

# SAFETY DATA SHEET



## 1. Identification

**Product identifier** West Nile - Innovator®  
**Other means of identification**  
**Synonyms** WEST NILE - INNOVATOR® \* West Nile INNOVATOR \* West Nile Virus Vaccine  
**Recommended use** Veterinary vaccine  
**Recommended restrictions** Not for human use

### Manufacturer/Importer/Supplier/Distributor information

**Company Name (US)** Zoetis Inc.  
10 Sylvan Way  
Parsippany, New Jersey 07054 (USA)  
**Rocky Mountain Poison and Drug Center** 1-866-531-8896  
**Product Support/Technical Services** 1-800-366-5288  
**Emergency telephone numbers** CHEMTREC (24 hours): 1-800-424-9300  
International CHEMTREC (24 hours): +1-703-527-3887  
**Company Name (EU)** Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium  
**Emergency telephone number** International CHEMTREC (24 hours): +1-703-527-3887  
**Contact E-Mail** VMIPSrecords@zoetis.com

## 2. Hazard(s) identification

**Physical hazards** Not classified.  
**Health hazards** Not classified.  
**Environmental hazards** Not classified.  
**OSHA defined hazards** Not classified.

### Label elements

**Hazard symbol** None.  
**Signal word** None.  
**Hazard statement** The mixture does not meet the criteria for classification.  
**Precautionary statement**  
**Prevention** Observe good industrial hygiene practices.  
**Response** Wash hands after handling.  
**Storage** Store away from incompatible materials.  
**Disposal** Dispose of waste and residues in accordance with local authority requirements.

**Hazard(s) not otherwise classified (HNOC)** None known.

**Supplemental information** Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Squalene		111-02-4	<5

Chemical name	Common name and synonyms	CAS number	%
Formaldehyde		50-00-0	<0.1
Neomycin Free Base		1404-04-2	<0.1
Polymyxin B		1404-26-8	<0.1
Thimerosal		54-64-8	<0.1
Saline suspension		Mixture	*
West Nile Virus, killed		Not assigned	*

**Composition comments** \* Non-hazardous Ingredients  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

#### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
<b>Ingestion</b>	Rinse mouth. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
<b>Most important symptoms/effects, acute and delayed</b>	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically. Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome.
<b>General information</b>	For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.  Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.
<b>Environmental precautions</b>	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

### Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapor. Avoid accidental injection. Wash thoroughly after handling. When using, do not eat, drink or smoke. Wear personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

### Conditions for safe storage, including any incompatibilities

Store out of direct sunlight in dark, dry conditions. @ 2 - 7°C (36 - 45°F). Do not freeze. Store in original tightly closed container. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

#### Zoetis

##### Components

##### Type

##### Value

Neomycin Free Base (CAS 1404-04-2)

TWA

100 µg/m<sup>3</sup>

#### US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

##### Components

##### Type

##### Value

Formaldehyde (CAS 50-00-0)

STEL

2 ppm

TWA

0.75 ppm

#### US. OSHA Table Z-2 (29 CFR 1910.1000)

##### Components

##### Type

##### Value

Thimerosal (CAS 54-64-8)

Ceiling

0.04 mg/m<sup>3</sup>

TWA

0.01 mg/m<sup>3</sup>

#### US. ACGIH Threshold Limit Values

##### Components

##### Type

##### Value

Formaldehyde (CAS 50-00-0)

Ceiling

0.3 ppm

Thimerosal (CAS 54-64-8)

STEL

0.03 mg/m<sup>3</sup>

TWA

0.01 mg/m<sup>3</sup>

#### US. NIOSH: Pocket Guide to Chemical Hazards

##### Components

##### Type

##### Value

Formaldehyde (CAS 50-00-0)

Ceiling

0.1 ppm

TWA

0.016 ppm

Thimerosal (CAS 54-64-8)

STEL

0.03 mg/m<sup>3</sup>

TWA

0.01 mg/m<sup>3</sup>

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Exposure guidelines

#### US - California OELs: Skin designation

Thimerosal (CAS 54-64-8)

Can be absorbed through the skin.

#### US - Tennessee OELs: Skin designation

Thimerosal (CAS 54-64-8)

Can be absorbed through the skin.

#### US ACGIH Threshold Limit Values: Skin designation

Thimerosal (CAS 54-64-8)

Can be absorbed through the skin.

#### US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Thimerosal (CAS 54-64-8)

Can be absorbed through the skin.

### Control banding approach

Polymyxin B: Zoetis 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)

### Appropriate engineering controls

Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

<b>Skin protection</b>	
<b>Hand protection</b>	Wear impervious gloves if skin contact is possible.
<b>Other</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. 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. 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.
<b>Thermal hazards</b>	Not applicable.
<b>General hygiene considerations</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

<b>Appearance</b>	Suspension
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Color</b>	Pink.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Non-flammable
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.

