SAFETY DATA SHEETS

This SDS packet was issued with item:

078465845

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

078418295 078465837

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).

078036801 078189578

SAFETY DATA SHEET

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

Product Identifier

Material Name: Tetanus Toxoid

Trade Name: Tetanus Toxoid
Chemical Family: Not determined

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: Cloudy white suspension

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: Non-hazardous in accordance with international standards for workplace safety.

Other Hazards

Short Term: In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

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

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

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Thimerosal	54-64-8	200-210-4	T+; R26/27/28; 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)	<0.1
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)	<0.1
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)	<0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Polysorbate 80	9005-65-6	Not Listed	Not Listed	Not Listed	*
Tetanus toxoid	93384-51-1	297-262-3	Not Listed	Not Listed	*
Neomycin Free Base	1404-04-2	215-766-3	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

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.

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

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

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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.

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
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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Polymyxin B

Zoetis OEB OEB 2 - Sensitizer (control exposure to the range of 100ug/m^3 to < 1000ug/m^3, provide additional precautions to protect from skin contact)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. 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: Suspension
Color: Cloudy white
Odor: No data available.
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
Solubility: Soluble: Water, methanol,
pH: 6-8
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:

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

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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: Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: 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

Polysorbate 80
Rat Intravenous LD 50 1790 mg/kg
Mouse Oral LD 50 25g/kg

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

Formaldehyde
Rat Oral LD50 800 mg/kg

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

Thimerosal
Eye Irritation Rabbit Mild

Formaldehyde
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate Severe
Skin Sensitization Positive

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

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11. TOXICOLOGICAL INFORMATION

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

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Formaldehyde
Embryo / Fetal Development Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity
Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

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

Polymyxin B
In Vitro Negative
In Vivo Negative

Formaldehyde
In Vitro Bacterial Mutagenicity (Ames) Bacteria Positive
In Vitro Chromosome Aberration Rodent Positive
In Vitro Sister Chromatid Exchange Rodent Positive
In Vivo Chromosome Aberration Not specified Positive

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

Formaldehyde
2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors
2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

Carcinogen Status: None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Formaldehyde
IARC: Group 1 (Carcinogenic to Humans)
NTP: Known Human Carcinogen
OSHA: Listed

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12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. This product contains trace quantities of mercury and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP).

Formaldehyde

RCRA - U Series Wastes Listed

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

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

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15. REGULATORY INFORMATION

Polysorbate 80

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Tetanus toxoid

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

Thimerosal

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	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

Polymyxin B

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

Neomycin Free Base

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity initial date 10/1/92
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	215-766-3

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	Schedule 2
for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	200-001-8

16. OTHER INFORMATION

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

H300 - Fatal if swallowed
H301 - Toxic if swallowed
H302 - Harmful if swallowed
H310 - Fatal in contact with skin
H314 - Causes severe skin burns and eye damage
H317 - May cause an allergic skin reaction
H330 - Fatal if inhaled
H331 - Toxic if inhaled
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H350 - May cause cancer
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

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

R33 - Danger of cumulative effects.
R34 - Causes burns.
R40 - Limited evidence of a carcinogenic effect
R43 - May cause sensitization by 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.
R42/43 - May cause sensitization by inhalation and skin contact.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information. 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.

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End of Safety Data Sheet

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SAFETY DATA SHEET

1. Identification

Product identifier **Tetanus Toxoid**

Other means of identification None.

Recommended use Veterinary vaccine

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (US) Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)

Rocky Mountain Poison and Drug Center 1-866-531-8896

Product Support/Technical Services 1-800-366-5288

Emergency telephone numbers CHEMTREC (24 hours): 1-800-424-9300
International CHEMTREC (24 hours): +1-703-527-3887

Company Name (EU) Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

Contact E-Mail VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

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

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

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Squalene		111-02-4	<5
Formaldehyde		50-00-0	<0.1

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Chemical name	Common name and synonyms	CAS number	%
Neomycin Free Base		1404-04-2	<0.1
Polymyxin B		1404-26-8	<0.1
Thimerosal		54-64-8	<0.1
Tetanus toxoid		93384-51-1	*

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.

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

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.

General information

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

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

Unsuitable extinguishing media

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 methods

Use 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.

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7. Handling and storage

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

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

8. Exposure controls/personal protection

Occupational exposure limits

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

Zoetis

Components	Type	Value
Neomycin Free Base (CAS 1404-04-2)	TWA	100 µg/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 1910.1000)

Components	Type	Value
Thimerosal (CAS 54-64-8)	Ceiling	0.04 mg/m3
	TWA	0.01 mg/m3

US. ACGIH Threshold Limit Values

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm
	TWA	0.016 ppm
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

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

Exposure guidelines

US - California OELs: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US - Tennessee OELs: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

Control banding approach Polymyxin B: Zoetis OEB 2 - Sensitizer (control exposure to the range of 100ug/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.

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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	Cloudy white
Odor	Not available.
Odor threshold	Not available.
pH	6 - 8
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
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 density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble
Solubility (other)	Methanol
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

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

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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 products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation No adverse effects due to inhalation are expected.

Skin contact Prolonged skin contact may cause temporary irritation.

Formaldehyde — Species: Rabbit; 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 with acute exposures in sensitized patients.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
Acute		
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 1404-04-2)		
Acute		
Oral		
LD50	Rat	2750 mg/kg
Polymyxin B (CAS 1404-26-8)		
Acute		
Oral		
LD50	Mouse	790 mg/kg
Other		
LD50	Mouse	3980 ug/kg

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Components	Species	Test Results
Subcutaneous		
LD50	Rat	50 mg/kg
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 irritation Direct contact with eyes may cause temporary 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.

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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 - single exposure Not classified.

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.

Bioaccumulative potential No data available.

Mobility in soil 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.

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.

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14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Formaldehyde (CAS 50-00-0) Listed.

SARA 304 Emergency release notification

Formaldehyde (CAS 50-00-0) 100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Formaldehyde (CAS 50-00-0)
Cancer
Skin sensitization
Respiratory sensitization
Eye irritation
Skin irritation
respiratory tract irritation
Acute toxicity
Flammability

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

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

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Formaldehyde (CAS 50-00-0)
Thimerosal (CAS 54-64-8)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Formaldehyde (CAS 50-00-0)

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

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

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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 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 04-17-2014

Revision date 05-05-2017

Version # 03

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

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