

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078575648

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

078929130



## MATERIAL SAFETY DATA SHEET

Product Id: West Nile Innovator + EW

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Code: RM1000196

Product Name: West Nile Innovator + EW

Common Name: West Nile Encephalitis Virus, Equine Encephalomyelitis Virus (Eastern and Western strains), Equine Influenza Virus (Prague 56 and Kentucky 97 strains), killed virus vaccine

Supplier: Fort Dodge Animal Health  
800 5th Street NW  
PO Box 518  
Fort Dodge, IA 50501

General Information No.: (515) 955-4600  
Emergency Telephone No.: (515) 955-6033

Emergency Telephone Number: (800) 424-9300

General Telephone Number: (515) 955-4600

Prepared By: Environmental, Health + Safety

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

| Components  | Weight %     | ACGIH TWA: | CAS-No. | Wyeth OEG:      | Units for TWAs, STELs, ACGIH, OSHA: |
|---|--------------|------------|---------|-----------------|-------------------------------------|
| Killed virus<br>None  | Unknown      | None       | NA      | Not Established | mg/m3                               |
| Adjuvant  | Trade secret | None       | NA      | Not Established | mg/m3                               |
| May contain thimerosal, neomycin, formalin, polymyxin B and/or amphotericin B as a preservative | <0.01        | None       | Various | Not Established | mg/m3                               |

### 3. HAZARDS IDENTIFICATION

Inhalation: Inhalation exposure is unlikely when product is used as directed in a well-ventilated space.

Skin Contact: None known. If product contacts skin, wash thoroughly with soap and water.

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Seek medical attention if symptoms occur.

**Ingestion:** Seek medical attention immediately. Provide physician with MSDS, package insert, and product container.

**Eye Contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical attention. May cause eye irritation.

#### 4. FIRST AID MEASURES

**Eye Contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical attention. May cause eye irritation.

**Skin Contact:** No known effect. After contact with skin, wash immediately with plenty of water.

**Inhalation:** No specific data. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek medical attention.

**Ingestion:** If ingested, seek medical advice immediately and show the container or the label.

**Aggravated Conditions:** None known.

**Notes to Physician:** For self-inoculation, immediately wash injection site with soap and water. Bleeding, if present, from the puncture wound should be encouraged. Direct treatment at control of symptoms.

#### 5. FIRE FIGHTING MEASURES

**Extinguishing Media and Fire Fighting Instructions:** Aqueous solutions are non-flammable. Use DRY chemicals, CO2, water spray or alcohol foam.

**Special Hazards:** None. Dispose of fire debris and contaminated fire fighting water in accordance with regulations.

**Personal Protective Equipment:** No special precautions or equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

**Methods For Cleaning Up:** Absorb with an inert material and place in an appropriate waste disposal container.

**Personal Precautions:** Put on appropriate personal protective equipment (see Section 8).

**Environmental Precautions:** Dike spill area and do not allow product to reach sewage system and surface or ground water.

#### 7. HANDLING AND STORAGE

##### Handling

**Technical Measures/Precautions:** No special technical measures required when product is used as directed on label or package insert.

**Safe Handling Advice:** No special precautions required. Avoid contact with eyes. After handling, always

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wash hands thoroughly with soap and water.

#### Storage

**Technical Measures/Storage Conditions:**

Keep only in original container. Keep at temperature not exceeding 7°C. Keep out of the reach of children.

**Incompatible Products:**

No information available

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Engineering Measures:**

No special measures required.

#### Personal Protective Equipment

**Respiratory Protection:**

A respirator is not needed under normal and intended conditions of product use.

**Hand Protection:**

Latex gloves

**Skin and Body Protection:**

Gloves, Latex. Wear overalls or long sleeved shirt and long trousers.

**Eye Protection:**

Safety glasses with side-shields.

**Hygiene Measures:**

Avoid contact with skin, eyes and clothing.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Color:**

Reddish-white

**Odor:**

Odorless

**pH:**

6 - 8

**Boiling Point/Range:**

Not applicable

**Melting Point/Range:**

Not determined

**Density:**

Not determined

**Vapor Density:**

not determined

**Physical State:**

Opaque liquid

**Vapor Pressure:**

not determined

**Viscosity**

Not applicable

**Partition Coefficient:**

Not applicable

**Solubility:**

Easily soluble in cold water, hot water. methanol n-octanol Acetone Diethyl ether

**Solubility in Other Solvents:**

None known

**Flash Point:**

Not applicable

**Explosion limits**

**- upper**

no data available

**- lower**

no data available

**Autoignition Temperature:**

Not applicable

**Decomposition Temperature:**

Not applicable

**Dust Explosivity**

Not applicable.

### 10. STABILITY AND REACTIVITY

**Stability:**

Stable.

