# SAFETY DATA SHEETS

## This SDS packet was issued with item:

078848717

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078848725

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

# MATERIAL SAFETY DATA SHEET

*Intervet Schering-Plough Animal Health 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:** **EquiNile with Havlogen**

**SYNONYM(S):** EquiNile with Havlogen
West Nile Virus Vaccine, Killed Flavivirus Chimera

**MSDS NUMBER:** SP002579

**EMERGENCY NUMBER(S):** 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

(908) 423-6000 (24/7/365) English Only
Emergencies - CHEMTREC:
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**INFORMATION:** Animal Health Technical Services:
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**MERCK 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

Liquid
Pinkish White
Odor unknown
May cause allergic reactions in susceptible individuals (preservatives).
Possible risk of harm to the unborn child.
*May cause effects to:*
fetus

**POTENTIAL HEALTH EFFECTS:**

The toxicological properties of this material have not been fully characterized in humans and animals. Therefore, laboratory or process control systems and appropriate work practices should be in place to minimize the potential for inhalation exposure, skin contact, eye contact, or ingestion when working with this material.

This product is a vaccine for use in animals. This vaccine is not pathogenic to humans. Local irritation to the eyes, skin, or respiratory tract may occur following direct contact or inhalation of the product. As with any vaccine, exposure may cause hypersensitivity reactions.

## LISTED CARCINOGENS

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

**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

**CLASS:** Killed Virus

**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.

## CHEMICAL COMPOSITION

| INGREDIENT | CAS NUMBER | PERCENT |
|---|---|---|
| West Nile/Yellow Fever Chimera Virus (Inactivated) | | Varies |
| Glycerin | 56-81-5 | Varies |
| Edetate Disodium | 6381-92-6 | <10 |
| Preservative (Thimerosal) | 54-64-8 | <1 |
| Gentamicin Sulfate (Preservative) | 1405-41-0 | <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.

## SECTION 4. FIRST AID MEASURES

**NOTE TO PHYSICIAN:**

Animal health workers, research workers, and veterinarians who use adjuvanted inactivated bacterins or viral vaccines are at risk for accidental self-inoculations or needle stick exposures. Victims should seek medical treatment at once and inform attending physicians the name(s) of the organism(s) contained in the inactivated bacterin or viral vaccine and type (if contained in the vaccine) of adjuvant used (i.e., oil, aluminum hydroxide, etc.). Adjuvants heighten the immune response by increasing the attraction of white blood cells (neutrophils, macrophages, and lymphocytes) to the vaccination sites.

These types of biologic products can cause adverse allergic or hypersensitivity reactions in humans, sometimes with serious consequences, who have accidentally self-inoculated themselves or have had needle-stick exposures.

Allergic or anaphylactic (Type 1 Hypersensitivities) reactions can be caused by the adjuvants, inactivated bacteria, inactivated viruses, or other bacterin or vaccine components to which accidental needle-stick exposed humans have been previously sensitized. These reactions usually occur shortly after inoculation and are characterized by difficulty in breathing, sometimes rapid skin eruptions, or rashes, and shaking.

Immediate inoculation of epinephrine is recommended to be given by attending physicians to affected humans. These emergency procedures should be followed by other supportive treatments. Delayed-type hypersensitivities may be serious in humans who have accidentally self-inoculated themselves because the hands or fingers are often involved. Clinical signs or symptoms include swelling, redness, pain, and loss of function at the inoculation sites. Microscopically, many of these adverse reactions are characterized by granulomatous inflammation.

Residues of the adjuvanted inactivated bacterins or viral vaccines are often present in the granulomas. Neutrophils are present in the early stages of these reactions, followed by macrophages and lymphocytes. Some of the macrophages may have coalesced to form multinucleated foreign-body type giant cells in granulomas of several weeks duration.

In addition to hypersensitivities, other problems which may be suffered by a victim of accidental self-inoculation or needle stick exposure are contaminated wounds at the injection site, and/or tetanus. Physical trauma of tissues may be caused by the injection needles at the vaccination sites. Accidental injection site(s) should be immediately washed thoroughly with soap and water. Bleeding, if present, from the puncture wound(s) should be encouraged as this helps drain adjuvanted inactivated bacterin(s) and viral vaccine(s) from the inoculation or needle-stick site(s).

Successive conservative treatment with warm packs and bandaging, or splinting, or immobilization of injured parts have been reported by attending physicians. Opening, debridement, and draining of the lesion have also been reported. If a granulomatous nodule persists, or there is excessive swelling and loss of function, surgical excision of the lesions may be the only satisfactory treatment. No treatment or inadequate treatment can result in severe swelling and extensive tissue damage which unfortunately have resulted in immobilization or loss of fingers.

Antibiotics may be a necessary part of the treatment of these injuries as contamination may occur. Animal health workers, research workers, veterinarians, and other people at risk using adjuvanted bacterins or viral vaccines should keep themselves current with tetanus toxoid immunizations. People who have had accidental self-inoculations or needle-stick exposures should be given booster tetanus toxoid vaccinations or primary series of tetanus vaccinations if deemed necessary by attending physicians.

As indicated, the bacteria and viruses in adjuvanted inactivated bacterins and viral vaccines have been killed. Therefore, there should be no concerns involving the causation of infectious diseases by the inactivated organisms in humans. They are noninfectious.

## 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 ($CO_2$), 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:**
Refrigerate. 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.<br><br>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

| INGREDIENT | CAS NUMBER | ACGIH TLV (TWA) | OSHA PEL (TWA) |
|---|---|---|---|
| Glycerin | 56-81-5 | 10 $mg/m^3$ | 15 $mg/m^3$ |

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**FORM:** Liquid
**COLOR:** Pinkish White
**ODOR:** Odor unknown
**pH:** 7 at 100% solution
**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:**
None known.

**HAZARDOUS POLYMERIZATION PRODUCTS / REACTIONS:**
Does not occur.

**HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:**
Mercury (thimerosal).

## SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of this material 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**

**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:**
Thimerosal is a primary skin irritant.

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

**EYE:**
Administration of 8 ug thimerosal into rabbit eyes produced mild irritant effects.

Gentamicin sulfate was slightly irritating to the eyes of rabbits.

**ORAL:**
Thimerosal: Oral LD50: 75 mg/kg (rat); Oral LD50: 91 mg/kg (mouse).

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

**ADDITIONAL INFORMATION:**
Gentamicin sulfate: Intravenous LD50: 96 mg/kg

Gentamicin sulfate: Intramuscular LD50: 371-384 mg/kg (rat)
Clinical signs included hypoactivity, increased water consumption, and irregular respiration. Contains Gentamicin sulfate which is an aminoglycoside. Aminoglycosides are associated with significant nephrotoxicity and neurotoxicity, the latter manifested by ototoxiciy, numbness, and convulsions.

**REPEAT DOSE TOXICITY DATA**

**SUBCHRONIC / CHRONIC TOXICITY:**
Varied, repeated animal studies dosing mice via intraperitoneal and oral exposure for dosing periods ranging from 6 days to 22 weeks with Thimerosal showed effects on blood, spleen, and brain on neocrospy. Increases in humoral immune responses were noted in multiple organs including allergic reactions. Autoimmune reactions were observed in the kidney, ureter, bladder, and respiratory system.

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:**
Rats doses intraperitoneally with as low as 130 mg/kg thimerosal on days 6 through 18 of pregnancy showed effects on fertility: post implantation mortality.

In another study, rats dosed subcutaneously at doses as low as 104 mg/kg for one year showed uterine tumor development as well as tumors at the site of application.

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. Aminoglycosides can cause fetal harm as they can cross the placenta, however, it is not known whether fetal harm or effects on the reproductive capacity can be caused by exposure to gentamicin sulfate by pregnant women.

**MUTAGENICITY / GENOTOXICITY:**
Thimerosal was shown to be mutagenic in varied micronucleus tests, Chinese hamaster ovary DNA damage and sex chromosome loss and nondisjunction assays.

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

## SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

**ECOTOXICITY DATA**

**INGREDIENT ECOTOXICITY**

Thimerosal:
24 - hr LC50 (Oncorrhynchus mykiss): 53.5 to 68.4 mg/L.
48 - hr LC50 (Oncorrhynchus mykiss): 18.6 to 24.2 mg/L.
24 - hr LC50 (Lepomis macrochirus): 87 to 139 mg/L.
48 - hr LC50 (Oncorrhynchus mykiss): 57.6 to 72.2 mg/L.

**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

| INGREDIENT | TSCA |
|---|---|
| Glycerin | X |
| Preservative (Thimerosal) | X |

Substances not included in the table above are TSCA exempt or not regulated under TSCA.

