

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Mycoplasma Hypopneumoniae Bacterin</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	RespiSure * RESPISURE-ONE® * RespiSure-ONE® * RespiSure-ONE * Respisure One Mycoplasma Hypneumoniae vaccine * Stellamune Mycoplasma * Stellamune Once * Respisure (EU) * Stellamune Mono Dose/Injection * Stellamune One * Stellamune UNO
<b>Recommended use</b>	Veterinary vaccine
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (USA)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison &amp; Drug Safety</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-888-963-8471
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300  International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (CA)</b>	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
<b>Emergency telephone number</b>	CHEMTREC (24 hours): 1-800-424-9300
<b>Contact E-Mail</b>	productsupport@zoetis.com
<b>Product Support</b>	1-800-461-0917
	All Safety Data Sheets are available via our Zoetis Canada website at <a href="https://www.zoetis.ca/sds/sds.aspx">https://www.zoetis.ca/sds/sds.aspx</a>
<b>Supplier</b>	Not available.
<b>2. Hazard identification</b>	
<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.
<b>Label elements</b>	
<b>Hazard symbol</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement</b>	The mixture does not meet the criteria for classification.
<b>Precautionary statement</b>	
<b>Prevention</b>	Observe good industrial hygiene practices.
<b>Response</b>	Wash hands after handling.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of waste and residues in accordance with local authority requirements.
<b>Supplemental information</b>	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.
<b>Other hazards</b>	None known.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Sorbitan oleate		1338-43-8	<5
Mineral oil, white		8042-47-5	1
Merthiolate (as mercury)		54-64-8	##
Mycoplasma Hyopneumoniae		Not assigned	*
Polysorbate 80		9005-65-6	*

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

**Composition comments**      ## Trace  
\* Non-hazardous Ingredients

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	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.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
<b>Ingestion</b>	If swallowed, do NOT induce vomiting. Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
<b>Most important symptoms/effects, acute and delayed</b>	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. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.
<b>Indication of immediate medical attention and special treatment needed</b>	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.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	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. Clean surface thoroughly to remove residual contamination.  Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.  Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

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

**Conditions for safe storage, including any incompatibilities** Store out of direct sunlight in dark, dry conditions. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. Store away from incompatible materials (see Section 10 of the SDS). Keep away from heat, sparks and open flame.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value	Form
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>	
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m <sup>3</sup>	Inhalable fraction.

#### Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2), as amended

Components	Type	Value	Form
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>	
Mineral oil, white (CAS 8042-47-5)	STEL	10 mg/m <sup>3</sup>	Mist.
	TWA	5 mg/m <sup>3</sup>	Mist.

#### Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Merthiolate (as mercury) (CAS 54-64-8)	Ceiling	0.1 mg/m <sup>3</sup>	
	STEL	0.03 mg/m <sup>3</sup>	
Mineral oil, white (CAS 8042-47-5)	TWA	1 mg/m <sup>3</sup>	Mist.

#### Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act), as amended

Components	Type	Value	Form
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>	
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m <sup>3</sup>	Inhalable fraction.

#### Canada. New Brunswick OELs: Threshold Limit Values (TLVs) Based on the 1991 and 1997 ACGIH TLVs and BEIs Publication (New Brunswick Regulation 91-191)

Components	Type	Value	Form
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>	
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m <sup>3</sup>	Inhalable fraction.

#### Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents), as amended

Components	Type	Value	Form
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>	
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m <sup>3</sup>	Inhalable fraction.

#### Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety), as amended

Components	Type	Value	Form
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>	

**Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety), as amended**

Components	Type	Value	Form
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m <sup>3</sup>	Inhalable dusts and mists.

**Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21), as amended**

Components	Type	Value
Mineral oil, white (CAS 8042-47-5)	15 minute	10 mg/m <sup>3</sup>

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Control banding approach</b>	Not available.
<b>Appropriate engineering controls</b>	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear impervious gloves if skin contact is possible.
<b>Other</b>	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection</b>	In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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.
<b>Thermal hazards</b>	Not applicable.
<b>General hygiene considerations</b>	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**

<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Colour</b>	White.
<b>Odour</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Boiling point or initial boiling point and boiling range</b>	>100 °C (>212 °F)
<b>Flammability</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit – upper (%)</b>	Not available.
<b>Flash point</b>	Non-flammable
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>pH</b>	> 6 - < 8
<b>Kinematic viscosity</b>	Not available.
<b>Solubility</b>	
<b>Solubility (water)</b>	Soluble
<b>Partition coefficient (n-octanol/water) (log value)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Density and/or relative density</b>	Not available.
<b>Vapour density</b>	Not available.