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**Conditions to Avoid:** This product is stable.

**Materials to Avoid:** None

**Polymerization:** None known

**Hazardous Decomposition Products:** None

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity:**

**LC50/Inhalation/rat =** not determined

**Principle Routes of Exposure:** None

**Eye Contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical attention. May cause eye irritation.

**Skin Contact:** None known. If product contacts skin, wash thoroughly with soap and water. Seek medical attention if symptoms occur.

**Ingestion:** Seek medical attention immediately. Provide physician with MSDS, package insert, and product container.

**Inhalation:** No evidence of risk in humans.

**Chronic Toxicity:**

**Target Organs** None

**Specific Effects:** Not determined

**Sensitization:** Not known to be a skin sensitizer.

**Carcinogenic Effects:** There are no known effects from chronic exposure to this product. No evidence of human carcinogenic effects.

**Mutagenic Effects:** Adverse health effects are considered unlikely when the product is administered according to label directions.

**Teratogenic Effects:** No evidence of risk in humans. No known human teratogenic effect.

**Reproductive Toxicity:** Not considered to be toxic for the reproductive system.

**Aggravated Conditions:** None known.

## 12. ECOLOGICAL INFORMATION

**Environmental Fate:** Not evaluated. No known significant effects or critical hazards.

**Environmental Hazards:** None

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|                                   |  |
|-----------------------------------|--|
| <b>Ecotoxicity Effects:</b>       | This product has no known eco-toxicological effects.   |
| <b>Aquatic Toxicity:</b>          | Not determined.  |
| <b>Mobility:</b>                  | No data available  |
| <b>Bioaccumulation:</b>           | Not determined   |
| <b>Environmental Precautions:</b> | Dike spill area and do not allow product to reach sewage system and surface or ground water. |

### 13. DISPOSAL CONSIDERATIONS

|                                |  |
|--------------------------------|--|
| <b>Waste/Unused Products:</b>  | Waste must be disposed of in accordance with federal, state and local environmental control regulations. |
| <b>Contaminated Packaging:</b> | Not applicable   |

### 14. TRANSPORT INFORMATION

#### DOT (Road/Rail Transport)

|                                       |                 |
|---------------------------------------|-----------------|
| <b>UN/ID Number:</b>                  | Not controlled. |
| <b>Proper Shipping Name:</b>          | Not controlled. |
| <b>Hazard Class:</b>                  | Not controlled. |
| <b>Packing Group:</b>                 | Not controlled. |
| <b>DOT Reportable Quantity (lbs):</b> | Not controlled. |
| <b>Marine Pollutant:</b>              | No              |

#### ICAO/IATA (Air Transport):

|                              |                 |
|------------------------------|-----------------|
| <b>UN/ID Number:</b>         | Not controlled. |
| <b>Proper Shipping Name:</b> | Not controlled. |
| <b>Hazard Class:</b>         | Not controlled. |
| <b>Packing Group:</b>        | Not controlled. |

#### IMO/IMDG (Maritime Transport):

|                          |                 |
|--------------------------|-----------------|
| <b>UN/ID Number:</b>     | Not controlled. |
| <b>Hazard Class:</b>     | Not controlled. |
| <b>Packing Group:</b>    | Not controlled. |
| <b>Marine Pollutant:</b> | No              |

### 15. REGULATORY INFORMATION

|                           |                |
|---------------------------|----------------|
| <b>Other Regulations:</b> | Not controlled |
|---------------------------|----------------|

### 16. OTHER INFORMATION

|                       |                          |
|-----------------------|--------------------------|
| <b>Revision Date:</b> | 6/1/2007                 |
| <b>Product Name:</b>  | West Nile Innovator + EW |

**Additional Advice:** Use this product only in accordance with the directions provided on the product label or the package insert.

The information provided in this MSDS is based on current knowledge. However, this does not constitute a warranty by the Company for that information. The product user is responsible for the appropriate and intended handling, use, and disposal of this product in accordance with label or package insert precautions and this information. All materials may present unknown hazards and should be used with caution.

\*\*\* End of Safety Data Sheet \*\*\*

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Product Name: West Nile Innovator + EW

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** West Nile Innovator + EW

**Trade Name:** West Nile Innovator

**Synonyms:** West Nile Encephalitis Virus, Equine Encephalomyelitis Virus (Eastern and Western strains), Equine Influenza Virus (Prague 56 and Kentucky 97 strains), killed virus vaccine

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary Vaccine

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison Control Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Reddish-white liquid

