



MATERIAL SAFETY DATA SHEET

Revision date: 28-Mar-2013

Version: 1.1

Page 1 of 8

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

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Material Name: CORTISPORIN Ointment (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP)

Trade Name:	CORTISPORIN
Synonyms:	Neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP ointment
Chemical Family:	Not applicable
Intended Use:	Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance:	Off-white translucent ointment
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information:	
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) .
Known Clinical Effects:	Drugs of this class may cause hypersensitivity reactions allergic skin rash, kidney toxicity (nephrotoxicity). May cause ototoxicity (harmful effects on the ear).
EU Indication of danger:	Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

MATERIAL SAFETY DATA SHEET

Material Name: CORTISPORIN Ointment (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP)

Revision date: 28-Mar-2013

Page 2 of 8

Version: 1.1

2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Hydrocortisone acetate	50-03-3	200-004-4	Not Listed	1
Neomycin Sulfate	1405-10-3	215-773-1	Xn;R42/43 Repr.Cat.3;R63	0.7
Polymyxin B sulfate	1405-20-5	215-774-7	Xn;R22 Xn;R42/43	0.1
White petrolatum	8009-03-8	232-373-2	Carc. Cat.2;R45	*
Bacitracin Zinc	1405-89-6	215-787-8	Not Listed	1.1

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.
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.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

MATERIAL SAFETY DATA SHEET

Material Name: CORTISPORIN Ointment (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP)

Revision date: 28-Mar-2013

Page 3 of 8

Version: 1.1

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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

General 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.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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)

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)

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.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

MATERIAL SAFETY DATA SHEET

Material Name: CORTISPORIN Ointment (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP)

Revision date: 28-Mar-2013

Page 4 of 8

Version: 1.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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

Physical State:	Ointment	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

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

11. TOXICOLOGICAL INFORMATION

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

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

Neomycin Sulfate

Rat	Oral	LD 50	2750 mg/kg
Mouse	Oral	LD 50	2880 mg/kg
Mouse	Intraperitoneal	LD 50	116 mg/kg
Rat	Subcutaneous	LD 50	633 mg/kg
Mouse	Subcutaneous	LD 50	275 mg/kg

Polymyxin B sulfate

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

Hydrocortisone acetate

Mouse	IP	LD50	2300 mg/kg
Rat	SC	LD50	449 mg/kg

MATERIAL SAFETY DATA SHEET

Material Name: CORTISPORIN Ointment (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP)

Revision date: 28-Mar-2013

Page 5 of 8

Version: 1.1

11. TOXICOLOGICAL INFORMATION

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

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

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

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.

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

Neomycin Sulfate

MATERIAL SAFETY DATA SHEET

Material Name: CORTISPORIN Ointment (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP)

Revision date: 28-Mar-2013

Page 6 of 8

Version: 1.1

12. ECOLOGICAL INFORMATION

Daphnia magna (Water Flea) OECD EC50 48 Hours 68 mg/L

Salmo gairdneri (Trout) OECD NOEC 96 Hours >1000 mg/L

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

Neomycin Sulfate

Activated sludge OECD EC50 3 Hours 399 mg/L

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

EU Symbol: Not classified

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

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.

Hydrocortisone acetate

MATERIAL SAFETY DATA SHEET

Material Name: CORTISPORIN Ointment (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP)

Revision date: 28-Mar-2013

Page 7 of 8

Version: 1.1

15. REGULATORY INFORMATION

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
	Schedule 3
EU EINECS/ELINCS List	200-004-4

Neomycin Sulfate

California Proposition 65	developmental toxicity initial date 10/1/92
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-773-1

Polymyxin B sulfate

Australia (AICS):	Present
EU EINECS/ELINCS List	215-774-7

White petrolatum

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

Bacitracin Zinc

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-787-8

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 mentioned in Section 3

R22 - Harmful if swallowed.
R45 - May cause cancer.
R63 - Possible risk of harm to the unborn child.
R42/43 - May cause sensitization by inhalation and skin contact.

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

Reasons for Revision: Updated Section 2 - Hazard Identification.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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

MATERIAL SAFETY DATA SHEET

Material Name: CORTISPORIN Ointment (neomycin and
polymyxin B sulfates, bacitracin zinc, and hydrocortisone
ointment, USP)

Revision date: 28-Mar-2013

Page 8 of 8

Version: 1.1
