

MATERIAL SAFETY DATA SHEET

Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension USP

Revision Date: 02/20/2008

SECTION 1: PRODUCT IDENTIFICATION

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| Product Name | Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension USP |
| Common Name/Trade Name | Same as above |
| Manufacturer | Paddock Laboratories, Inc. |
| Synonyms | NA |
| Chemical Name | NA |
| Chemical Family | Antibiotic/Corticosteroid |
| Chemical Formula | NA |

SECTION 2: COMPOSITION AND INGREDIENTS

| CHEMICAL NAME | CAS# | % | OSHA PEL | ACGIH TLV |
|----------------------|------------|------|----------------------------|----------------------------|
| Hydrocortisone | 50-23-7 | = 1 | NA | NA |
| Neomycin Sulfate | 1405-10-3 | <1 | NA | NA |
| Polymyxin B Sulfate | 1405-20-5 | <1 | NA | NA |
| Cetyl Alcohol | 36653-82-4 | = 1 | NA | NA |
| Polyoxyl 40 stearate | 9004-99-3 | = 1 | NA | NA |
| Polysorbate 80 | 9005-65-6 | 1 | NA | NA |
| Thimerosol | 54-64-8 | 0.01 | 0.1 mg (Hg)/m ³ | 0.1 mg (Hg)/m ³ |
| Purified Water | 7732-18-5 | = 1 | NA | NA |

SECTION 3: HAZARDS IDENTIFICATION

Eye: Redness, swelling and itching of the eye. Not an ophthalmic suspension. May cause hypersensitivity in some individuals.

Skin: Rash, swelling and itching due to hypersensitivity. Not a topical preparation. It has been shown, though not in humans, that through large doses or prolonged topical administration adrenocorti-costeroids may be systemically adsorbed by pregnant mothers and produce fetal abnormalities.

Ingestion: May be toxic. May cause allergic reaction (hyper-sensitivity) and could result in gastrointestinal irritation. Large doses may induce kidney injury, blood disorders, adrenal gland suppression, Cushing's syndrome, hyper-glycemia, and possibly birth defects in pregnant mothers.

Inhalation: Not likely for a liquid preparation because evaporation at controlled room temperature is minimal. May cause irritation, and repeated or prolonged inhalation of vapors at high concentration can induce central nervous system depression indicated by dizziness, headaches, and drowsiness.

Chronic Effects: Hypersensitization is possible in some individuals. Long term use may cause ototoxicity.

Target Organs: Kidney, skin and brain.

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to Neomycin Sulfate, Polymyxin B Sulfate, Hydrocortisone or any of the components of the product. Anaphylactic cross-reactions may occur for corticosteroids and antibiotics including kanamycin, paromomycin, streptomycin and possibly gentamicin. This medication is contraindicated for patients with herpes simplex, vaccinia and varicella infections. As with other anti-microbial preparations, prolonged use may result in overgrowth of nonsusceptible organisms including, fungi. Appropriate measures should be taken if this occurs. Patients with chronic otitis medius may develop ototoxicity due to Neomycin.

Potential Acute and Chronic Health Effects

Pregnancy Comments

Hydrocortisone appears in the milk of nursing mothers when orally administered, so caution should be exercised when prescribing Neomycin Sulfate, Polymyxin B Sulfate, Hydrocortisone Otic Suspension Non-Buffered. Additional details are available on the package insert or in the Physicians Desk Reference.

SECTION 4: FIRST AID MEASURES

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| Skin Exposure | Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated. |
| Eye Exposure | Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician. |
| Inhalation | Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician. |
| Ingestion | Wash out mouth and drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. Contact physician. |

SECTION 5: FIRE / EXPLOSION HAZARDS & FIREFIGHTING MEASURES

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| Flammability of the Product | NA |
| Auto-ignition Temperature | NA |
| Flash Points | NA |
| Flammable Limits (in air by volume, %) | Lower: NA Upper: NA |
| Fire Extinguishing Equipment | Use extinguishing agent suitable for type of surrounding fire. Water Spray: Will froth if sprayed into burning material Foam: OK Carbon Dioxide: OK Dry Chemical: OK |
| Unusual Fire and Explosion Hazards | Emits toxic fumes; Mercury Vapors (Hg), Sulfur Oxides (SOx), Nitrogen Oxides (NOx), Sodium Oxides (NaOx) when burning |
| Explosion Hazards in presence of Various substances | NA |
| Firefighting Procedures | Firefighters should wear full protective gear including self contained breathing apparatus. Do not spray water into burning material. |

