SAFETY DATA SHEETS

This SDS packet was issued with item:

078929131

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

078929356

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).

078442516 078500033

SAFETY DATA SHEET



1. Identification

Product identifier West Nile - Innovator®

Other means of identification

WEST NILE - INNOVATOR® * West Nile INNOVATOR * West Nile Virus Vaccine **Synonyms**

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

1-800-366-5288

Services

Emergency telephone

CHEMTREC (24 hours): 1-800-424-9300

numbers

International CHEMTREC (24 hours): +1-703-527-3887

Zoetis Belgium S.A. Company Name (EU)

> Mercuriusstraat 20 1930 Zaventem

Emergency telephone

number

International CHEMTREC (24 hours): +1-703-527-3887

VMIPSrecords@zoetis.com **Contact E-Mail**

2. Hazard(s) identification

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

Label elements

Hazard symbol None. None. Signal word

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

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

Inhalation

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

Skin contact

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.

Eve 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

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

General information

media

Specific hazards arising from

the chemical

Special protective equipment and precautions for firefighters

Fire fighting equipment/instructions

Specific methods

General fire hazards

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Do not use water jet as an extinguisher, as this will spread the fire.

During fire, gases hazardous to health may be formed.

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

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

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

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.

Material name: West Nile - Innovator®

729 Version #: 01 Issue date: 05-04-2017

SDS US

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 1910.100	1-1050)	
Components	Туре	Value	
Formaldehyde (CAS 50-00-0)	STEL	2 ppm	
,	TWA	0.75 ppm	
US. OSHA Table Z-2 (29 CFR 1910).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	nical 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 engineeringKeep 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

Wear impervious gloves if skin contact is possible. Hand protection

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

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

No personal respiratory protective equipment normally required. In case of insufficient ventilation. Respiratory protection

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 Liquid. Physical state Liquid. **Form** Pink. Color

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

range

Non-flammable Flash point **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.

Not available. Vapor pressure Vapor density Not available. Not available. Relative density

Solubility(ies)

Solubility (water) Not available. Partition coefficient Not available.

(n-octanol/water)

Not available. **Auto-ignition temperature Decomposition temperature** Not available. Not available. **Viscosity**

Other information

Explosive properties Not explosive. Oxidizing properties Not oxidizing.

10. Stability and reactivity

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

Material is stable under normal conditions. **Chemical stability**

Possibility of hazardous No dangerous reaction known under conditions of normal use.

reactions

Version #: 01 Issue date: 05-04-2017

Material name: West Nile - Innovator® SDS US 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

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.

Formaldehyde Species: Rabbit

Severity: Moderate Severe

Eye contactDirect contact with eyes may cause temporary irritation.

Thimerosal

Species: Rabbit

Species: Rabbit Severity: Mild

Formaldehyde Species: Rabbit Severity: Severe

Ingestion Expected to be a low ingestion hazard.

Species

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.

Test Results

Information on toxicological effects

Acute toxicity Components

•	•	
Formaldehyde (CAS 50-00-	-0)	
<u>Acute</u>		
Inhalation		
LC50	Rat	0.48 mg/l, 4 Hours
Oral		
LD50	Rat	800 mg/kg
		100 mg/kg
<u>Chronic</u>		
Inhalation		
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)	
<u>Acute</u>		
Oral		
LD50	Rat	2750 mg/kg
Polymyxin B (CAS 1404-26	i-8)	
<u>Acute</u>		
Oral		
LD50	Mouse	790 mg/kg
Other		
LD50	Mouse	3980 ug/kg
Subcutaneous		
LD50	Rat	50 mg/kg

Material name: West Nile - Innovator®
729 Version #: 01 Issue date: 05-04-2017

SDS US

5/9

Components Species Test Results

Thimerosal (CAS 54-64-8)

Acute

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 mutagenicityNo 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 toxicityThis 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

Specific target organ toxicity repeated exposure

Not classified.

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. No data available.

Bioaccumulative potential

No data available. Mobility in soil 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.

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 regulationsThis 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

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

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

Not regulated.

(SDWA)

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

Material name: West Nile - Innovator®

729 Version #: 01 Issue date: 05-04-2017

SDS US

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 region	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	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 informationThis document has undergone significant changes and should be reviewed in its entirety.