<b>Conditions to avoid</b>	Contact with incompatible materials. Sunlight. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
<b>Incompatible materials</b>	Strong oxidizing agents. This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	No adverse effects due to inhalation are expected.
<b>Skin contact</b>	Prolonged skin contact may cause temporary irritation.
Formaldehyde	Species: Rabbit Severity: Moderate Severe
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
Thimerosal	Species: Rabbit Severity: Mild
Formaldehyde	Species: Rabbit Severity: Severe

**Ingestion** Expected to be a low ingestion hazard.

**Symptoms related to the physical, chemical and toxicological characteristics** Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

### Information on toxicological effects

#### Acute toxicity

Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
<b>Acute</b>		
<b>Inhalation</b>		
LC50	Rat	0.48 mg/l, 4 Hours
<b>Oral</b>		
LD50	Rat	800 mg/kg 100 mg/kg
<b>Chronic</b>		
<b>Inhalation</b>		
LOAEL	Mouse	15 ppm, 2 years Tumors
	Rat	15 ppm, 9 days Respiratory system 6 ppm, 2 years Tumors
Neomycin Free Base (CAS 1404-04-2)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	2750 mg/kg
Polymyxin B (CAS 1404-26-8)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	790 mg/kg
<b>Other</b>		
LD50	Mouse	3980 ug/kg
<b>Subcutaneous</b>		
LD50	Rat	50 mg/kg

Components	Species	Test Results
Thimerosal (CAS 54-64-8)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	91 mg/kg
	Rat	75 mg/kg
<b>Subcutaneous</b>		
LD50	Rat	98 mg/kg
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye Contact</b>		
Thimerosal	Species: Rabbit Severity: Mild	
Formaldehyde	Species: Rabbit Severity: Severe	
<b>Respiratory or skin sensitization</b>		
<b>ACGIH sensitization</b>		
FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization Respiratory sensitization	
<b>Respiratory sensitization</b>	Not a respiratory sensitizer.	
<b>Skin sensitization</b>	This product contains formaldehyde and merthiolate which are considered to be skin sensitizers. This product is not expected to cause skin sensitization.	
<b>Germ cell mutagenicity</b>		
No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.		
<b>Mutagenicity</b>		
Formaldehyde	In Vitro Bacterial Mutagenicity (Ames) Result: Positive Species: Bacteria	
	In Vitro Chromosome Aberration Result: Positive Species: Rodent	
	In Vitro Sister Chromatid Exchange Result: Positive Species: Rodent	
Polymyxin B	In Vitro Result: Negative	
Formaldehyde	In Vivo Chromosome Aberration Result: Positive Species: Not specified	
Polymyxin B	In Vivo Result: Negative	
<b>Carcinogenicity</b>		
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. No known carcinogens are present at greater than 0.1%.		
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Formaldehyde (CAS 50-00-0)	1 Carcinogenic to humans.	
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
Formaldehyde (CAS 50-00-0)	Cancer	
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Formaldehyde (CAS 50-00-0)	Known To Be Human Carcinogen.	
<b>Reproductive toxicity</b>	This product is not expected to cause reproductive or developmental effects.	

## Developmental effects

Formaldehyde

185 mg/kg/day Embryo / Fetal Development, Not teratogenic  
Maternal toxicity  
Species: Mouse  
Organ: Oral

40 ppm Embryo / Fetal Development, Not Teratogenic  
Maternal Toxicity  
Species: Rat  
Organ: Inhalation

<b>Specific target organ toxicity - single exposure</b>	Not classified.
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.
<b>Aspiration hazard</b>	Not an aspiration hazard.
<b>Chronic effects</b>	Prolonged inhalation may be harmful.
<b>Further information</b>	Allergic reactions are possible. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

## 12. Ecological information

<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.
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Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
<b>Aquatic</b>		
Crustacea	EC50 Water flea ( <i>Daphnia pulex</i> )	4.3 - 7.8 mg/l, 48 hours
Fish	LC50 Striped bass ( <i>Morone saxatilis</i> )	10.302 - 16.743 mg/l, 96 hours
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Bioaccumulative potential</b>	No data available.	
<b>Mobility in soil</b>	No data available.	
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	

## 13. Disposal considerations

<b>Disposal instructions</b>	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. 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). Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company. This product contains trace quantities of mercury, releases to the environment should be avoided.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as dangerous goods.

**IATA**

Not regulated as dangerous goods.

**IMDG**

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not established.**15. Regulatory information****US federal regulations** This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Formaldehyde (CAS 50-00-0) Listed.

**SARA 304 Emergency release notification**

Formaldehyde (CAS 50-00-0) 100 LBS

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**Formaldehyde (CAS 50-00-0) Cancer  
Skin sensitization  
Respiratory sensitization  
Eye irritation  
Skin irritation  
respiratory tract irritation  
Acute toxicity  
Flammability**Superfund Amendments and Reauthorization Act of 1986 (SARA)****Hazard categories** Immediate Hazard - No  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No**SARA 302 Extremely hazardous substance**

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
Formaldehyde	50-00-0	100	500		

**SARA 311/312 Hazardous chemical** No**SARA 313 (TRI reporting)**  
Not regulated.**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**Formaldehyde (CAS 50-00-0)  
Thimerosal (CAS 54-64-8)**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Formaldehyde (CAS 50-00-0)

**Safe Drinking Water Act (SDWA)** Not regulated.**US state regulations** WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.**US - California Proposition 65 - CRT: Listed date/Carcinogenic substance**

Formaldehyde (CAS 50-00-0) Listed: January 1, 1988

**US - California Proposition 65 - CRT: Listed date/Developmental toxin**

Thimerosal (CAS 54-64-8) Listed: July 1, 1990



**US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))**

Formaldehyde (CAS 50-00-0)

**International Inventories**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

**Issue date** 05-04-2017

**Version #** 01

**Disclaimer** 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. The information in the sheet was written based on the best knowledge and experience currently available.

**Revision information** This document has undergone significant changes and should be reviewed in its entirety.