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MSD Animal Health  
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## MATERIAL SAFETY DATA SHEET

MSD 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:** Optimmune Ophthalmic Ointment

**SYNONYM(S):** Optimmune Ophthalmic Ointment  
None

**MSDS NUMBER:** SP000155

**EMERGENCY NUMBER(S):** (908) 423-6000 (24/7/365) English Only  
Schering-Plough Security Control Center (908) 820-6921 (24 Hours)

**INFORMATION:** +52 (55) 57 28 44 44 (Xochimilco Mexico)

**MERCK SDS HELPLINE:** +1 (908) 473-3371 (Worldwide)  
Monday to Friday, 9am to 5pm (US Eastern Time)

### SECTION 2. HAZARDS IDENTIFICATION

#### EMERGENCY OVERVIEW

Colorless to light yellow  
Ointment  
Odor unknown  
May cause cancer.  
*May cause effects to:*  
immune system  
kidney  
liver

**EU CLASSIFICATION(S):** Carc.Cat.2;R45

#### POTENTIAL HEALTH EFFECTS:

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. However, there are data to describe the toxicological properties of the individual ingredients. The following summary is based upon available information about the individual ingredients of the mixture(s), or of the expected properties of the mixture(s).

Cyclosporine is an immunosuppressive agent. Kidney toxicity is a critical side effect with nearly all patients that receive the drug. Long term treatment of cyclosporine can result in chronic kidney damage. Cyclosporine has been classified as a human carcinogen based on studies in humans, which indicate a causal relationship between exposure to cyclosporine and human cancer.

Effects in animal studies suggest a low order of acute toxicity. Effects seen in repeat dose studies are consistent with the pharmacological immunosuppressive activity of the drug. Kidney and liver effects have been observed at toxic dose levels.

Petrolatum may cause allergic contact dermatitis. Ingestion of petrolatum may cause laxative effects and may result in abdominal cramps and diarrhea. If aspirated, this product may cause lipid pneumonia or lipid granuloma of the lung; however, petrolatum does not present a high risk of aspiration.

### LISTED CARCINOGENS

INGREDIENT	CAS NUMBER	OSHA	IARC	NTP	ACGIH
Cyclosporine	59865-13-3		1	K	

### SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

**PRODUCT USE:** Veterinary product

**CHEMICAL FORMULA:** Mixture.

The formulations for these products are proprietary information. These formulations have the same hazardous profile; however, the presence of hazardous ingredients may vary by formulation. 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

INGREDIENT	CAS NUMBER	EC NUMBER	EU CLASSIFICATION	PERCENT
Cyclosporine	59865-13-3			0.2
Petrolatum	8009-03-8	232-373-2	Carc.Cat.2; R45	50-60

**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.

See section 15 for EU hazard classification symbols and risk and safety phrases.

### 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:** This product contains cyclosporine, an immunosuppressive agent, which is known to cause cancer and kidney damage in humans.

## SECTION 5. FIRE FIGHTING MEASURES

### FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

### SPECIAL FIRE FIGHTING PROCEDURES:

Wear full protective clothing and self-contained breathing apparatus (SCBA).

### SUITABLE EXTINGUISHING MEDIA:

Carbon dioxide (CO<sub>2</sub>), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

### PERSONAL PRECAUTIONS:

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

### 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. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

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 in a cool, dry, well ventilated area.

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

## SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

### 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:** Ointment  
**COLOR:** 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 at ambient temperature.

**INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:**  
 None known.

**HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:**  
 No dangerous decomposition if used according to manufacturer's specifications.

## SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture.

### ACUTE TOXICITY DATA

**ORAL:**  
 Cyclosporine: Oral LD50: 1480 mg/kg (rat)  
 Toxic signs observed during the determination of the oral LD50 in rats included hyperventilation, drowsiness, muscle spasm, piloerection, weight loss and diarrhea.

**DERMAL AND RESPIRATORY SENSITIZATION:**  
 Petrolatum was not a skin sensitizer in guinea pigs.

### REPEAT DOSE TOXICITY DATA

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**SUBCHRONIC / CHRONIC TOXICITY:**

Three month oral toxicity studies in rats and rhesus monkeys and a one year oral toxicity study in dogs were conducted with cyclosporine. Rats dosed at 45 mg/kg/day and greater exhibited serious nephro- and hepatotoxicity. Immunosuppressive activity was observed in rats at 14 mg/kg/day; however, this was attributed to the pharmacological activity of the material and was not considered a toxic effect. There were no signs of toxicity observed in monkeys or dogs at doses up to 300 mg/kg/day except for a high incidence of infectious lesions in dogs which was attributed to the immunosuppressive activity of cyclosporine.

**REPRODUCTIVE / DEVELOPMENTAL TOXICITY:**

Two-generation reproduction and peri and postnatal development studies were conducted in rats and developmental toxicity studies were conducted in rats and rabbits with cyclosporine. No reproductive or developmental toxicity was observed at dose levels that were not maternally toxic. No effect levels were 15 mg/kg/day for reproductive effects, 17 mg/kg/day for developmental effects in rats and 30 mg/kg/day for developmental effects in rabbits.

**MUTAGENICITY / GENOTOXICITY:**

Cyclosporine was negative in a bacterial mutagenicity study (Ames), in mouse and Chinese hamster micronucleus assays, in a chromosome aberration assay in Chinese hamster bone marrow cells, and in a dominant lethal test in male mice. Cyclosporine and its metabolites were negative in V79 Chinese hamster fibroblasts in the HGPRT test system.

**CARCINOGENICITY:**

There was no evidence of carcinogenicity in rats or mice given cyclosporine at doses up to 8 or 16 mg/kg/day, respectively.

There was no evidence of carcinogenicity when petrolatum was given to mice dermally or subcutaneously or in rats intraperitoneally or orally.

<b>SECTION 12. ECOLOGICAL INFORMATION</b>
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**ECOTOXICITY DATA**

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

**ENVIRONMENTAL DATA**

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

<b>SECTION 13. DISPOSAL CONSIDERATIONS</b>
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**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.

<b>SECTION 14. TRANSPORT INFORMATION</b>
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This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

<b>SECTION 15. REGULATORY INFORMATION</b>
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**TSCA LISTING**

INGREDIENT	TSCA
Petrolatum	X

**EUROPEAN UNION REGULATIONS:**

The classification presented below is based on the active ingredient(s) and individual hazardous ingredients in the product formulation.

Indication of Danger: T - Toxic.

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Risk Phrases:  
R45 - May cause cancer.

Safety Phrases:  
S53 - Avoid exposure - obtain special instructions before use.

## 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:**

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**MERCK SDS HELPLINE:**

+1 (908) 473-3371 (Worldwide)  
Monday to Friday, 9am to 5pm (US Eastern Time)

**MSDS CREATION DATE:**

06-Jul-1995

**SIGNIFICANT CHANGES (LAM SUBFORMAT):**

New regional format, New Language (Latin-American Spanish), OEB