SECTION 6: SPILL AND LEAK PROCEDURES

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| Spills | Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or |
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scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

SECTION 7: HANDLING AND STORAGE

Work and Hygiene Practices

Avoid getting this product ON YOU or IN YOU. Do not eat, drink or smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Storage and Handling Practices

Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.
Store product upright in original containers with the cap tightly closed at a controlled room temperature 15°-30° C (59°- 86° F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls

In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process, which will maintain the dust and vapor, levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

Personal Protection

Respiratory Protection

(29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.
Warning: Do not use air-purifying respirators in oxygen-depleted environments. No respiratory protection is required in the clinical or home environment.

Eye Protection

Safety glasses or goggles.

Hand Protection

Gloves.

Body Protection

Lab coat.

SECTION 9: PHYSICAL / CHEMICAL PROPERTIES

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| Physical state and appearance | White to off-white, flowing suspension |
| Molecular Weight | NA |
| Boiling Point | NA |
| Vapor Density (AIR=1) | NA |
| Vapor Pressure (mm Hg) | NA |
| Melting/Freezing Point | NA |
| pH | NA |
| Water Solubility | Miscible |
| Specific Gravity (Water =1) | 1.0 |
| Water Reactivity | NA |
| Volatility | NA |
| Odor | NA |

SECTION 10: STABILITY AND REACTIVITY

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| Stability | This product is stable. |
| Incompatible Temperature | Extreme heat or cold |
| Incompatible Materials | This product has no incompatibilities except those of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations. |
| Conditions of Instability | NA |
| Hazardous Polymerization | Should not occur |
| Hazardous Decomposition | Mercury vapor, Sulfur oxides (SOX), nitrogen oxides (NOX), sodium oxides (NaOX) and emits toxic fumes. |
| Conditions to Avoid | Extreme heat or cold |

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicity

36653-82-4 **Cetyl Alcohol** (Palmityl alcohol)

May cause irritation to eyes, skin, respiratory tract and gastrointestinal system. Repeated and prolonged exposure may cause hypersensitivity in some individuals. Chemical is a normal constituent of the human body and is considered non-toxic. Gastrointestinal system irritation symptoms are hypermotility and diarrhea. Irritation SKN-HMN 75mg/kg mild. Oral-rat LD50 5 gm/kg.

50-23-7 **Hydrocortisone**

May cause irritation to eyes, skin and respiratory tract. Prolonged or repeated contact can cause hypersensitivity (anaphylactic) in some individuals. May cause allergic reaction if inhaled, ingested or on contact with the skin. Adverse reactions include suppression of adrenal gland secretion, Cushing's syndrome, water retention, electrolyte imbalance, and hyper-glycemia. Studies in animals indicate that topical adrenocorticoids, when used in large amounts, can be systemically absorbed and may cause fetal abnormalities. Human pregnancy studies have not been done. IP-rat LD50 150 mg/kg, SC-rat LD50 449 mg/kg.

1404-04-2 **Neomycin Sulfate**

Prolonged or repeated contact can cause hypersensitivity (anaphylactic) in some individuals. People sensitive to one aminoglycoside antibiotic may also be sensitive to neomycin sulfate. High level overdosage may be toxic to kidneys (nephrotoxicity) and may cause hearing difficulties (ototoxicity) and diminished balance. Oral- rat LD50 2750 mg/kg.

1404-26-8 **Polymyxin B Sulfate**

May cause irritation to skin, mucous membranes and respiratory tract. Prolonged and repeated contact can produce hypersensitivity (anaphylactic) in some individuals. Overexposure may produce dizziness, diminished muscular coordination, kidney damage (nephrotoxicity), and sensory disturbances. This material is not readily adsorbed into the gut and does not present a toxicological hazard. IV- mouse LD50 5.4 mg/kg, IP- mouse 20.5 mg/kg, Oral- mouse 790 mg/kg, SC- mouse LD50 59.5 mg/kg.

