



MATERIAL SAFETY DATA SHEET

Revision date: 06-Dec-2006

Version: 2.4

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

Pfizer Animal Health
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CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Erysipelothrix Rhusiopathiae-Mycoplasma Hyopneumoniae Bacterin

Trade Name: RespiSure-ONE/ER Bac Plus; RespiSure/ER Bac Plus
Chemical Family: Mixture
Intended Use: Veterinary Vaccine

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Formaldehyde	50-00-0	200-001-8	0.1 - 1.0
Merthiolate (as mercury)	54-64-8	200-210-4	##

Ingredient	CAS Number	EU EINECS List	%
Mycoplasma Hyopneumoniae	NOT ASSIGNED	Not listed	*
Amphigen base	NOT ASSIGNED	Not listed	*
Aluminum hydroxide gel	21645-51-2	244-492-7	*
Erysipelothrix rhusiopathiae	NOT ASSIGNED	Not listed	*
EDTA	60-00-4	200-449-4	*
Water, purified	7732-18-5	231-791-2	90

Additional Information:

* Proprietary

Trace

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

3. HAZARDS IDENTIFICATION

Appearance: Liquid
Signal Word: WARNING

Statement of Hazard: Contains formaldehyde: potential cancer hazard
May cause sensitization of the skin and respiratory system
May cause eye, skin and respiratory tract irritation

Additional Hazard Information:

Short Term:

May cause eye, skin and respiratory tract irritation. May cause allergic skin reaction. 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.

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EU Indication of danger: Irritant

EU Hazard Symbols:



EU Risk Phrases:

R43 - May cause sensitization by skin contact.

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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Hazardous Combustion Products: Not known

Fire Fighting Procedures: Dike and collect water used to fight fire.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

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General Handling: Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment.

Storage Conditions: Store under refrigeration in closed container.

Storage Temperature: 2-7°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Formaldehyde

OSHA - Final PELs - TWAs:	= 0.75 ppm TWA
OSHA - Specifically Regulated Chemicals	= 0.5 ppm Action Level
	= 0.75 ppm TWA
	= 2 ppm STEL Irritant and potential cancer hazard - see 29 CFR 1910.1048
ACGIH Ceiling Threshold Limit:	= 0.3 ppm Ceiling
ACGIH - Sensitizer Designation	Sensitizer
Australia STEL	= 2 ppm STEL
	= 2.5 mg/m ³ STEL
Australia TWA	= 1 ppm TWA
	= 1.2 mg/m ³ TWA

Merthiolate (as mercury)

OSHA - Final PELs - TWAs:	= 0.01 mg/m ³ TWA
ACGIH Threshold Limit Value (TWA)	= 0.01 mg/m ³ TWA
ACGIH Threshold Limit Value (STEL)	= 0.03 mg/m ³ STEL
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia STEL	= 0.03 mg/m ³ STEL
Australia TWA	= 0.01 mg/m ³ TWA

See exposure limits for component (s) listed above.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Exposure monitoring may be necessary to determine requirements.

Personal Protective Equipment:

Hands:	Wear impervious gloves if skin contact is possible.
Eyes:	Safety glasses or goggles
Skin:	Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.
Respiratory protection:	In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	No data available.	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
pH:	7.0 +/- 1.5		
Boiling Point (°C):	>100		
Specific Gravity:	1.0 +/- 0.2		
Flash Point (Liquid) (°C):	Non-flammable		

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10. STABILITY AND REACTIVITY

Stability: Stable
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: None known
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The primary hazards are due to the formaldehyde content.

Acute Toxicity: (Species, Route, End Point, Dose)

Merthiolate (as mercury)

Rat Oral LD50 75 mg/kg
Rat Subcutaneous LD50 98 mg/kg

Aluminum hydroxide gel

Rat Intraperitoneal LD50 150 mg/kg

EDTA

Rat Oral LD50 > 2000 mg/kg
Rat Oral LD50 4500 mg/kg

Formaldehyde

Rat Oral LD50 800 mg/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Inhalation Acute Toxicity

Not determined for this mixture. However, irritation may occur based on effects of individual components.

Ingestion Acute Toxicity

See Acute toxicity table.

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

Merthiolate (as mercury)

Eye Irritation Rabbit Mild

Formaldehyde

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate Severe

Skin Irritation / Sensitization

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

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

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9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

Subchronic Effects

Rats exposed to 15 ppm formaldehyde vapor for six hours/day for up to nine days showed an acute cell degeneration, necrosis and inflammation in the nasal cavities. Inhalation exposure to formaldehyde for up to 90 days produced interstitial inflammation in the lungs of dogs, rats, monkeys, rabbits and guinea pigs.

Chronic Effects/Carcinogenicity

In rats, several inhalation studies have shown that formaldehyde induces squamous-cell carcinomas and necrosis of the nasal cavity. Formaldehyde also showed cocarcinogenic effects when inhaled, ingested, or applied to the skin of rodents.

Reproduction & Developmental Toxicity: (Study Type, 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

Reproductive Effects

Not considered to be a reproductive hazard.

Teratogenicity

Formaldehyde has been tested by inhalation, oral, and dermal routes and has not been shown to be teratogenic in animals.

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

Mutagenicity

Formaldehyde has been reported to be active in many short-term tests, both in vitro and in vivo.

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:

Contains formaldehyde: potential cancer hazard.

Formaldehyde

IARC:

Group 1

NTP:

Reasonably Anticipated To Be A Carcinogen

OSHA:

Present

12. ECOLOGICAL INFORMATION

Environmental Overview:

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

13. DISPOSAL CONSIDERATIONS

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Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. 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

waste number U122

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant

EU Risk Phrases:
R43 - May cause sensitization by skin contact.

EU Safety Phrases:
S24 - Avoid contact with skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
Contains formaldehyde: potential cancer hazard
May cause sensitization of the skin and respiratory system
May cause eye, skin and respiratory tract irritation

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



Aluminum hydroxide gel

Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
EU EINECS List

Present
Present
244-492-7

Formaldehyde

CERCLA/SARA 313 Emission reporting
CERCLA/SARA Hazardous Substances
and their Reportable Quantities:

= 0.1 % de minimis concentration
= 100 lb final RQ
= 45.4 kg final RQ

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CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 100 lb EPCRA RQ
California Proposition 65	carcinogen, initial date 1/1/88 (gas)
OSHA - Specifically Regulated Chemicals	= 0.5 ppm Action Level = 0.75 ppm TWA = 2 ppm STEL Irritant and potential cancer hazard - see 29 CFR 1910.1048
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 6
EU EINECS List	200-001-8
Merthiolate (as mercury)	
CERCLA/SARA 313 Emission reporting	= 1.0 % Supplier notification limit
California Proposition 65	Developmental
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-210-4
EDTA	
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	200-449-4
Water, purified	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet