



MSD Animal Health  
Wim de Körverstraat 35  
5831 AN Boxmeer  
Netherlands

## SAFETY DATA SHEET

MSD 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

**SDS NAME:** ORALVAX-HE

**SYNONYM(S):** ORALVAX-HE  
Hemorrhagic Enteritis Vaccine, Live Virus  
Fowl Pox Vaccine, Live Virus

**SDS Number:** SP000426

**EMERGENCY NUMBER(S):** +1 (908) 423-6000 (24/7/365) English Only  
+31 (0) 485-587777 (MSD Animal Health - Boxmeer, Netherlands)  
EU Transportation Emergencies - Carechem24:  
+44 (0)208 762 8322 (24 hours/7 days/week)

**INFORMATION:** +31 (0) 485-587600 (MSD Animal Health - Boxmeer, Netherlands)

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

**SDS EMAIL:** spmsds@spcorp.com

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### SECTION 2. HAZARDS IDENTIFICATION

This preparation has not been classified as dangerous according to EC Directive 1999/45/EC.

#### EMERGENCY OVERVIEW

Light Brown, Brown-White  
Powder  
Odorless  
May cause allergic reactions in susceptible individuals (preservatives).

#### POTENTIAL HEALTH EFFECTS:

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.

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Latest Revision Date: 12-Oct-2011

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## LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by IARC or EU Directive 90/394 (Annex I) in this mixture.

**ADDITIONAL INFORMATION:** This product contains a preservative which may cause allergic-type reactions, including anaphylactic shock, in susceptible individuals. Individuals allergic or sensitive to antibiotics similar to in this formulation may also be sensitive to this product.

### SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

**PRODUCT USE:** Vaccine  
**CLASS:** Live non-pathogenic virus  
**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.

Each dose contains  $10e2.9$  TCID<sub>50</sub> of hemorrhagic enteritis virus.

### CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	EU CLASSIFICATION	PERCENT
Hemorrhagic enteritis vaccine				Varies
Gentamicin Sulfate (Preservative)	1405-41-0	215-778-9	Repr. Cat.2;R61	<1

Fields in the above table that do not contain data indicate that the substance(s) have not been listed or classified according to EU criteria.

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 is a hemorrhagic enteritis vaccine. Accidental injection may cause local swelling, irritation, or redness at the injection site. This preparation contains preservatives (gentamicin sulfate) which may cause allergic reactions in susceptible individuals. Treat supportively and symptomatically.

### SECTION 5. FIRE FIGHTING MEASURES

#### FLAMMABILITY DATA:

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

**EXPLOSION HAZARDS:**

Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

**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:**

Avoid generation of dust during clean-up. 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****PRECAUTIONS FOR SAFE HANDLING****HANDLING:**

Avoid dust generation. 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.

**CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES****STORAGE:**

Refrigerate.

**SPECIFIC END USE(S)**

Refer to Section 1 for identified use(s).

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

<b>FORM:</b>	Powder
<b>COLOR:</b>	Light Brown, Brown-White
<b>ODOR:</b>	Odorless
<b>SOLUBILITY:</b>	
Water:	Not determined

See Section 5 for flammability/explosivity information.

### SECTION 10. STABILITY AND REACTIVITY

#### STABILITY/ REACTIVITY:

Stable under conditions specified in Section 7 of this SDS. No hazardous reactions known.

#### CONDITIONS AND MATERIALS TO AVOID:

Open flames and high temperatures.

#### HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:

No dangerous decomposition is expected if used according to manufacturer's specifications.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### ACUTE TOXICITY DATA

This product has not been tested for acute toxicity.

#### REPEAT DOSE TOXICITY DATA

This product has not been tested for repeat dose toxicity.

#### CARCINOGENICITY:

This material or product has not been evaluated for carcinogenicity.

### SECTION 12. ECOLOGICAL INFORMATION

#### 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.

### SECTION 13. DISPOSAL CONSIDERATIONS

#### WASTE TREATMENT METHODS

##### **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

The following classification is based on available data and is in accordance with European Union criteria.

##### **EUROPEAN UNION REGULATIONS:**

Based on available data, this material or product does not require labelling according to the EC directives. See recommended safety phrases below.

##### Safety Phrases:

S22 - Do not breathe dust.

S24/25 - Avoid contact with skin and eyes.

S36/37 - Wear suitable protective clothing and gloves.

### 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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##### **DEPARTMENT ISSUING MSDS:**

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

##### **MERCK SDS HELPLINE:**

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

##### **MSDS CREATION DATE:**

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##### **SUPERSEDES DATE:**

14-Dec-2009

##### **SIGNIFICANT CHANGES (EU SUBFORMAT):**

New regional format, OEB