# SAFETY DATA SHEETS

## This SDS packet was issued with item:

078929355

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

078830221 078830239 078929363

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

078442474 078500066 078500074

# SAFETY DATA SHEET



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

**Product Identifier**

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

**Trade Name:** WEST NILE-INNOVATOR® + VEWT
**Chemical Family:** Mixture

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

**Intended Use:** Veterinary Vaccine
**Restrictions on Use:** Not for human use

**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:** 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. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection. May be harmful if swallowed. May cause eye and skin irritation

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

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

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---|---|---|---|---|---|
| Thimerosal | 54-64-8 | 200-210-4 | T+; R26/27/28<br>R33<br>N;R50/53 | Acute Tox. 2 (H300)<br>STOT RE 2 (H373)<br>Acute Tox. 2 (H330) | ## |
| Polymyxin B | 1404-26-8 | 215-768-4 | Xn;R22<br>Xn;R42/43 | Acute Tox. 4 (H302)<br>Skin Sens. 1 (H317)<br>Resp Sens. 1 (H334) | ## |
| Neomycin sulfate | 1405-10-3 | Not Listed | Not Listed | Not Listed | ## |
| Formaldehyde | 50-00-0 | 200-001-8 | T; R23/24/25<br>C; R34<br>Carc.Cat.3; R40<br>R43 | Acute Tox. 3 (H301)<br>Skin Corr. 1B (H314)<br>Skin Sens. 1 (H317)<br>Carc. 2 (H351)<br>Acute Tox. 3 (H331) | ## |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---|---|---|---|---|---|
| EASTERN EQUINE ENCEPHALOMYELITIS | Not Assigned | Not Listed | Not Listed | Not Listed | * |
| WESTERN EQUINE ENCEPHALOMYELITIS | Not Assigned | Not Listed | Not Listed | Not Listed | * |
| Venezuelan Equine Enchephalomyelitis | Not Assigned | Not Listed | Not Listed | Not Listed | * |
| West Nile Virus, killed | Not assigned | Not Listed | Not Listed | Not Listed | * |
| Tetanus toxoid | 93384-51-1 | 297-262-3 | Not Listed | Not Listed | * |

**Additional Information:** ## Trace
* Proprietary
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**

# 4. 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:** No data available

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

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

**Notes to Physician:** Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome.

# 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 spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**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**

# 7. HANDLING AND STORAGE

Avoid accidental injection. Use with adequate ventilation. Minimize generating airborne mists and vapors. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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

| | |
|---|---|
| **Storage Conditions:** | Store as directed by product packaging. |
| **Storage Temperature:** | 2-7°C. Do not freeze. |
| **Incompatible Materials:** | This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals. |
| **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.**

**Neomycin sulfate**

| | |
|---|---|
| **Zoetis OEL TWA 8-hr** | 100µg/m$^3$, Sensitizer |

**Formaldehyde**

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

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| **OSHA - Specifically Regulated Chemicals** | 2 ppm<br>0.5 ppm<br>0.75 ppm |
| **Poland OEL - TWA** | 0.5 mg/m$^3$ |
| **Romania OEL - TWA** | 1 ppm<br>1.20 mg/m$^3$ |
| **Slovakia OEL - TWA** | 0.3 ppm<br>0.37 mg/m$^3$ |
| **Slovenia OEL - TWA** | 0.5 ppm<br>0.62 mg/m$^3$ |
| **Sweden OEL - TWAs** | 0.3 ppm<br>0.37 mg/m$^3$ |
| **Switzerland OEL -TWAs** | 0.3 ppm<br>0.37 mg/m$^3$ |

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$^3$ to < 1000ug/m$^3$, provide additional precautions to protect from skin contact) |

**Exposure Controls**

| | |
|---|---|
| **Engineering Controls:** | Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. |
| **Personal Protective Equipment:** | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). |
| **Hands:** | Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations. |
| **Eyes:** | Wear safety glasses or goggles if eye contact is possible. |
| **Skin:** | Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. |
| **Respiratory protection:** | If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---|---|---|---|
| **Physical State:** | Opaque liquid | **Color:** | Reddish white |
| **Odor:** | Odorless | **Odor Threshold:** | No data available. |
| **Molecular Formula:** | Mixture | **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.

**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

**Flammablity:**
**Autoignition Temperature (Solid) (°C):** No data available
**Flammability (Solids):** No data available
**Flash Point (Liquid) (°C):** Non-flammable
**Upper Explosive Limits (Liquid) (% by Vol.):** No data available
**Lower Explosive Limits (Liquid) (% by Vol.):** No data available
**Polymerization:** Will not occur

## 10. STABILITY AND REACTIVITY

**Reactivity:** No data available
**Chemical Stability:** Stable under normal conditions of use.
**Possibility of Hazardous Reactions**
**Oxidizing Properties:** None
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
**Incompatible Materials:** This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
**Hazardous Decomposition Products:** Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

## 11. TOXICOLOGICAL INFORMATION

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

**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

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

**Formaldehyde**
Rat Oral LD50 800 mg/kg

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

# 11. TOXICOLOGICAL INFORMATION

**Thimerosal**
Eye Irritation Rabbit Mild

**Formaldehyde**
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate Severe

**Skin Irritation / Sensitization** This product contains formaldehyde and merthiolate which are considered to be skin sensitizers.

**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
9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory 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

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

**Polymyxin B**
*In Vitro* Negative
*In Vivo* Negative

**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

**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:** The environmental characteristics of this material have not been fully evaluated. 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).

**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:**

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

# 15. REGULATORY INFORMATION

**EASTERN EQUINE ENCEPHALOMYELITIS**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **EU EINECS/ELINCS List** | Not Listed |

**WESTERN EQUINE ENCEPHALOMYELITIS**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **EU EINECS/ELINCS List** | Not Listed |

**Venezuelan Equine Enchephalomyelitis**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **EU EINECS/ELINCS List** | Not Listed |

**West Nile Virus, killed**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **EU EINECS/ELINCS List** | Not Listed |

**Tetanus toxoid**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **Standard for the Uniform Scheduling for Drugs and Poisons:** | Schedule 4 |
| **EU EINECS/ELINCS List** | 297-262-3 |

**Thimerosal**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **EU EINECS/ELINCS List** | 200-210-4 |

**Polymyxin B**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **EU EINECS/ELINCS List** | 215-768-4 |

**Neomycin sulfate**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | developmental toxicity initial date 10/1/92 internal use |
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS/ELINCS List** | Not Listed |

# 15. REGULATORY INFORMATION

**Formaldehyde**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | 0.1 % |
| **CERCLA/SARA Hazardous Substances and their Reportable Quantities:** | 100 lb<br>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<br>0.5 ppm<br>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<br>Schedule 6 |
| **EU EINECS/ELINCS List** | 200-001-8 |

# 16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

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

R22 - Harmful if swallowed.
R33 - Danger of cumulative effects.
R34 - Causes burns.
R40 - Limited evidence of a carcinogenic effect
R43 - May cause sensitization by skin contact.
R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.
R42/43 - May cause sensitization by inhalation and skin contact.
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 8 - Exposure Controls / Personal Protection.

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

Zoetis Inc. believes that the information contained in this Material 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**