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Not Classified

**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

**Short Term:** May cause eye irritation. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

## Hazardous

| Ingredient     | CAS Number | EU EINECS/ELINCS List | EU Classification                                | GHS Classification   | %  |
|----------------|------------|-----------------------|--|--|----|
| Formaldehyde   | 50-00-0    | 200-001-8             | T; R23/24/25<br>C; R34<br>Carc.Cat.3; R40<br>R43 | Acute Tox. 3<br>(H301)<br>Skin Corr. 1B<br>(H314)<br>Skin Sens. 1<br>(H317)<br>Carc. 1A (H350)<br>Acute Tox. 3<br>(H331)                                   | ## |
| Thimerosal     | 54-64-8    | 200-210-4             | T+; R26/27/28;<br>R33<br>N; R50/53               | Acute Tox. 2<br>(H300)<br>Acute Tox. 1<br>(H310)<br>STOT RE 2 (H373)<br>Acute Tox. 2<br>(H330)<br>Acute Aquatic 1<br>(H400)<br>Chronic Aquatic 1<br>(H410) | ## |
| Amphotericin B | 1397-89-3  | 215-742-2             | Not Listed                                       | Not Listed   | ## |
| Neomycin B     | 119-04-0   | 204-292-2             | Xn;R22<br>Xn;R42/43<br>Repr.Cat.3;R63            | Acute Tox. 4;H302<br>Resp. Sens.<br>1;H334<br>Skin Sens.1;H317<br>Repr.2;H361  | ## |
| Polymyxin B    | 1404-26-8  | 215-768-4             | Xn;R22<br>Xn;R42/43                              | Acute Tox. 4<br>(H302)<br>Skin Sens. 1<br>(H317)<br>Resp Sens. 1<br>(H334)   | ## |

| Ingredient                                | CAS Number   | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---|--------------|-----------------------|-------------------|--------------------|---|
| Equine Influenza Virus (Prague 56 strain) | Not assigned | Not Listed            | Not Listed        | Not Listed         | * |
| Adjuvant                                  | NA           | Not Listed            | Not Listed        | Not Listed         | * |
| EASTERN EQUINE ENCEPHALOMYELITIS          | Not Assigned | Not Listed            | Not Listed        | Not Listed         | * |
| WESTERN EQUINE ENCEPHALOMYELITIS          | Not Assigned | Not Listed            | Not Listed        | Not Listed         | * |
| Equine Influenza Virus, Kentucky 97 (EIV) | Not Assigned | Not Listed            | Not Listed        | Not Listed         | * |
| West Nile Virus, killed                   | Not assigned | Not Listed            | Not Listed        | Not Listed         | * |

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**Additional Information:** \* Proprietary  
## Trace  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of the spill if it is safe to do so. Wipe up with a damp cloth and place in container for disposal. Clean contaminated surface thoroughly.

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**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment. Avoid accidental injection.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Formaldehyde

|   |   |
|---|---|
| ACGIH Ceiling Threshold Limit:          | 0.3 ppm   |
| ACGIH - Sensitizer Designation          | Sensitizer  |
| Australia STEL                          | 2 ppm   |
|   | 2.5 mg/m <sup>3</sup>   |
| Australia TWA                           | 1 ppm   |
|   | 1.2 mg/m <sup>3</sup>   |
| Austria OEL - MAKs                      | 0.5 ppm   |
|   | 0.6 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                      | 1.0 mg/m <sup>3</sup>   |
| Czech Republic OEL - TWA                | 0.5 mg/m <sup>3</sup>   |
| Estonia OEL - TWA                       | 0.5 ppm   |
|   | 0.6 mg/m <sup>3</sup>   |
| Finland OEL - TWA                       | 0.3 ppm   |
|   | 0.37 mg/m <sup>3</sup>  |
| France OEL - TWA                        | 0.5 ppm   |
| Germany (DFG) - MAK                     | 0.3 ppm   |
|   | 0.37 mg/m <sup>3</sup> no irritation should occur during mixed exposure |
| Greece OEL - TWA                        | 2 ppm   |
|   | 2.5 mg/m <sup>3</sup>   |
| Hungary OEL - TWA                       | 0.6 mg/m <sup>3</sup>   |
| Ireland OEL - TWAs                      | 2 ppm   |
|   | 2.5 mg/m <sup>3</sup>   |
| Japan - OELs - Ceilings                 | 0.2 ppm   |
|   | 0.24 mg/m <sup>3</sup>  |
| Latvia OEL - TWA                        | 0.5 mg/m <sup>3</sup>   |
| Lithuania OEL - TWA                     | 0.5 ppm   |
|   | 0.6 mg/m <sup>3</sup>   |
| Netherlands OEL - TWA                   | 0.15 mg/m <sup>3</sup>  |
| Vietnam OEL - TWAs                      | 0.5 mg/m <sup>3</sup>   |
| OSHA - Final PELs - TWAs:               | 0.75 ppm  |
| OSHA - Specifically Regulated Chemicals | 2 ppm   |
|   | 0.5 ppm   |
|   | 0.75 ppm  |

