



# MATERIAL SAFETY DATA SHEET

Revision date: 01-Mar-2013

Version: 1.0

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

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**Material Name: PEDIOTIC Suspension Sterile (neomycin and polymyxin B sulfates and hydrocortisone otic suspension, USP)**

<b>Trade Name:</b>	PEDIOTIC
<b>Synonyms:</b>	Neomycin and polymyxin b sulfates and hydrocortisone otic suspension, usp suspension
<b>Chemical Family:</b>	Not applicable
<b>Intended Use:</b>	Pharmaceutical product used as antibiotic agent

## 2. HAZARDS IDENTIFICATION

**Appearance:** suspension

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

**Additional Hazard Information:**

<b>Short Term:</b>	May be harmful if swallowed. May cause allergic reaction (based on components) .
<b>Long Term:</b>	Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus (based on components)
<b>EU Indication of danger:</b>	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.

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### 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	0.35
Polymyxin B sulfate	1405-20-5	215-774-7	Xn;R22 Xn;R42/43	0.1
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Thimerosal	54-64-8	200-210-4	N; R50/53 R33 T+; R26/27/28	0.01
Sulfuric acid	7664-93-9	231-639-5	C;R35	**
Cetyl alcohol	36653-82-4	253-149-0	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*

#### Additional Information:

\* Proprietary

\*\* to adjust pH

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.

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**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.

### 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/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>  
Belgium OEL - TWA 1 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Bulgaria OEL - TWA	1.0 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>

#### Cetyl alcohol

Germany - TRGS 900 - TWAs	20 ppm
	200 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)

#### 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.

#### Personal Protective Equipment:

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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>pH:</b>	4.1		
<b>Polymerization:</b>	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)

##### **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

##### **Thimerosal**

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

##### **Polysorbate 80**

Rat Oral LD50 25 g/kg

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### 11. TOXICOLOGICAL INFORMATION

#### 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

#### Sulfuric acid

Rat Oral LD50 2140 mg/kg

#### Cetyl alcohol

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

#### Propylene glycol

Mouse Oral LD50 22,000 mg/kg  
Rat Oral LD50 20,000 mg/kg  
Rabbit Dermal LD50 20,800 mg/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)

##### Thimerosal

Eye Irritation Rabbit Mild

##### Neomycin Sulfate

Skin Irritation Rabbit Moderate  
Eye Irritation Rabbit Minimal

##### Sulfuric acid

Eye Irritation Rabbit Severe

##### Propylene glycol

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

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

##### Polymyxin 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  
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

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### 11. TOXICOLOGICAL INFORMATION

#### 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)

OSHA:

Listed

### 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

<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	3 Hours	399 mg/L
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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. 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

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

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

### Neomycin Sulfate

California Proposition 65	developmental toxicity initial date 10/1/92
Inventory - United States TSCA - Sect. 8(b)	Present

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### 15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	215-773-1
<b>Polymyxin B sulfate</b>	
Australia (AICS):	Present
EU EINECS/ELINCS List	215-774-7
<b>Propylene glycol</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0
<b>Thimerosal</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-210-4
<b>Water for injection</b>	
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
<b>Sulfuric acid</b>	
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
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
<b>Cetyl alcohol</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	253-149-0
<b>Polysorbate 80</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

**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 R phrases mentioned in Section 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.

**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**