



# SAFETY DATA SHEET

Revision date: 22-May-2015

Version: 2.0

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

### Product Identifier

**Material Name:** CORTISPORIN Ophthalmic Suspension Sterile  
(neomycin and polymyxin B sulfates and hydrocortisone ophthalmic suspension, USP)

**Trade Name:** CORTISPORIN  
**Synonyms:** Neomycin and polymyxin B sulfates and hydrocortisone ophthalmic suspension, USP  
**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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Other Hazards** No data available  
**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**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	EU Classification	GHS Classification	%
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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Cetyl alcohol	36653-82-4	253-149-0	Not Listed	Not Listed	*
Glyceryl monostearate	31566-31-1	250-705-4	Not Listed	Not Listed	*
Hydrocortisone acetate	50-03-3	200-004-4	Not Listed	Not Listed	1
Mineral oil	8012-95-1	232-384-2	Not Listed	Not Listed	*
Neomycin Sulfate	1405-10-3	215-773-1	Xn;R42/43 Repr.Cat.3;R63	Resp. Sens. 1 (H334) Skin Sens.1(H317) Repro. 2 (H361d) Aq. Acute 3 (H402) Aq. Chronic 3 (H412)	0.35
Polymyxin B sulfate	1405-20-5	215-774-7	Xn;R22 Xn;R42 Xi; R43	Acute Tox.4 (H302) Skin Sens.1 (H317) Resp Sens.1 (H334)	0.1
Propylene glycol	57-55-6	200-338-0	Not Listed	Not Listed	*
Sulfuric acid	7664-93-9	231-639-5	C; R35	Skin Corr. 1A (H314)	**
Thimerosal	54-64-8	200-210-4	T+; R26/27/28; R33 N; R50/53	Acute Tox.2 (H300) Acute Tox. 1(H310) STOT RE 2 (H373) Acute Tox.2 (H330) Acute Aquatic 1 (H400) Chronic Aquatic 1 (H410)	0.01

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Polyoxyethylene stearate	9004-99-3	Not Listed	Not Listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	Not Listed	*

**Additional Information:**

\* Proprietary

\*\* to adjust pH

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.

**For the full text of the R phrases and 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.

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**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### 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 CO<sub>2</sub>, 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 fire fighting 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. Clean up 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):** Pharmaceutical drug product

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Cetyl alcohol

Germany - TRGS 900 - TWAs  
20 ppm  
200 mg/m<sup>3</sup>

#### Glyceryl monostearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>  
Lithuania OEL - TWA 5 mg/m<sup>3</sup>  
Sweden OEL - TWAs 5 mg/m<sup>3</sup>

#### Mineral oil

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

#### Neomycin Sulfate

Pfizer OEL TWA-8 Hr: 100 µg/m<sup>3</sup>, Sensitizer

#### Propylene glycol

Australia TWA 150 ppm  
474 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 150 ppm  
470 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>  
Latvia OEL - TWA 7 mg/m<sup>3</sup>  
Lithuania OEL - TWA 7 mg/m<sup>3</sup>

#### Sulfuric acid

ACGIH Threshold Limit Value (TWA) 0.2 mg/m<sup>3</sup>  
Australia STEL 3 mg/m<sup>3</sup>  
Australia TWA 1 mg/m<sup>3</sup>  
Austria OEL - MAKs 0.1 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Belgium OEL - TWA	1 mg/m <sup>3</sup>
Bulgaria OEL - TWA	0.05 mg/m <sup>3</sup>
Cyprus OEL - TWA	0.05 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
	0.05 mg/m <sup>3</sup>
Denmark OEL - TWA	0.05 mg/m <sup>3</sup>
Estonia OEL - TWA	0.05 mg/m <sup>3</sup>
Finland OEL - TWA	0.05 mg/m <sup>3</sup>
France OEL - TWA	0.05 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	0.1 mg/m <sup>3</sup>
Germany (DFG) - MAK	0.1 mg/m <sup>3</sup>
Greece OEL - TWA	0.05 mg/m <sup>3</sup>
Hungary OEL - TWA	0.05 mg/m <sup>3</sup>
Ireland OEL - TWAs	1 mg/m <sup>3</sup>
Japan - OELs - Ceilings	1 mg/m <sup>3</sup>
Latvia OEL - TWA	0.05 mg/m <sup>3</sup>
Lithuania OEL - TWA	0.05 mg/m <sup>3</sup>
Luxembourg OEL - TWA	0.05 mg/m <sup>3</sup>
Malta OEL - TWA	0.05 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.05 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	1 mg/m <sup>3</sup>
Poland OEL - TWA	1 mg/m <sup>3</sup>
	0.05 mg/m <sup>3</sup>
Portugal OEL - TWA	0.2 mg/m <sup>3</sup>
Romania OEL - TWA	0.05 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.1 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.05 mg/m <sup>3</sup>
Spain OEL - TWA	0.05 mg/m <sup>3</sup>
Sweden OEL - TWAs	0.1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	0.1 mg/m <sup>3</sup>
Vietnam OEL - TWAs	1 mg/m <sup>3</sup>

