

SAFETY DATA SHEETS

This SDS packet was issued with item:

078038678

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).

078038660



Triple-ET Innovator

Material Safety Data Sheet

WW MSDS No. 4867-20

Section 1. Product and Company Identification

Manufactured/ Supplied by	Fort Dodge Animal Health 800 5th Street NW P.O. Box 518 Fort Dodge, IA 50501 Phone: 515-955-4600 Fax: 515-955-9149	Date of Preparation	12 November 2001
		Product No.	4867-20
Product Trade Name	Triple-ET Innovator	Formula No.	NA
Common Name	Equine Encephalomyelitis (Eastern, Western, and Venezuelan) Vaccine (killed virus) - Tetanus Toxoid (killed)	CAS No.	NA
Synonyms	Fluvac	U.N. No.	NA
Chemical Formula	NA	EINECS No.	NA
Chemical Family	Veterinary Vaccine.	In Case of Emergency 515-955-6033	
Material Uses	Veterinary Biological.		
Packaging	Vial. Prefilled syringe/tube.		
Formula Type	Injectable solution.		

Section 2. Composition - Information on Ingredients

Name of Ingredients	CAS No.	Conc.	EU Symbol	R Phrase
1) Killed virus 2) Adjuvant	NA	Unknown Trade Secret <0.01%		
3) May contain thimerosal, neomycin, formalin, polymyxin B, and/or amphotericin B as a preservative.	Various			

Section 3. Hazards Identification - Summary of Primary Effects and Critical Hazards

Acute Health Effects	Vaccine contains inactivated virus and is not pathogenic. Adverse health effects are considered unlikely when the product is administered according to label directions.
Chronic Health Effects	Not considered to be toxic for humans.
Environmental Hazards	Releases of small quantities are unlikely to affect adversely the functioning of water treatment plants.

Section 4. First Aid Measures - (by medical responders using "Universal Precautions")

Eye Contact	May cause eye irritation.
Skin Contact	NO KNOWN EFFECT. After contact with skin, wash immediately with plenty of water.
Inhalation	No specific data.
Ingestion	If ingested, seek medical advice immediately and show the container or the label.

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Obtained by Global Safety Management, 1-813-435-5161 - www.GSMSDS.com

Notes to Medical Doctor 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.

Section 5. Fire-Fighting Measures

Extinguishing Media and Instructions	Aqueous solutions are non-flammable. Use DRY chemicals, CO2, alcohol foam or water spray.
Special Exposure Hazards	None. Dispose of fire debris and contaminated fire fighting water in accordance with regulations.
Special Fire Fighting Protective Equipment	Full fire-fighting attire and approved certified self-contained breathing apparatus worn only by qualified persons.

Section 6. Accidental Release Measures

Small Spill Guidelines	Absorb with an inert material and place in an appropriate waste disposal container.
Large Spill Guidelines	Absorb with an inert material and put the spilled material in an appropriate waste disposal. Call for assistance on disposal.
Environmental Precautions	Keep out of waterways.

Section 7. Handling and Storage

Handling (ventilation and fire prevention)	No special measures required.
Storage (conditions and limitations)	Keep only in the original container at a temperature not exceeding 7 deg. C. S02- Keep out of the reach of children

Section 8. Exposure Controls and Personal Protection - (normal and intended use)

Exposure Guidelines				
Component	REG. Limit	OSHA (PEL)	ACGIH (TLV®)	Company Guideline
No hazardous ingredients				
Engineering Design and Control Measures	No special measures required.			
Protective Clothing				
Eyes	Safety glasses.			
Skin	Gloves, Latex			
Hands	Gloves, Latex			
Respiratory	A respirator is not needed under normal and intended conditions of product use.			

Section 9. Physical and Chemical Properties

Physical State and Appearance	Opaque liquid	Odor	Odorless.
Molecular Weight	unknown	Color	Reddish-white.
Boiling Point	unknown	pH	6 - 8
Melting/Freezing Point	unknown		
Density/Bulk Density	unknown		

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Vapor Pressure	unknown
Vapor Density	unknown
Viscosity	unknown
Partition Coefficient	unknown
Solubility	Easily soluble in cold water, hot water, methanol, diethyl ether, n-octanol, acetone.
Flash Point	NA
Autoignition Point	NA
Explosion Limits	NA
Dust Explosivity	NA

Section 10. Stability and Reactivity

Conditions to Avoid and Incompatibility The product is stable.

Decomposition Products None.

Section 11. Toxicological Information**Acute Effects**

Component	Test	Result	Route	Species
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No hazardous ingredients

Eye Contact Mildly irritating to the eyes.

