SAFETY DATA SHEETS

This SDS packet was issued with item:

078929365

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

078829487 078830213

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).

078500041 078500058

SAFETY DATA SHEET



1. Identification

Product identifier West Nile-Innovator®+EWT

Other means of identification

Synonyms WEST NILE INNOVATOR + EWT * Encephalomyelitis-West Nile Virus Vaccine, Eastern &

Western, Killed Virus, Tetanus Toxoid

Veterinary vaccine Recommended use **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. Not classified. **Health hazards** Not classified. **Environmental hazards OSHA** defined hazards Not classified.

Label elements

None. Hazard symbol 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.

Store away from incompatible materials. Storage

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
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
EASTERN EQUINE ENCEPHALOMYELITIS		Not Assigned	*
Saline suspension		Mixture	*
Tetanus toxoid		93384-51-1	*
West Nile Virus, killed		Not assigned	*
WESTERN EQUINE ENCEPHALOMYELITIS		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

Inhalation Skin contact Move to fresh air. Call a physician if symptoms develop or persist.

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.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove

contact lenses, if present and easy to do.

Ingestion 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.

Most important symptoms/effects, acute and delayed

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.

Indication of immediate medical attention and special treatment needed

General information

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.

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

Suitable extinguishing media

Unsuitable extinguishing media

_ ...

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

Move containers from fire area if you can do so without risk.

Specific methodsUse standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

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.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

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	Туре	Value	
Neomycin Free Base (CAS 1404-04-2)	TWA	100 μg/m3	
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	0.1000)		
Components	Туре	Value	
Thimerosal (CAS 54-64-8)	Ceiling	0.04 mg/m3	
(TWA	0.01 mg/m3	
US. ACGIH Threshold Limit Value	s		
Components	Туре	Value	
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	
US. NIOSH: Pocket Guide to Cher	mical Hazards		
Components	Туре	Value	
Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm	
	TWA	0.016 ppm	
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	

Biological limit valuesNo 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/m3 to <

1000ug/m3, 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.

Skin protection

Hand protection Wear impervious gloves if skin contact is possible.

Other Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable

coveralls, etc.) in both production and laboratory areas.

Respiratory protection 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.

Thermal hazards Not applicable.

General hygiene considerations

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

Appearance Suspension
Physical state Liquid.
Form Liquid.

Color Pink. - Pinkish White.

Odor Not available.
Odor threshold Not available.
pH Not available.
Melting point/freezing point Not available.
Initial boiling point and boiling Not available.

range

Flash point Non-flammable
Evaporation rate Not available.
Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Sunlight. Store at 2-7°C. Prolonged exposure to higher

temperatures may adversely affect potency. Do not freeze.

Incompatible materials Strong oxidizing agents. This material can be denatured or inactivated by a variety of organic

solvents, salts or heavy metals.

Hazardous decomposition

Formaldehyde

products

No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

InhalationNo adverse effects due to inhalation are expected.Skin contactProlonged skin contact may cause temporary irritation.

Species: Rabbit

with acute exposures in sensitized patients.

Severity: Moderate Severe

Eye contact 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

Information on toxicological effects

Acute toxicity

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

Components Species Test Results

Polymyxin B (CAS 1404-26-8)

Acute

Oral

LD50 Mouse 790 mg/kg

Other

LD50 Mouse 3980 ug/kg

Subcutaneous

LD50 Rat 50 mg/kg

Thimerosal (CAS 54-64-8)

<u>Acute</u>

Oral

LD50 Mouse 91 mg/kg
Rat 75 mg/kg

Subcutaneous

LD50 Rat 98 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation. **Serious eye damage/eye** Direct contact with eyes may cause temporary irritation.

irritation

Eye Contact

Thimerosal Species: Rabbit

Severity: Mild

Formaldehyde Species: Rabbit

Severity: Severe

Respiratory or skin sensitization

ACGIH sensitization

FORMALDEHYDE (CAS 50-00-0) Dermal sensitization
Respiratory sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product contains formaldehyde and merthiolate which are considered to be skin sensitizers.

This product is not expected to cause skin sensitization.

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Mutagenicity

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

Carcinogenicity

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%.

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0) 1 Carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Formaldehyde (CAS 50-00-0) Cancer US. National Toxicology Program (NTP) Report on Carcinogens

Formaldehyde (CAS 50-00-0)

Known To Be Human Carcinogen.

Reproductive toxicity

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

Specific target organ toxicity -

Not classified.

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Further information 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

Ecotoxicity

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.

Components Species Test Results

Formaldehyde (CAS 50-00-0)

Aquatic

Crustacea EC50 Water flea (Daphnia pulex) 4.3 - 7.8 mg/l, 48 hours

Fish LC50 Striped bass (Morone saxatilis) 10.302 - 16.743 mg/l, 96 hours

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential Mobility in soil

No data available. No data available.

Other adverse effects

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

Disposal instructions 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.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

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.

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SDS US

Waste from residues / unused

products

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).

Contaminated packaging

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

Not established.

Annex II of MARPOL 73/78 and

the IBC Code

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

Cancer

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Formaldehyde (CAS 50-00-0)

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 Threshold Threshold Threshold quantity planning quantity planning quantity, planning quantity, (pounds) (pounds) lower value upper value (pounds) (pounds)

500

SARA 311/312 Hazardous

chemical

Formaldehyde

No

50-00-0

100

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 No.

(SDWA)

Not regulated.

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SDS US

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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

Country(s) or reg	gion Inventory name	On inventory (yes/no)*
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

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

Issue date 05-04-2017

Version # 01

DisclaimerZoetis 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.

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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).