

SAFETY DATA SHEETS

This SDS packet was issued with item:

078818496

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

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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: PRESTIGE V + WNV with HAVLOGEN

SYNONYM(S): PRESTIGE V + WNV with HAVLOGEN
Encephalomyelitis-Rhinopneumonitis-Influenza-West Nile Virus Vaccine, Eastern & Western, Killed Virus,
Killed Flavivirus Chimera, Tetanus Toxoid

MSDS NUMBER: SP002140

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

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SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Liquid
Pinkish White
Odor unknown
May cause allergic reactions in susceptible individuals.

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 product. Accidental injection may cause local swelling, irritation or necrosis at the injection site. 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:

This product contains a preservative or preservatives which may cause allergic-type reactions, including anaphylactic shock, in susceptible individuals.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS
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PRODUCT USE: Vaccine

CLASS: Killed Virus/Toxoid

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
Eastern Equine Encephalomyelitis Virus (Inactivated)		Varies
West Nile/Yellow Fever Chimera Virus (Inactivated)		Varies
Western Equine Encephalomyelitis (inactivated)		Varies
Equine Herpesvirus Type 1 Virus (Inactivated)		Varies
Equine Influenza Virus (Inactivated)		Varies
Equine Herpesvirus Type 4 Virus (Inactivated)		Varies
C. tetanus toxoid (inactivated)		Varies
Adjuvant	Mixture	10
Glycerin	56-81-5	8-10%
Thimerosal (Preservative)	54-64-8	<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: This product is a vaccine. Accidental injection may cause local swelling, irritation or necrosis at the injection site. This preparation contains a preservative or antibiotic or both which may cause allergic reactions in susceptible individuals.

SECTION 5. FIRE FIGHTING MEASURES
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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 (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:

Refrigerate at 2 to 7 deg C.

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

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

S-P HEALTH HAZARD CATEGORY (HHC):

The Schering-Plough Health Hazard Category (HHC) for this material is HHC3. Materials in this category are considered high health hazards. 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.

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:	<p>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.</p> <p>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.</p>

EXPOSURE LIMIT VALUES

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Glycerin	56-81-5	10 mg/m ³	15 mg/m ³ 5 mg/m ³
Thimerosal (Preservative)	54-64-8	0.01 mg/m ³	0.01 mg/m ³

INGREDIENT	CAS NUMBER	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)	OSHA PEL (STEL / SKIN)	OSHA PEL (CEIL)
Thimerosal (Preservative)	54-64-8	S* 0.03			0.04 mg/m ³

Fields in the above table(s) that do not contain data indicate that exposure limits are not available for those endpoints. S* - Skin Notation

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Liquid
COLOR: Pinkish White
ODOR: Odor unknown
pH: 7.0
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 DECOMPOSITION PRODUCTS / REACTIONS:
Mercury (thimerosal)

SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of this material have not been fully characterized in humans or animals.

ACUTE TOXICITY DATA

This material or product has not been tested for acute toxicity.

INHALATION:

Glycerin: Inhalation LC50 (1hr): >570 mg/m³ [>0.57 mg/L] (rat)

SKIN:

Glycerin: Skin LD50: >10,000 mg/kg (rabbit)
Glycerin was slightly irritating to the skin of rabbits.

EYE:

Glycerin was slightly irritating to the eyes of rabbits.

ORAL:

Glycerin: Oral LD50: 12,600 mg/kg (rat) Glycerin: Practically not toxic

REPEAT DOSE TOXICITY DATA

This product has not been tested for repeat dose toxicity.

MUTAGENICITY / GENOTOXICITY:

Glycerin was negative in a bacterial mutagenicity study (Ames). Glycerin was positive in chromosome aberration studies in rat bone marrow and sperm cells; however, it was negative in an occupational cytogenetics chromosome aberration study.

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

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

INGREDIENT ECOTOXICITY

Glycerin: 96-hr LC50 (trout): 50-67 mg/L
 Glycerin: 96-hr LC50 (goldfish): >5000 mg/L
 Glycerin: Toxicity threshold-cell multiplication inhibition test (algae): 2900 mg/L

ENVIRONMENTAL DATA

There are no environmental data available for these products or their components.

SECTION 13. DISPOSAL CONSIDERATIONS
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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.

SECTION 14. TRANSPORT INFORMATION
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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
Thimerosal (Preservative)	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	CTR TK	MARTK
Glycerin			sn 3319		X
Thimerosal (Preservative)	D	X	sn 2414		X

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

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations. "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

X: Listed on applicable state hazardous substance or right-to-know lists.

D: Developmental hazard

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).

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MSDS CREATION DATE:

09-Oct-2009

SECTIONS CHANGED (US SUBFORMAT):

New SDS

SIGNIFICANT CHANGES (US SUBFORMAT):

New regional format