Skin Contact No evidence of risk in humans.

Inhalation No evidence of risk in humans.

Ingestion Not considered to be toxic for humans.

Chronic Effects

Target Organs None.

Adverse Effects Statements Not known.

Sensitization No evidence.

Carcinogenic Effects There is no known effect 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 Effects Not considered to be toxic for the reproductive system.

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

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Section 12. Ecological Information

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

Environmental Hazards Releases of small quantities are unlikely to affect adversely the functioning of water treatment plants.

Ecotoxicity

Component	Species	Period	Result
No hazardous ingredients			

Other

Section 13. Disposal Considerations

Waste Handling and Disposal Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Note: The waste generator must be informed of and follow all applicable rules and regulations for the handling and disposal of waste.

Section 14. Transport Information

Proper Shipping Name, Primary Class, UNNA Number, Packaging Group Not regulated

ADR/RID Classification (Road and Rail Transport) Not controlled under ADR of the EEC.

ADNR Classification (Inland Waterways) Not controlled under ADNR (Europe).

IMO/IMDG Class (Maritime Transport) Not controlled under IMDG.

ICAO/IATA (Air Transport) Not controlled under IATA.

CEPIC Tremcard

HI Kemler

U.S.A. DOT Class Not a DOT controlled material (United States).

RQ

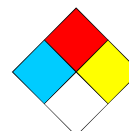
NFPA

Health

Flammability

Reactivity

Specific hazard



Packaging Instructions

Section 15. Regulatory Information and Warning Labels

(R) Risk Phrases R36- Irritating to eyes.

(S) Safety Phrases S02- Keep out of the reach of children S25- Avoid contact with eyes S26- In case of contact with eyes, rinse immediately with plenty of water. S28- After contact with skin, wash immediately with plenty of water.

NOTE: This product has been classified in accordance with applicable country-specific regulations.

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Section 16. Other Key Information

Other Considerations See product label and package insert for additional information.

19 January 2002 **Responsible for MSDS:** Global Engineering, Environmental and Safety

Fort Dodge Animal Health -- within American Home Products Corporation

Notice to Reader

** This symbol indicates information which has changed from the previous MSDS.*

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 precautions and this information. All materials may present unknown hazards and should be used with caution.

MSDSs available in multiple languages



MATERIAL SAFETY DATA SHEET

Product Id: Triple-ET Innovator

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Code: RM1000200

Product Name: Triple-ET Innovator

Common Name: Equine Encephalomyelitis Virus (Venezuelan, Eastern and Western strains) Vaccine (killed virus) and Tetanus Toxoid 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	Unknown	None	NA	Not Established	mg/m3
None					
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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Product Name: Triple-ET Innovator

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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Product Name: Triple-ET Innovator

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

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

DOT (Road/Rail Transport)

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

ICAO/IATA (Air Transport):

UN/ID Number:	Not controlled.
Proper Shipping Name:	Not controlled.
Hazard Class:	Not controlled.
Packing Group:	Not controlled.

IMO/IMDG (Maritime Transport):

UN/ID Number:	Not controlled.
Hazard Class:	Not controlled.
Packing Group:	Not controlled.
Marine Pollutant:	No

15. REGULATORY INFORMATION

Other Regulations:	Not controlled
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16. OTHER INFORMATION

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Product Name:	Triple-ET Innovator

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

Product Identifier

Material Name: Triple-ET Innovator

Trade Name: Triple-ET Innovator

Synonyms: Equine Encephalomyelitis Virus (Venezuelan, Eastern and Western strains) Vaccine (killed virus) and Tetanus Toxoid 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 opaque 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 and skin 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.

ZT00275

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Material Name: Triple-ET Innovator
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
WESTERN EQUINE ENCEPHALOMYELITIS	Not Assigned	Not Listed	Not Listed	Not Listed	*
Tetanus toxoid	93384-51-1	297-262-3	Not Listed	Not Listed	*
Adjuvant	NA	Not Listed	Not Listed	Not Listed	*
Venezuelan Equine Encephalomyelitis	Not Assigned	Not Listed	Not Listed	Not Listed	*
EASTERN EQUINE ENCEPHALOMYELITIS	Not Assigned	Not Listed	Not Listed	Not Listed	*

Additional Information:

* Proprietary

Trace

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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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.
- 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

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7. HANDLING AND STORAGE

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.

