

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: Guardian Vaccine

SYNONYM(S): Bovine Rotavirus-Coronavirus Vaccine-Clostridium Perfringens Types C&D-Escherichia Coli Bacterin-Toxoid

MSDS NUMBER: SP001601

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:
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For Poultry: (800) 219-9286

SCHERING-PLOUGH MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time) .

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Oily liquid
White to off-white, Opaque
Odor unknown

May be an aspiration hazard if ingested (mineral oil).
May cause allergic reactions in susceptible individuals.
May be irritating to eyes, skin or respiratory tract.

POTENTIAL HEALTH EFFECTS:

This product is a vaccine for use in animals. This vaccine is not pathogenic to humans or animals. Local irritation to the eyes, skin, or respiratory tract may occur following direct contact or inhalation of the lyophilized product. As with any vaccine, exposure may cause hypersensitivity reactions. Accidental injection may cause local swelling, irritation or necrosis at the injection site. Oral ingestion may cause gastrointestinal effects including nausea, vomiting, and diarrhea.

Ingestion of mineral oil may cause laxative effect, nausea, dehydration or lipid pneumonia. Long-term dermal exposure to mineral oil may cause dermatitis and oil acne.

LISTED CARCINOGENS

This product contains a highly refined grade of mineral oil which is not classified as a carcinogen by IARC or NTP. Fields in the above table that do not contain data indicate that the materials have not been classified as human or animal carcinogens.

ADDITIONAL INFORMATION: The preservatives in the product(s) may cause allergic-type reactions, including anaphylactic shock, in susceptible individuals. Individuals allergic or sensitive to antibiotics similar to those used as preservatives in the formulation(s) may also be sensitive to the product(s).

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Vaccine
CLASS: Killed Virus and Bacteria
CHARACTERISTIC: Killed
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.

The product(s) may contain preservatives, as listed, in concentrations less than 1%.

CHEMICAL COMPOSITION

CHEMICAL NAME	CAS NUMBER	PERCENT
Rotavirus Typ GB.		Varies
Rotavirus Type G10.		Varies
Coronavirus Type 1.		Varies
Coronavirus Type 3.		Varies
Escherichia coli K99 (pili).		Varies
C. perfringens Type C toxoid (inactivated).		Varies
C. perfringens Type D toxoid (inactivated).		Varies
Mineral Oil.	8012-95-1	60-70
Preservatives (Gentamicin and Thimerosal).		< 1

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: Vomiting is contraindicated due to the possibility of aspiration pneumonia. This product is a vaccine. Accidental injection may cause irritation and swelling. This vaccine contains non-degradable mineral oil; the deposited vaccine must be completely drained from the injection site immediately. If left untreated it may cause tissue necrosis. This preparation contains a preservative or antibiotic or both which may cause allergic reactions in susceptible individuals.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

SECTION 5. FIRE FIGHTING MEASURES

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 (CO₂), 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.

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 7 deg C.

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

CHEMICAL NAME	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Mineral Oil.	8012-95-1		5 mg/m ³ Mist.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Oily liquid
COLOR: White to off-white, Opaque
ODOR: Odor unknown
pH: 7.2
SOLUBILITY:
Water: Insoluble

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Mercury.

SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. The information presented below pertains to the following individual ingredients, and not to the mixture(s).

ACUTE TOXICITY DATA

SKIN:
Mineral Oil: Slight irritant

EYE:
Mineral Oil: Moderately irritating.

ORAL:
Mineral Oil: Oral LD50: 22,000 mg/kg (mouse)

SENSITIZATION:
Mineral oil was not a skin sensitizer in guinea pigs.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Female rats received mineral oil in the diet at dosages up to 20,000 ppm for 90 days. Effects observed included increased liver, kidney, and spleen weights, and enlargement of the lymph nodes together with granulomatous lipid granules.

CARCINOGENICITY:
There was no evidence of carcinogenicity in animals exposed to mineral oil mist at 100 mg/m³ or higher for as long as two years.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

This product has not been tested for ecotoxicity.

ENVIRONMENTAL DATA

There are no environmental data available for this product.

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

CHEMICAL NAME	TSCA
Mineral Oil.	Listed

U.S. STATE REGULATIONS

CHEMICAL NAME	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Mineral Oil.					Listed.

CHEMICAL NAME	PARTK	MNRTK	MIRTK	ILRTK	LARTK	RIRTK
Mineral Oil.		Listed.		Listed.		Listed.

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).

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Occupational and Environmental Toxicology
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