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                       |                        |
|-----------------------|------------------------|
| Poland OEL - TWA      | 0.5 mg/m <sup>3</sup>  |
| Romania OEL - TWA     | 1 ppm                  |
|                       | 1.20 mg/m <sup>3</sup> |
| Slovakia OEL - TWA    | 0.3 ppm                |
|                       | 0.37 mg/m <sup>3</sup> |
| Slovenia OEL - TWA    | 0.5 ppm                |
|                       | 0.62 mg/m <sup>3</sup> |
| Sweden OEL - TWAs     | 0.3 ppm                |
|                       | 0.37 mg/m <sup>3</sup> |
| Switzerland OEL -TWAs | 0.3 ppm                |
|                       | 0.37 mg/m <sup>3</sup> |

#### Neomycin B

Zoetis OEL TWA 8-hr 100µg/m<sup>3</sup>Sensitizer

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### Polymyxin B

Zoetis OEB OEB 2 - Sensitizer (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>, provide additional precautions to protect from skin contact)

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

##### Hands:

Wear impervious gloves if skin contact is possible.

##### Eyes:

Safety glasses or goggles

##### Skin:

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

##### Respiratory protection:

If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Liquid

#### Odor:

Odorless

#### Molecular Formula:

Mixture

#### Color:

Reddish

#### Odor Threshold:

No data available.

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

#### Water Solubility:

Soluble

#### pH:

6-8

#### Melting/Freezing Point (°C):

No data available

#### Boiling Point (°C):

No data available.

#### Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

#### Decomposition Temperature (°C):

No data available.

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Evaporation Rate (Gram/s): No data available  
Vapor Pressure (kPa): No data available  
Vapor Density (g/ml): No data available  
Relative Density: No data available  
Viscosity: No data available

### Flammability:

Autoignition Temperature (Solid) (°C): No data available  
Flammability (Solids): No data available  
Flash Point (Liquid) (°C): No data available  
Upper Explosive Limits (Liquid) (% by Vol.): No data available  
Lower Explosive Limits (Liquid) (% by Vol.): No data available

## 10. STABILITY AND REACTIVITY

Reactivity: No data available  
Chemical Stability: Stable under normal conditions of use.  
Possibility of Hazardous Reactions  
Oxidizing Properties: No data available  
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.  
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers  
Hazardous Decomposition Products: No data available

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

**General Information:** Toxicological properties of the formulation have not been fully investigated. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The information included in this section describes the potential hazards of the individual ingredients.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### Thimerosal

Rat Oral LD50 75 mg/kg  
Mouse Oral LD50 91 mg/kg  
Rat Subcutaneous LD50 98mg/kg

#### Neomycin B

Rat Oral LD 50 1250 mg/kg  
Mouse IV LD50 24mg/kg

#### Formaldehyde

Rat Oral LD50 800 mg/kg

#### Polymyxin B

Mouse Oral LD50 790 mg/kg  
Mouse Para-periosteal LD50 3980ug/kg  
Rat Subcutaneous LD50 50mg/kg

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### 11. TOXICOLOGICAL INFORMATION

#### Amphotericin B

Rat Oral LD50 > 5000 mg/kg  
Rat Para-periosteal LD50 1.6mg/kg  
Rat Intraperitoneal LD50 > 5000mg/kg  
Mouse Intravenous LD50 1.2mg/kg  
Mouse Intraperitoneal LD50 27.7mg/kg

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Thimerosal

Eye Irritation Rabbit Mild

##### Formaldehyde

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Moderate Severe  
Skin Sensitization Positive

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Formaldehyde

90 Day(s) Dog Inhalation Not Specified Lungs  
90 Day(s) Rat Inhalation Not Specified Lungs  
90 Day(s) Monkey Inhalation Not Specified Lungs  
90 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

##### Amphotericin B

30 Day(s) Dog Intravenous 37 mg/kg/day LOAEL Kidney  
2 Month(s) Dog Intravenous 16.5 mg/kg/day LOAEL Kidney  
13 Week(s) Rat Oral 2 mg/kg/day NOAEL Male reproductive system, Female reproductive system  
13 Week(s) Dog Oral 1.6 mg/kg/day NOAEL Male reproductive system, Female reproductive system

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Formaldehyde

Embryo / Fetal Development Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity  
Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

##### Amphotericin B

Embryo / Fetal Development Rat Oral 7.5 mg/kg/day NOAEL Not teratogenic, Fetotoxicity  
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Formaldehyde

*In Vitro* Bacterial Mutagenicity (Ames) Bacteria Positive  
*In Vitro* Chromosome Aberration Rodent Positive  
*In Vitro* Sister Chromatid Exchange Rodent Positive  
*In Vivo* Chromosome Aberration Not specified Positive

##### Polymyxin B

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### 11. TOXICOLOGICAL INFORMATION

*In Vitro* Negative

*In Vivo* Negative

#### Amphotericin B

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

*In Vivo* Micronucleus Mouse Negative

*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors

2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

#### Carcinogen Status:

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

#### Formaldehyde

IARC: Group 1 (Carcinogenic to Humans)

NTP: Known Human Carcinogen

OSHA: Listed

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

Environmental properties have not been thoroughly investigated. This product contains trace quantities of mercury, releases to the environment should be avoided.

#### Toxicity:

No data available

#### Persistence and Degradability:

No data available

#### Bio-accumulative Potential:

No data available

#### Mobility in Soil:

No data available

### 13. DISPOSAL CONSIDERATIONS

#### Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. This product contains trace quantities of mercury and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP).

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### Formaldehyde

RCRA - U Series Wastes

Listed

## 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

WHMIS hazard class:

None required

#### Equine Influenza Virus (Prague 56 strain)

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

EU EINECS/ELINCS List

Not Listed

#### Formaldehyde

CERCLA/SARA 313 Emission reporting

0.1 %

CERCLA/SARA Hazardous Substances  
and their Reportable Quantities:

100 lb

45.4 kg

CERCLA/SARA - Section 302 Extremely Hazardous  
TPQs

500 lb

CERCLA/SARA - Section 302 Extremely Hazardous  
Substances EPCRA RQs

100 lb

California Proposition 65

carcinogen initial date 1/1/88 gas

OSHA - Specifically Regulated Chemicals

2 ppm

0.5 ppm

0.75 ppm

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

Standard for the Uniform Scheduling  
for Drugs and Poisons:

Schedule 2

Schedule 6

EU EINECS/ELINCS List

200-001-8

#### Thimerosal

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

developmental toxicity initial date 7/1/90



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### 15. REGULATORY INFORMATION

|  |                              |
|--|------------------------------|
| Inventory - United States TSCA - Sect. 8(b)                        | Present                      |
| Australia (AICS):  | Present                      |
| REACH - Annex XVII - Restrictions on Certain Dangerous Substances: | Use restricted. See item 18. |
| EU EINECS/ELINCS List  | 200-210-4                    |
| <b>Adjuvant</b>  |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | Not Listed                   |
| <b>Amphotericin B</b>  |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| Australia (AICS):  | Present                      |
| Standard for the Uniform Scheduling for Drugs and Poisons:         | Schedule 4                   |
| EU EINECS/ELINCS List  | 215-742-2                    |
| <b>Neomycin B</b>  |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| Australia (AICS):  | Present                      |
| Standard for the Uniform Scheduling for Drugs and Poisons:         | Schedule 4                   |
| EU EINECS/ELINCS List  | 204-292-2                    |
| <b>EASTERN EQUINE ENCEPHALOMYELITIS</b>                            |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | Not Listed                   |
| <b>WESTERN EQUINE ENCEPHALOMYELITIS</b>                            |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | Not Listed                   |
| <b>Equine Influenza Virus, Kentucky 97 (EIV)</b>                   |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | Not Listed                   |
| <b>West Nile Virus, killed</b>                                     |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | Not Listed                   |
| <b>Polymyxin B</b>   |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | 215-768-4                    |

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Material Name: West Nile Innovator + EW  
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### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H302 - Harmful if swallowed  
H317 - May cause an allergic skin reaction  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H301 - Toxic if swallowed  
H314 - Causes severe skin burns and eye damage  
H350 - May cause cancer  
H331 - Toxic if inhaled  
H300 - Fatal if swallowed  
H310 - Fatal in contact with skin  
H373 - May cause damage to organs through prolonged or repeated exposure  
H400 - Very toxic to aquatic life  
H410 - Very toxic to aquatic life with long lasting effects  
H361 - Suspected of damaging fertility or the unborn child  
H330 - Fatal if inhaled

Xn - Harmful  
T - Toxic  
C - Corrosive  
Carcinogenic: Category 3  
T+ - Very toxic  
N - Dangerous for the environment  
Toxic to Reproduction: Category 3

R22 - Harmful if swallowed.  
R34 - Causes burns.  
R40 - Limited evidence of a carcinogenic effect  
R33 - Danger of cumulative effects.  
R63 - Possible risk of harm to the unborn child.  
R42/43 - May cause sensitization by inhalation and skin contact.  
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.  
R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.  
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 16 - Other Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**

# SAFETY DATA SHEET



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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** West Nile Innovator + EW

**Trade Name:** West Nile Innovator

**Synonyms:** West Nile Encephalitis Virus, Equine Encephalomyelitis Virus (Eastern and Western strains), Equine Influenza Virus (Prague 56 and Kentucky 97 strains), killed virus vaccine

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary Vaccine

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison Control Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Reddish-white liquid