Neomycin B

Zoetis OEL TWA 8-hr 100µg/m³Sensitizer

Formaldehyde

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Slovakia OEL - TWA	0.3 ppm 0.37 mg/m ³
Slovenia OEL - TWA	0.5 ppm 0.62 mg/m ³
Sweden OEL - TWAs	0.3 ppm 0.37 mg/m ³
Switzerland OEL -TWAs	0.3 ppm 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/m³ to < 1000ug/m³, 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	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		

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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

No data available

Products:

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

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

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11. TOXICOLOGICAL INFORMATION

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

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

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11. TOXICOLOGICAL INFORMATION

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).

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.

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15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

Neomycin 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

Amphotericin 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

Polymyxin B

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

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

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15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 6
EU EINECS/ELINCS List	200-001-8
WESTERN EQUINE ENCEPHALOMYELITIS	
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
Adjuvant	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Venezuelan Equine Encephalomyelitis	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
EASTERN EQUINE ENCEPHALOMYELITIS	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Thimerosal	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity initial date 7/1/90
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

16. OTHER INFORMATION

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

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H302 - Harmful if swallowed
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
H361 - Suspected of damaging fertility or the unborn child
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
H330 - Fatal if inhaled
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

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

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.
R34 - Causes burns.
R40 - Limited evidence of a carcinogenic effect
R33 - Danger of cumulative effects.
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

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

Product Identifier

Material Name: Triple-ET Innovator

Trade Name: Triple-ET Innovator

Synonyms: Equine Encephalomyelitis Virus (Venezuelan, Eastern and Western strains) Vaccine (killed virus) and Tetanus Toxoid 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 opaque 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 and skin 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	%
Neomycin B	119-04-0	204-292-2	Xn;R22 Xn;R42/43 Repr.Cat.3;R63	Acute Tox. 4;H302 Resp. Sens. 1;H334 Skin Sens.1;H317 Repr.2;H361	##
Amphotericin B	1397-89-3	215-742-2	Not Listed	Not Listed	##
Polymyxin B	1404-26-8	215-768-4	Xn;R22 Xn;R42/43	Acute Tox. 4 (H302) Skin Sens. 1 (H317) Resp Sens. 1 (H334)	##
Formaldehyde	50-00-0	200-001-8	T; R23/24/25 C; R34 Carc.Cat.3; R40 R43	Acute Tox. 3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Carc. 1A (H350) Acute Tox. 3 (H331)	##
Thimerosal	54-64-8	200-210-4	T+; R26/27/28; R33 N; R50/53	Acute Tox. 2 (H300) Acute Tox. 1 (H310) STOT RE 2 (H373) Acute Tox. 2 (H330) Acute Aquatic 1 (H400) Chronic Aquatic 1 (H410)	##

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
WESTERN EQUINE ENCEPHALOMYELITIS	Not Assigned	Not Listed	Not Listed	Not Listed	*
Tetanus toxoid	93384-51-1	297-262-3	Not Listed	Not Listed	*
Adjuvant	NA	Not Listed	Not Listed	Not Listed	*
Venezuelan Equine Encephalomyelitis	Not Assigned	Not Listed	Not Listed	Not Listed	*
EASTERN EQUINE ENCEPHALOMYELITIS	Not Assigned	Not Listed	Not Listed	Not Listed	*

Additional Information:

* Proprietary

Trace

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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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.
- 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

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7. HANDLING AND STORAGE

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.

Neomycin B

Zoetis OEL TWA 8-hr 100µg/m³Sensitizer

Formaldehyde

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Slovakia OEL - TWA	0.3 ppm 0.37 mg/m ³
Slovenia OEL - TWA	0.5 ppm 0.62 mg/m ³
Sweden OEL - TWAs	0.3 ppm 0.37 mg/m ³
Switzerland OEL -TWAs	0.3 ppm 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/m³ to < 1000ug/m³, 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	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		

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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

No data available

Products:

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

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

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11. TOXICOLOGICAL INFORMATION

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

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

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Material Name: Triple-ET Innovator
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11. TOXICOLOGICAL INFORMATION

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

Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOEL Tumors
2 Year(s) Mouse Inhalation 15 ppm LOEL 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).

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.

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15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

Neomycin 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

Amphotericin 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

Polymyxin B

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

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

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15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 6
EU EINECS/ELINCS List	200-001-8
WESTERN EQUINE ENCEPHALOMYELITIS	
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
Adjuvant	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Venezuelan Equine Encephalomyelitis	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
EASTERN EQUINE ENCEPHALOMYELITIS	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Thimerosal	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity initial date 7/1/90
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

16. OTHER INFORMATION

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

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H302 - Harmful if swallowed
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
H361 - Suspected of damaging fertility or the unborn child
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
H330 - Fatal if inhaled
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

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

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.
R34 - Causes burns.
R40 - Limited evidence of a carcinogenic effect
R33 - Danger of cumulative effects.
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