Schering-Plough Animal Health Corporation
556 Morris Avenue
Summit, NJ 07901

MATERIAL SAFETY DATA SHEET

Schering-Plough urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: **Gentocin Ophthalmic Solution**

SYNONYM(S): Gentamicin Ophthalmic Solution

MSDS NUMBER: SP000375

EMERGENCY NUMBER(S): Schering-Plough Security Control Center (908) 820-6921 (24 hours)

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

SCHERING-PLOUGH MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 629-3657 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time) .

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Solution
Clear, Colorless to light yellow
Odor unknown

May cause allergic reactions in susceptible individuals.

May cause effects to:
kidney
nervous system
ear

POTENTIAL HEALTH EFFECTS:

The health hazard information presented below is for the active ingredient in this product.

Gentamicin sulfate, an active ingredient, is an aminoglycoside antibiotic that acts by inhibiting normal protein synthesis in susceptible bacteria. Gentamicin sulfate may be irritating to the eyes and skin. It may cause damage to the nervous system and kidneys. Balance and hearing problems may occur as well as numbness and convulsions. Gentamicin sulfate may produce severe reactions in persons allergic or sensitized to aminoglycoside antibiotics. Exposure to gentamicin sulfate by individuals already using potent diuretics should be avoided.

Aminoglycosides may cross the placenta and cause fetal harm. There have been reports of total irreversible bilateral congenital deafness in children whose mothers received aminoglycosides including gentamicin during pregnancy. In animal reproduction studies, fetal kidney effects were noted at doses higher than human clincial doses. In other reproductive studies, no effects on fertility or fetal harm were observed. Small amounts of gentamicin have been shown to be excreted in breast milk.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Veterinary product

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

CHEMICAL NAME	CAS NUMBER	PERCENT
Gentamicin Sulfate.	1405-41-0	0.3

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

NOTE TO PHYSICIAN: Gentamicin sulfate is a aminoglycoside antibiotic. Allergic reactions may occur in susceptible individuals. Exposure to gentamicin sulfate by individuals already using potent diuretics should be avoided.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: > 93.3 deg C (> 200 deg F)

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO2), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Keep personnel away from the clean-up area. Wear appropriate personal protective equipment as specified in Section 8.

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:
Store between 2 and 30 deg C (36 and 86 deg F).

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

S-P HEALTH HAZARD CATEGORY (HHC):
Gentamicin Sulfate: The Schering-Plough Health Hazard Category (HHC) for this material is HHC3. Materials in this category are considered high health hazards. Typical occupational exposure limits for materials in this category range between 10-50 mcg/m^3 (8-hr TWA). Health Hazard Categories are intended to be a component of workplace risk assessment. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

HHC/OEG NOTATION(S):
Gentamicin Sulfate: This material has a notation of "A" for its ability to cause immediate allergic hypersensitivity reactions or anaphylaxis.

EXPOSURE CONTROLS:
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
Eye Protection:	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection:	In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance. In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES

No exposure limits are available for the active ingredient(s) or any other hazardous ingredient in this formulation.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Solution
COLOR:	Clear, Colorless to light yellow
ODOR:	Odor unknown
SOLUBILITY:	
Water:	Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
Open flames and high temperatures.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon monoxide. Carbon dioxide (CO2).

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below is for the active ingredient(s) in this product.

ACUTE TOXICITY DATA

INHALATION:
Gentamicin sulfate: LC50: > 0.20 mg/L (rat)
In an acute inhalation toxicity study, rats given 0.20 mg/L (maximum attainable concentration) exhibited labored breathing and eye closure during exposure to gentamicin sulfate. Nasal discharge was noted for several days followed by recovery.

SKIN:
Gentamicin sulfate was slightly irritating to the skin of rabbits (PII 1.0).

EYE:
Eye irritation studies using Gentamicin Ophthalmic Solutions (0.1% and 0.3%) were performed in rabbits. The concentrations tested were non-irritating, no significant changes were observed in the cornea, iris or conjunctivae of any of the animals tested.

ORAL:
Gentamicin sulfate: Oral LD50: > 5000 mg/kg (rat)

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
A subacute (2-week) study was conducted in cynomolgus monkeys with intravenous injections of gentamicin sulfate at dose levels of 2.5 to 30 mg/kg/day. Mortality was observed at 30 mg/kg following administration of the first dose. Clinical observations including hypoactivity, labored breathing, reduced body weight, and renal toxicity resulted from treatment [NOEL: 2.5 mg/kg/day]. No adverse effects were observed in rats given gentamicin sulfate for 20 mg/kg/day for 24 days or in cats given 10 mg/kg/day for 40 days. Gentamicin sulfate administered to dogs at 6 mg/lb/day, 6 days weekly for 3 weeks, caused no detectable kidney damage. At higher doses impairment of equilibrium and renal function were observed in these species.

Oral subchronic (13-14 weeks) studies with gentamicin sulfate were conducted in rats and dogs. Dose levels ranged from 3.9 to 232.8 mg/kg/day in rats and 2 to 120 mg/kg in dogs. Soft stools and abnormal urinalysis (increased ketone bodies), both in the high dose group, were the only effects noted in rats [NOEL: 19.4 mg/kg/day]. In dogs, no adverse clinical reactions were noted and liver and kidney function were normal [NOEL: 120 mg/kg].

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
In rats and guinea pigs, fetal renal abnormalities have been reported after administration of gentamicin to the dam. In guinea pigs, transient renal abnormalities were observed in the fetus after the administration of 4 mg/kg of gentamicin to the mother. In two reproduction studies, rats were administered 75 mg/kg gentamicin (10 to 15 times the human dose) in saline for 12 days from day 10 of gestation to delivery (intraperitoneal injection) or on days 7-11 and 14-18 of pregnancy (intramuscular injection). Adverse effects reported included lesions in the developing kidney, reduced rate of early nephrogenesis, general growth retardation, and alterations of the glomeruli and proximal tubules. Other animal reproduction studies in rats did not exhibit any evidence of impaired fertility or harm to the fetus following exposure to gentamicin sulfate. No adverse effects were observed in the offspring of rabbits given 0.8 to 3.6 mg/kg intramuscularly on gestation days 6 to 16.

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

There are no ecototoxicity data available for this product or its components.

ENVIRONMENTAL DATA

There are no environmental data available for this product or its components.

SECTION 13. DISPOSAL CONSIDERATIONS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

This material or product is not subject to TSCA requirements.

U.S. STATE REGULATIONS

Check state requirements for ingredient listing.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

DEPARTMENT ISSUING MSDS:	Global Safety and Environmental Affairs Occupational and Environmental Toxicology Schering-Plough Corporation 1095 Morris Avenue Union, NJ 07083 USA.
SCHERING-PLOUGH MSDS HELPLINE:	(800) 770-8878 (US and Canada) (908) 629-3657 (Worldwide) Monday to Friday, 9am to 5pm (US Eastern Time) .
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