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Not Classified

**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

**Short Term:** May cause eye irritation. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

## Hazardous

| Ingredient     | CAS Number | EU EINECS/ELINCS List | EU Classification                                | GHS Classification   | %  |
|----------------|------------|-----------------------|--|--|----|
| Formaldehyde   | 50-00-0    | 200-001-8             | T; R23/24/25<br>C; R34<br>Carc.Cat.3; R40<br>R43 | Acute Tox. 3<br>(H301)<br>Skin Corr. 1B<br>(H314)<br>Skin Sens. 1<br>(H317)<br>Carc. 1A (H350)<br>Acute Tox. 3<br>(H331)                                   | ## |
| Thimerosal     | 54-64-8    | 200-210-4             | T+; R26/27/28;<br>R33<br>N; R50/53               | Acute Tox. 2<br>(H300)<br>Acute Tox. 1<br>(H310)<br>STOT RE 2 (H373)<br>Acute Tox. 2<br>(H330)<br>Acute Aquatic 1<br>(H400)<br>Chronic Aquatic 1<br>(H410) | ## |
| Amphotericin B | 1397-89-3  | 215-742-2             | Not Listed                                       | Not Listed   | ## |
| Neomycin B     | 119-04-0   | 204-292-2             | Xn;R22<br>Xn;R42/43<br>Repr.Cat.3;R63            | Acute Tox. 4;H302<br>Resp. Sens.<br>1;H334<br>Skin Sens.1;H317<br>Repr.2;H361  | ## |
| Polymyxin B    | 1404-26-8  | 215-768-4             | Xn;R22<br>Xn;R42/43                              | Acute Tox. 4<br>(H302)<br>Skin Sens. 1<br>(H317)<br>Resp Sens. 1<br>(H334)   | ## |

| Ingredient                                | CAS Number   | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---|--------------|-----------------------|-------------------|--------------------|---|
| Equine Influenza Virus (Prague 56 strain) | Not assigned | Not Listed            | Not Listed        | Not Listed         | * |
| Adjuvant                                  | NA           | Not Listed            | Not Listed        | Not Listed         | * |
| EASTERN EQUINE ENCEPHALOMYELITIS          | Not Assigned | Not Listed            | Not Listed        | Not Listed         | * |
| WESTERN EQUINE ENCEPHALOMYELITIS          | Not Assigned | Not Listed            | Not Listed        | Not Listed         | * |
| Equine Influenza Virus, Kentucky 97 (EIV) | Not Assigned | Not Listed            | Not Listed        | Not Listed         | * |
| West Nile Virus, killed                   | Not assigned | Not Listed            | Not Listed        | Not Listed         | * |

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**Additional Information:** \* Proprietary  
## Trace  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of the spill if it is safe to do so. Wipe up with a damp cloth and place in container for disposal. Clean contaminated surface thoroughly.

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**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment. Avoid accidental injection.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Formaldehyde

|   |   |
|---|---|
| ACGIH Ceiling Threshold Limit:          | 0.3 ppm   |
| ACGIH - Sensitizer Designation          | Sensitizer  |
| Australia STEL                          | 2 ppm   |
|   | 2.5 mg/m <sup>3</sup>   |
| Australia TWA                           | 1 ppm   |
|   | 1.2 mg/m <sup>3</sup>   |
| Austria OEL - MAKs                      | 0.5 ppm   |
|   | 0.6 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                      | 1.0 mg/m <sup>3</sup>   |
| Czech Republic OEL - TWA                | 0.5 mg/m <sup>3</sup>   |
| Estonia OEL - TWA                       | 0.5 ppm   |
|   | 0.6 mg/m <sup>3</sup>   |
| Finland OEL - TWA                       | 0.3 ppm   |
|   | 0.37 mg/m <sup>3</sup>  |
| France OEL - TWA                        | 0.5 ppm   |
| Germany (DFG) - MAK                     | 0.3 ppm   |
|   | 0.37 mg/m <sup>3</sup> no irritation should occur during mixed exposure |
| Greece OEL - TWA                        | 2 ppm   |
|   | 2.5 mg/m <sup>3</sup>   |
| Hungary OEL - TWA                       | 0.6 mg/m <sup>3</sup>   |
| Ireland OEL - TWAs                      | 2 ppm   |
|   | 2.5 mg/m <sup>3</sup>   |
| Japan - OELs - Ceilings                 | 0.2 ppm   |
|   | 0.24 mg/m <sup>3</sup>  |
| Latvia OEL - TWA                        | 0.5 mg/m <sup>3</sup>   |
| Lithuania OEL - TWA                     | 0.5 ppm   |
|   | 0.6 mg/m <sup>3</sup>   |
| Netherlands OEL - TWA                   | 0.15 mg/m <sup>3</sup>  |
| Vietnam OEL - TWAs                      | 0.5 mg/m <sup>3</sup>   |
| OSHA - Final PELs - TWAs:               | 0.75 ppm  |
| OSHA - Specifically Regulated Chemicals | 2 ppm   |
|   | 0.5 ppm   |
|   | 0.75 ppm  |

