetics	Mouse	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Positive

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

Neomycin Sulfate

2 Year(s)	Rat	Oral	25 mg/kg/day	NOAEL	Not carcinogenic
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Carcinogen Status:

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

12. ECOLOGICAL INFORMATION

Environmental Overview:

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity:

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

Neomycin Sulfate

<i>Daphnia magna</i> (Water Flea)	OECD	EC50	48 Hours	68 mg/L
<i>Salmo gairdneri</i> (Trout)	OECD	NOEC	96 Hours	>1000 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Neomycin Sulfate

Activated sludge	OECD	EC50	399 mg/L
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Persistence and Degradability:

No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Neomycin Sulfate

Predicted	7.4	Log D	1.20
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Mobility in Soil:

No data available

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13. DISPOSAL CONSIDERATIONS

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 waste water 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.

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.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Hydrocortisone acetate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS/ELINCS List	Schedule 3 200-004-4

Mineral oil

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-384-2

Neomycin Sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity 10/1/1992 internal use
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-773-1

Polymyxin B sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
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15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	215-774-7
Water, purified	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Poloxamer 188	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
White petrolatum	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 28.
REACH - Carcinogens Category 2:	Present
EU EINECS/ELINCS List	232-373-2
Propylene glycol	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0
Emulsifying wax	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Methylparaben	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

Additional Information:

White petrolatum is not classified as a carcinogen. Nota N applies since the full refining history is known and it can be shown that the substances from which the petroleum jelly was produced are not a carcinogen.

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16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Carcinogenicity-Cat.1B; H350 - May cause cancer
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 23-Oct-2018
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

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.

End of Safety Data Sheet