### U.S. STATE REGULATIONS

| INGREDIENT | California Proposition 65 | CARTK | NJRTK | CTRTK | MARTK |
|---|---|---|---|---|---|
| Glycerin | | | 3319 | | X |
| Preservative (Thimerosal) | D | X | | | |

| INGREDIENT | PARTK | MNRTK | MIRTK | RIRTK |
|---|---|---|---|---|
| Glycerin | X | X | | X |
| Preservative (Thimerosal) | X | | X | |

"WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

D: Developmental hazard

## 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 & the Environment
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889

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

**MSDS CREATION DATE:** 05-Jul-2011

**SIGNIFICANT CHANGES (US SUBFORMAT):** New regional format

Intervet
Schering-Plough Animal Health

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

# MATERIAL SAFETY DATA SHEET

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**MSDS NAME:** **EquiNile with Havlogen**

**SYNONYM(S):** EquiNile with Havlogen
West Nile Virus Vaccine, Killed Flavivirus Chimera

**MSDS NUMBER:** SP002579

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### EMERGENCY OVERVIEW

Liquid
Pinkish White
Odor unknown
May cause allergic reactions in susceptible individuals (preservatives).
Possible risk of harm to the unborn child.
*May cause effects to:*
fetus

**POTENTIAL HEALTH EFFECTS:**

The toxicological properties of this material have not been fully characterized in humans and animals. Therefore, laboratory or process control systems and appropriate work practices should be in place to minimize the potential for inhalation exposure, skin contact, eye contact, or ingestion when working with this material.

This product is a vaccine for use in animals. This vaccine is not pathogenic to humans. Local irritation to the eyes, skin, or respiratory tract may occur following direct contact or inhalation of the product. As with any vaccine, exposure may cause hypersensitivity reactions.

## LISTED CARCINOGENS

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

**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

**CLASS:** Killed Virus

**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.

## CHEMICAL COMPOSITION

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|---|---|---|
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| Glycerin | 56-81-5 | Varies |
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**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.

## SECTION 4. FIRST AID MEASURES

**NOTE TO PHYSICIAN:**

Animal health workers, research workers, and veterinarians who use adjuvanted inactivated bacterins or viral vaccines are at risk for accidental self-inoculations or needle stick exposures. Victims should seek medical treatment at once and inform attending physicians the name(s) of the organism(s) contained in the inactivated bacterin or viral vaccine and type (if contained in the vaccine) of adjuvant used (i.e., oil, aluminum hydroxide, etc.). Adjuvants heighten the immune response by increasing the attraction of white blood cells (neutrophils, macrophages, and lymphocytes) to the vaccination sites.

These types of biologic products can cause adverse allergic or hypersensitivity reactions in humans, sometimes with serious consequences, who have accidentally self-inoculated themselves or have had needle-stick exposures.

Allergic or anaphylactic (Type 1 Hypersensitivities) reactions can be caused by the adjuvants, inactivated bacteria, inactivated viruses, or other bacterin or vaccine components to which accidental needle-stick exposed humans have been previously sensitized. These reactions usually occur shortly after inoculation and are characterized by difficulty in breathing, sometimes rapid skin eruptions, or rashes, and shaking.

Immediate inoculation of epinephrine is recommended to be given by attending physicians to affected humans. These emergency procedures should be followed by other supportive treatments. Delayed-type hypersensitivities may be serious in humans who have accidentally self-inoculated themselves because the hands or fingers are often involved. Clinical signs or symptoms include swelling, redness, pain, and loss of function at the inoculation sites. Microscopically, many of these adverse reactions are characterized by granulomatous inflammation.

Residues of the adjuvanted inactivated bacterins or viral vaccines are often present in the granulomas. Neutrophils are present in the early stages of these reactions, followed by macrophages and lymphocytes. Some of the macrophages may have coalesced to form multinucleated foreign-body type giant cells in granulomas of several weeks duration.

In addition to hypersensitivities, other problems which may be suffered by a victim of accidental self-inoculation or needle stick exposure are contaminated wounds at the injection site, and/or tetanus. Physical trauma of tissues may be caused by the injection needles at the vaccination sites. Accidental injection site(s) should be immediately washed thoroughly with soap and water. Bleeding, if present, from the puncture wound(s) should be encouraged as this helps drain adjuvanted inactivated bacterin(s) and viral vaccine(s) from the inoculation or needle-stick site(s).

Successive conservative treatment with warm packs and bandaging, or splinting, or immobilization of injured parts have been reported by attending physicians. Opening, debridement, and draining of the lesion have also been reported. If a granulomatous nodule persists, or there is excessive swelling and loss of function, surgical excision of the lesions may be the only satisfactory treatment. No treatment or inadequate treatment can result in severe swelling and extensive tissue damage which unfortunately have resulted in immobilization or loss of fingers.

Antibiotics may be a necessary part of the treatment of these injuries as contamination may occur. Animal health workers, research workers, veterinarians, and other people at risk using adjuvanted bacterins or viral vaccines should keep themselves current with tetanus toxoid immunizations. People who have had accidental self-inoculations or needle-stick exposures should be given booster tetanus toxoid vaccinations or primary series of tetanus vaccinations if deemed necessary by attending physicians.

As indicated, the bacteria and viruses in adjuvanted inactivated bacterins and viral vaccines have been killed. Therefore, there should be no concerns involving the causation of infectious diseases by the inactivated organisms in humans. They are noninfectious.

## 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 ($CO_2$), 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.

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**STORAGE:**
Refrigerate. 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.<br><br>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

| INGREDIENT | CAS NUMBER | ACGIH TLV (TWA) | OSHA PEL (TWA) |
|---|---|---|---|
| Glycerin | 56-81-5 | 10 $mg/m^3$ | 15 $mg/m^3$ |

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **FORM:** | Liquid |
| **COLOR:** | Pinkish White |
| **ODOR:** | Odor unknown |
| **pH:** | 7 at 100% solution |
| **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:**
None known.

**HAZARDOUS POLYMERIZATION PRODUCTS / REACTIONS:**
Does not occur.

**HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:**
Mercury (thimerosal).

## SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of this material 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**

**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:**
Thimerosal is a primary skin irritant.

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

**EYE:**
Administration of 8 ug thimerosal into rabbit eyes produced mild irritant effects.

Gentamicin sulfate was slightly irritating to the eyes of rabbits.

**ORAL:**
Thimerosal: Oral LD50: 75 mg/kg (rat); Oral LD50: 91 mg/kg (mouse).

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

**ADDITIONAL INFORMATION:**
Gentamicin sulfate: Intravenous LD50: 96 mg/kg

Gentamicin sulfate: Intramuscular LD50: 371-384 mg/kg (rat)
Clinical signs included hypoactivity, increased water consumption, and irregular respiration. Contains Gentamicin sulfate which is an aminoglycoside. Aminoglycosides are associated with significant nephrotoxicity and neurotoxicity, the latter manifested by ototoxiciy, numbness, and convulsions.

**REPEAT DOSE TOXICITY DATA**

**SUBCHRONIC / CHRONIC TOXICITY:**
Varied, repeated animal studies dosing mice via intraperitoneal and oral exposure for dosing periods ranging from 6 days to 22 weeks with Thimerosal showed effects on blood, spleen, and brain on neocrospy. Increases in humoral immune responses were noted in multiple organs including allergic reactions. Autoimmune reactions were observed in the kidney, ureter, bladder, and respiratory system.

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:**
Rats doses intraperitoneally with as low as 130 mg/kg thimerosal on days 6 through 18 of pregnancy showed effects on fertility: post implantation mortality.

In another study, rats dosed subcutaneously at doses as low as 104 mg/kg for one year showed uterine tumor development as well as tumors at the site of application.

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. Aminoglycosides can cause fetal harm as they can cross the placenta, however, it is not known whether fetal harm or effects on the reproductive capacity can be caused by exposure to gentamicin sulfate by pregnant women.

**MUTAGENICITY / GENOTOXICITY:**
Thimerosal was shown to be mutagenic in varied micronucleus tests, Chinese hamaster ovary DNA damage and sex chromosome loss and nondisjunction assays.

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

## SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

**ECOTOXICITY DATA**

**INGREDIENT ECOTOXICITY**

Thimerosal:
24 - hr LC50 (Oncorrhynchus mykiss): 53.5 to 68.4 mg/L.
48 - hr LC50 (Oncorrhynchus mykiss): 18.6 to 24.2 mg/L.
24 - hr LC50 (Lepomis macrochirus): 87 to 139 mg/L.
48 - hr LC50 (Oncorrhynchus mykiss): 57.6 to 72.2 mg/L.

**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

| INGREDIENT | TSCA |
|---|---|
| Glycerin | X |
| Preservative (Thimerosal) | X |

Substances not included in the table above are TSCA exempt or not regulated under TSCA.

### U.S. STATE REGULATIONS

| INGREDIENT | California Proposition 65 | CARTK | NJRTK | CTRTK | MARTK |
|---|---|---|---|---|---|
| Glycerin | | | 3319 | | X |
| Preservative (Thimerosal) | D | X | | | |

| INGREDIENT | PARTK | MNRTK | MIRTK | RIRTK |
|---|---|---|---|---|
| Glycerin | X | X | | X |
| Preservative (Thimerosal) | X | | X | |

"WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

D: Developmental hazard

## 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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