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                       |                        |
|-----------------------|------------------------|
| Poland OEL - TWA      | 0.5 mg/m <sup>3</sup>  |
| Romania OEL - TWA     | 1 ppm                  |
|                       | 1.20 mg/m <sup>3</sup> |
| Slovakia OEL - TWA    | 0.3 ppm                |
|                       | 0.37 mg/m <sup>3</sup> |
| Slovenia OEL - TWA    | 0.5 ppm                |
|                       | 0.62 mg/m <sup>3</sup> |
| Sweden OEL - TWAs     | 0.3 ppm                |
|                       | 0.37 mg/m <sup>3</sup> |
| Switzerland OEL -TWAs | 0.3 ppm                |
|                       | 0.37 mg/m <sup>3</sup> |

#### Neomycin B

Zoetis OEL TWA 8-hr 100µg/m<sup>3</sup>Sensitizer

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### Polymyxin B

Zoetis OEB OEB 2 - Sensitizer (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>, provide additional precautions to protect from skin contact)

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

##### Hands:

Wear impervious gloves if skin contact is possible.

##### Eyes:

Safety glasses or goggles

##### Skin:

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

##### Respiratory protection:

If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Liquid

#### Odor:

Odorless

#### Molecular Formula:

Mixture

#### Color:

Reddish

#### Odor Threshold:

No data available.

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

#### Water Solubility:

Soluble

#### pH:

6-8

#### Melting/Freezing Point (°C):

No data available

#### Boiling Point (°C):

No data available.

#### Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

#### Decomposition Temperature (°C):

No data available.

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Evaporation Rate (Gram/s): No data available  
Vapor Pressure (kPa): No data available  
Vapor Density (g/ml): No data available  
Relative Density: No data available  
Viscosity: No data available

### Flammability:

Autoignition Temperature (Solid) (°C): No data available  
Flammability (Solids): No data available  
Flash Point (Liquid) (°C): No data available  
Upper Explosive Limits (Liquid) (% by Vol.): No data available  
Lower Explosive Limits (Liquid) (% by Vol.): No data available

## 10. STABILITY AND REACTIVITY

Reactivity: No data available  
Chemical Stability: Stable under normal conditions of use.  
Possibility of Hazardous Reactions  
Oxidizing Properties: No data available  
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.  
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers  
Hazardous Decomposition Products: No data available

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

**General Information:** Toxicological properties of the formulation have not been fully investigated. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The information included in this section describes the potential hazards of the individual ingredients.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### Thimerosal

Rat Oral LD50 75 mg/kg  
Mouse Oral LD50 91 mg/kg  
Rat Subcutaneous LD50 98mg/kg

#### Neomycin B

Rat Oral LD 50 1250 mg/kg  
Mouse IV LD50 24mg/kg

#### Formaldehyde

Rat Oral LD50 800 mg/kg

#### Polymyxin B

Mouse Oral LD50 790 mg/kg  
Mouse Para-periosteal LD50 3980ug/kg  
Rat Subcutaneous LD50 50mg/kg



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### 11. TOXICOLOGICAL INFORMATION

#### Amphotericin B

Rat Oral LD50 > 5000 mg/kg  
Rat Para-periosteal LD50 1.6mg/kg  
Rat Intraperitoneal LD50 > 5000mg/kg  
Mouse Intravenous LD50 1.2mg/kg  
Mouse Intraperitoneal LD50 27.7mg/kg

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Thimerosal

Eye Irritation Rabbit Mild

##### Formaldehyde

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Moderate Severe  
Skin Sensitization Positive

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Formaldehyde

90 Day(s) Dog Inhalation Not Specified Lungs  
90 Day(s) Rat Inhalation Not Specified Lungs  
90 Day(s) Monkey Inhalation Not Specified Lungs  
90 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

##### Amphotericin B

30 Day(s) Dog Intravenous 37 mg/kg/day LOAEL Kidney  
2 Month(s) Dog Intravenous 16.5 mg/kg/day LOAEL Kidney  
13 Week(s) Rat Oral 2 mg/kg/day NOAEL Male reproductive system, Female reproductive system  
13 Week(s) Dog Oral 1.6 mg/kg/day NOAEL Male reproductive system, Female reproductive system

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Formaldehyde

Embryo / Fetal Development Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity  
Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

##### Amphotericin B

Embryo / Fetal Development Rat Oral 7.5 mg/kg/day NOAEL Not teratogenic, Fetotoxicity  
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Formaldehyde