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/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

#### Polymyxin B sulfate

**Pfizer Occupational Exposure Band (OEB):** OEB 2 - Sensitizer (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>, provide additional precautions to protect from skin contact)

#### 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).

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**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Suspension	<b>Color:</b>	No data available.
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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)**

**Polymyxin B sulfate**

No data available

**Hydrocortisone acetate**

No data available

**Water for injection**

No data available

**Neomycin Sulfate**

Predicted 7.4 Log D 1.20

**Sulfuric acid**

No data available

**Cetyl alcohol**

No data available

**Propylene glycol**

No data available

**Mineral oil**

No data available

**Polyoxyethylene stearate**

No data available

**Glyceryl monostearate**

No data available

**Thimerosal**

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:**

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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)

##### Polymyxin B sulfate

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

##### 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
Mouse	Subcutaneous	LD 50	275mg/kg

##### Sulfuric acid

Rat	Oral	LD50	2140 mg/kg
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##### Cetyl alcohol

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### 11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 5000 mg/kg  
Rabbit Dermal LD50 > 2,600 mg/kg  
Mouse Oral LD50 3200 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

#### Glyceryl monostearate

Mouse IP LD50 200 mg/kg

#### Thimerosal

Rat Oral LD50 75 mg/kg  
Mouse Oral LD50 91 mg/kg  
Rat Subcutaneous LD50 98mg/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

##### Sulfuric acid

Eye Irritation Rabbit Severe

##### Propylene glycol

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

##### Mineral oil

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

##### Thimerosal

Eye Irritation Rabbit Mild

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

##### Polyoxymyxin B sulfate

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

##### Neomycin Sulfate

6 Week(s) Dog Oral 100 mg/kg/day NOAEL No effects at maximum dose



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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

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

##### Neomycin Sulfate

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 present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

#### Sulfuric acid

##### IARC:

Group 1 (Carcinogenic to Humans)

### 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)

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### Neomycin Sulfate

Activated sludge OECD EC50 399 mg/L

**Persistence and Degradability:** No data available

### Bio-accumulative Potential:

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

### Neomycin Sulfate

Predicted 7.4 Log D 1.20

**Mobility in Soil:** No data available

## 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. This product contains trace quantities of mercury and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP).

## 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

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

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**15. REGULATORY INFORMATION**

**Cetyl alcohol**

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	253-149-0

**Glyceryl monostearate**

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	250-705-4

**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 Schedule 3
EU EINECS/ELINCS List	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 initial date 10/1/92 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
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	215-774-7

**Polyoxyethylene stearate**

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	Not Listed

**Propylene glycol**

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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

#### Sulfuric acid

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	1000 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	1000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	231-639-5

#### Thimerosal

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 18.
EU EINECS/ELINCS List	200-210-4

#### Water for injection

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

#### 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.

### 16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

## SAFETY DATA SHEET

**Material Name: CORTISPORIN Ophthalmic Suspension Sterile  
(neomycin and polymyxin B sulfates and hydrocortisone  
ophthalmic suspension, USP)  
Revision date: 22-May-2015**

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Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction  
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
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  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects  
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage  
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed  
Acute toxicity, dermal-Cat.1; H310 - Fatal in contact with skin

C - Corrosive  
T+ - Very toxic  
N - Dangerous for the environment  
Xi - Irritant  
Xn - Harmful  
Toxic to Reproduction: Category 3

R22 - Harmful if swallowed.  
R63 - Possible risk of harm to the unborn child.  
R35 - Causes severe burns.  
R33 - Danger of cumulative effects.  
R42/43 - May cause sensitization by inhalation and skin contact.  
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R26/27/28 - Very toxic by inhalation, in contact with skin and 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 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

**Revision date:** 22-May-2015  
Product Stewardship Hazard Communication

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

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**End of Safety Data Sheet**