<b>Particle characteristics</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidising properties</b>	Not oxidising.
<b>Specific gravity</b>	> 0.8 - < 1.2

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Sunlight. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
<b>Incompatible materials</b>	This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
<b>Hazardous decomposition products</b>	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.

Mineral oil, white  
Species: Rabbit  
Severity: Slight

**Eye contact** Direct contact with eyes may cause temporary irritation.

Merthiolate (as mercury)  
Species: Rabbit  
Severity: Mild

Mineral oil, white  
Species: Rabbit  
Severity: Slight

**Ingestion** May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

**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. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

### Information on toxicological effects

**Acute toxicity** Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
Merthiolate (as mercury) (CAS 54-64-8)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	75 mg/kg
<b>Subcutaneous</b>		
LD50	Rat	98 mg/kg
Mineral oil, white (CAS 8042-47-5)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	> 5000 mg/kg

Components	Species	Test Results
Polysorbate 80 (CAS 9005-65-6)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	25 g/kg
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Corrosivity</b>		
Mineral oil, white		Species: Rabbit Severity: Slight
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye contact</b>		
Merthiolate (as mercury)		Species: Rabbit Severity: Mild
Mineral oil, white		Species: Rabbit Severity: Slight
<b>Respiratory or skin sensitisation</b>		
<b>Respiratory sensitisation</b>	Not a respiratory sensitizer.	
<b>Skin sensitisation</b>	This product is not expected to cause skin sensitisation. This product contains merthiolate which is considered to be a skin sensitizer.	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Carcinogenicity</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
<b>ACGIH Carcinogens</b>		
Mineral oil, white (CAS 8042-47-5)		A4 Not classifiable as a human carcinogen.
<b>Canada - Manitoba OELs: carcinogenicity</b>		
Mineral oil, white (CAS 8042-47-5)		Not classifiable as a human carcinogen.
<b>Canada - Quebec OELs: Carcinogen category</b>		
Mineral oil, white (CAS 8042-47-5)		Suspected carcinogenic effect in humans.
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Mineral oil, white (CAS 8042-47-5)		3 Not classifiable as to carcinogenicity to humans.
<b>Reproductive toxicity</b>	This product is not expected to cause reproductive or developmental effects.	
<b>Specific target organ toxicity - single exposure</b>	Not classified.	
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.	
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.	
<b>Further information</b>	In the event of accidental injection, an allergic reaction may occur. 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.	
<b>12. Ecological information</b>		
<b>Ecotoxicity</b>	Avoid release to the environment. 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.	
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Bioaccumulative potential</b>	No data available.	
<b>Mobility in soil</b>	No data available.	
<b>Other adverse effects</b>	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

<b>Disposal instructions</b>	Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations. 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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	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.
<b>Waste from residues / unused products</b>	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.
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

<b>TDG</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not established.

### 15. Regulatory information

<b>Canadian regulations</b>	This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.	
<b>Controlled Drugs and Substances Act</b>	Not regulated.	
<b>Export Control List (CEPA 1999, Schedule 3)</b>	Merthiolate (as mercury) (CAS 54-64-8)	Substance subject to notification or consent.
<b>Greenhouse Gases</b>	Not listed.	
<b>Precursor Control Regulations</b>	Not regulated.	
<b>International regulations</b>		
<b>Stockholm Convention</b>	Not applicable.	
<b>Rotterdam Convention</b>	Merthiolate (as mercury) (CAS 54-64-8)	Pesticide
<b>Kyoto Protocol</b>	Not applicable.	
<b>Montreal Protocol</b>	Not applicable.	
<b>Basel Convention</b>	Not applicable.	

#### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No

Country(s) or region	Inventory name	On inventory (yes/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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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

**Issue date** 08-May-2017

**Revision date** 22-April-2024

**Version No.** 02

**Disclaimer** Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.

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