*In Vitro* Bacterial Mutagenicity (Ames) Bacteria Positive  
*In Vitro* Chromosome Aberration Rodent Positive  
*In Vitro* Sister Chromatid Exchange Rodent Positive  
*In Vivo* Chromosome Aberration Not specified Positive

##### Polymyxin B

ZT00284

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### 11. TOXICOLOGICAL INFORMATION

*In Vitro* Negative

*In Vivo* Negative

#### Amphotericin B

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

*In Vivo* Micronucleus Mouse Negative

*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors

2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

#### Carcinogen Status:

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

#### Formaldehyde

IARC: Group 1 (Carcinogenic to Humans)

NTP: Known Human Carcinogen

OSHA: Listed

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

Environmental properties have not been thoroughly investigated. This product contains trace quantities of mercury, releases to the environment should be avoided.

#### Toxicity:

No data available

#### Persistence and Degradability:

No data available

#### Bio-accumulative Potential:

No data available

#### Mobility in Soil:

No data available

### 13. DISPOSAL CONSIDERATIONS

#### Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. This product contains trace quantities of mercury and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP).

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### Formaldehyde

RCRA - U Series Wastes

Listed

## 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

WHMIS hazard class:

None required

#### Equine Influenza Virus (Prague 56 strain)

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

EU EINECS/ELINCS List

Not Listed

#### Formaldehyde

CERCLA/SARA 313 Emission reporting

0.1 %

CERCLA/SARA Hazardous Substances  
and their Reportable Quantities:

100 lb

CERCLA/SARA - Section 302 Extremely Hazardous  
TPQs

45.4 kg

CERCLA/SARA - Section 302 Extremely Hazardous  
Substances EPCRA RQs

500 lb

California Proposition 65

OSHA - Specifically Regulated Chemicals

carcinogen initial date 1/1/88 gas

2 ppm

0.5 ppm

0.75 ppm

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

Standard for the Uniform Scheduling  
for Drugs and Poisons:

Schedule 2

Schedule 6

EU EINECS/ELINCS List

200-001-8

#### Thimerosal

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

developmental toxicity initial date 7/1/90

## SAFETY DATA SHEET

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### 15. REGULATORY INFORMATION

|  |                              |
|--|------------------------------|
| Inventory - United States TSCA - Sect. 8(b)                        | Present                      |
| Australia (AICS):  | Present                      |
| REACH - Annex XVII - Restrictions on Certain Dangerous Substances: | Use restricted. See item 18. |
| EU EINECS/ELINCS List  | 200-210-4                    |
| <b>Adjuvant</b>  |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | Not Listed                   |
| <b>Amphotericin B</b>  |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| Australia (AICS):  | Present                      |
| Standard for the Uniform Scheduling for Drugs and Poisons:         | Schedule 4                   |
| EU EINECS/ELINCS List  | 215-742-2                    |
| <b>Neomycin B</b>  |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| Australia (AICS):  | Present                      |
| Standard for the Uniform Scheduling for Drugs and Poisons:         | Schedule 4                   |
| EU EINECS/ELINCS List  | 204-292-2                    |
| <b>EASTERN EQUINE ENCEPHALOMYELITIS</b>                            |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | Not Listed                   |
| <b>WESTERN EQUINE ENCEPHALOMYELITIS</b>                            |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | Not Listed                   |
| <b>Equine Influenza Virus, Kentucky 97 (EIV)</b>                   |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | Not Listed                   |
| <b>West Nile Virus, killed</b>                                     |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | Not Listed                   |
| <b>Polymyxin B</b>   |                              |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed                   |
| California Proposition 65  | Not Listed                   |
| EU EINECS/ELINCS List  | 215-768-4                    |

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### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H302 - Harmful if swallowed  
H317 - May cause an allergic skin reaction  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H301 - Toxic if swallowed  
H314 - Causes severe skin burns and eye damage  
H350 - May cause cancer  
H331 - Toxic if inhaled  
H300 - Fatal if swallowed  
H310 - Fatal in contact with skin  
H373 - May cause damage to organs through prolonged or repeated exposure  
H400 - Very toxic to aquatic life  
H410 - Very toxic to aquatic life with long lasting effects  
H361 - Suspected of damaging fertility or the unborn child  
H330 - Fatal if inhaled

Xn - Harmful  
T - Toxic  
C - Corrosive  
Carcinogenic: Category 3  
T+ - Very toxic  
N - Dangerous for the environment  
Toxic to Reproduction: Category 3

R22 - Harmful if swallowed.  
R34 - Causes burns.  
R40 - Limited evidence of a carcinogenic effect  
R33 - Danger of cumulative effects.  
R63 - Possible risk of harm to the unborn child.  
R42/43 - May cause sensitization by inhalation and skin contact.  
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.  
R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.  
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 16 - Other Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

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**End of Safety Data Sheet**