9004-99-3 **Polyoxyl 40 Stearate**

Little health hazard. Practically nonirritating to eyes. Inhalation suggested control figure for good hygiene 10 mg/m³. Oral-rat LD50 > 34.8 g/kg.

9005-65-6 Polysorbate 80

Limited toxicity data is available on this chemical. Screening tests indicate that it is not likely to irritate the eyes, skin, respiratory or digestive tract. Skin hypersensitization was not observed in 50 human subjects tested by patch test. The toxicity by ingestion is relatively mild. Oral-rat LD50 >38.0 g/kg. No other symptoms of exposure were recorded.

57-55-6 Propylene Glycol

May cause irritation to respiratory tract, digestive tract, eyes and skin. Prolonged or repeated contact can produce hypersensitivity (anaphylactic) in some individuals causing headache, nausea, dullness, abdominal spasms, vomiting and unconsciousness. Repeated exposure may also cause nystagmus and lymphocytosis. High vapor concentration exposure may cause central nervous system depression with headaches, dizziness and drowsiness. This material is adsorbed by inhalation, ingestion, and through the skin. Kidney injury and blood disorders may occur. Combustible liquid. Oral- rat LD50- 20 g/kg, Skin-rabbit LD50- 20800 mg/kg.

54-64-8 Thimerosal

May cause irritation to mucous membranes of lungs and eyes. Sensitization dermatitis may occur in persons previously exposed. Chemical burns can occur and may cause conjunctivitis in cases of chronic exposure. Contains mercury. Toxic by ingestion and possibly inhalation. Oral-rat LD50 75 mg/kg.

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| Suspected Cancer Agent | No |
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SECTION 12: ECOLOGICAL INFORMATION

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| Environmental Stability | Product administered to patients presents a negligible impact on the environment. |
| Ecotoxicity | NA |
| Products of Biodegradation | The products of degradation are more toxic. |
| Special Remarks | NA |

SECTION 13: WASTE DISPOSAL

Dispose of material according to local, state, and federal regulations.

SECTION 14: TRANSPORTATION INFORMATION

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| DOT classification | Not a DOT controlled material. |
| Identification | NA |
| DOT Label(s) Required | No |

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| SECTION 15: REGULATORY INFORMATION |
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| US SARA Reporting Requirements | <p>SECTION 302 Extremely Hazardous Substances: No Components Listed</p> <p>SECTION 311, 312 Hazard Categories: NA</p> <p>SECTION 313 Toxic Chemicals CAS# 54-64-8: Mercury compounds are subject to the reporting requirements of Section 313 of SARA Title III.</p> |
| Federal and State Regulations | <p>EPA Designations: RCRA Hazardous Waste (40 CFR 261.33) Not Listed</p> <p>FDA Designations: Prescription only medication. NDC No. 0574-4103-10 (10 ml)</p> <p>OSHA Designations: 29 CFR 1910.1000, Table Z Mercury compounds listed</p> |
| U.S. TSCA Inventory Status | NA |

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| SECTION 16: OTHER INFORMATION |
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DEFINITIONS OF ABBREVIATIONS USED:

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| ACGIH | American Conference of Governmental Industry Hygienists |
| CAS | Chemical Abstract Service |
| IARC | International Agency for Research on Cancer |
| IDLH | Immediately Dangerous to Life or Health Level |
| LC₅₀ | Medial Lethal Concentration |
| LD₅₀ | Medial Lethal Dose |
| MSHA | Mine Safety and Health Administration |
| NA | Not Available |
| ND | No Data |
| NE | Not Established |
| NIOSH | National Institute for Occupational Safety and Health |
| NTP | National Toxicology Program |
| OSHA | Occupational Safety and Health Administration |
| PEL | Permissible Exposure Limit |
| SARA | Superfund Amendments and Reauthorization Act |
| STEL | Short Term Exposure Limit |
| TLV | Threshold Limit Value |
| TWA | Time Weighted Average |

SECTION 17: DISCLAIMER

The information contained in this Material Safety Data Sheet has been compiled from reliable sources and is believed to be correct as of the date issued. It is the responsibility of the user to determine the appropriateness and applicability to their situation. Paddock Laboratories, Inc. disclaims any expressed or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental, or consequential damages from use or reliance on the above information.