

# SAFETY DATA SHEET



## 1. Identification

**Product identifier** Mycoplasma Hyopneumoniae Bacterin

### Other means of identification

#### Synonyms

RespiSure \* RESPISURE-ONE® \* RespiSure-ONE® \* RespiSure-ONE \* Respisure One  
Mycoplasma Hyopneumoniae vaccine \* Stellamune Mycoplasma \* Stellamune Once \* Respisure  
(EU) \* Stellamune Mono Dose/Injection \* Stellamune One \* Stellamune UNO

### Recommended use of the chemical and restrictions on use

**Recommended use** Veterinary vaccine

**Restrictions on use** Not for human use

### Details of manufacturer or importer

**Company Name (AU)** Zoetis Australia Pty Ltd  
ABN 94 156 476 425  
Level 6, 5 Rider Boulevard  
Rhodes NSW 2138 AUSTRALIA

**Tel** 1800 814 883

**Fax** (02) 8876 0444

**Email** productsupport.au@zoetis.com

**Emergency Phone** 1800 814 883 (all hours)

**Police and Fire Brigade** Dial 000

**If ineffective** Dial Poisons Information Centre (13 1126 from anywhere in Australia)

## 2. Hazard(s) identification

### Classification of the hazardous chemical

**Physical hazards** Not classified.

**Health hazards** Not classified.

**Environmental hazards** Not classified.

### Label elements, including precautionary statements

**Hazard symbol(s)** None.

**Signal word** None.

**Hazard statement(s)** The mixture does not meet the criteria for classification.

#### Precautionary statement(s)

**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.

**Other hazards which do not result in classification** 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

### Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
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	*

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

#### 4. First-aid measures

##### Description of necessary 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**                      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.

**Personal protection for first-aid responders**      You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call. 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.

**Symptoms caused by exposure**      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.

**Medical attention and special treatment**      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. This product contains mineral oil. In the event of accidental self-administration, it can cause significant pain and prolonged swelling for 6 to 24 months at the injection site, perhaps also involving the draining lymph nodes. Medical or surgical intervention may be required, especially if the site of injection involves a finger joint or tendon sheath. Accidental self-injection of this vaccine may result in cross- reaction with, and a false positive test results for human tuberculosis. Cases of accidental self-injection should also be reported to Zoetis on 1800 814 883.

#### 5. Fire-fighting measures

##### Extinguishing media

**Suitable extinguishing media**      Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**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 fire fighters**      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.

**Hazchem code**                      None.

**General fire hazards**              No unusual fire or explosion hazards noted.

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

#### 6. Accidental release measures

##### Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel**      Keep unnecessary personnel away.

**For emergency responders** Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

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

**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.

## 7. Handling and storage

**Precautions for safe handling** Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapour. 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.

## 8. Exposure controls and personal protection

**Control parameters** Follow standard monitoring procedures.

### Occupational exposure limits

#### Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m3

#### US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.

#### Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
Mineral oil, white (CAS 8042-47-5)	TWA	5 mg/m3	Respirable fraction.

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

### Exposure guidelines

#### US ACGIH Threshold Limit Values: Skin designation

Merthiolate (as mercury) (CAS 54-64-8)

Can be absorbed through the skin.

**Appropriate engineering controls** 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.

### Individual protection measures, for example personal protective equipment (PPE)

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended.

#### Skin protection

**Hand protection** Wear protective gloves. 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 engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.

**Thermal hazards** Not applicable.

**Hygiene measures** 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

**Physical state** Liquid.

**Form** Liquid.

**Colour** White.

**Odour** Not available.

**Odour threshold** Not available.

**pH** 6 - 8

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** > 100 °C (> 212 °F)

**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.

**Vapour pressure** Not available.

**Vapour density** Not available.

**Relative density** Not available.

### Solubility(ies)

**Solubility (water)** Soluble

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

### Other physical and chemical parameters

**Explosive properties** Not explosive.

**Oxidising properties** Not oxidising.

**Specific gravity** 0.8 - 1.2

## 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.

**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 oxidising 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 possible 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 exposure** 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.

**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
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/irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye contact</b>		
Merthiolate (as mercury)	Species: Rabbit	Severity: Mild

**Eye contact**  
Mineral oil, white

Species: Rabbit  
Severity: Slight

#### **Respiratory or skin sensitisation**

**Respiratory sensitisation** Not a respiratory sensitizer.

**Skin sensitisation** This product contains merthiolate which is considered to be a skin sensitizer. This product is not expected to cause skin sensitisation.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Carcinogenicity** Based on available data, the classification criteria are not met.

#### **ACGIH Carcinogens**

Mineral oil, white (CAS 8042-47-5)

A4 Not classifiable as a human carcinogen.

#### **IARC Monographs. Overall Evaluation of Carcinogenicity**

Mineral oil, white (CAS 8042-47-5)

3 Not classifiable as to carcinogenicity to humans.

**Reproductive toxicity** This product is not expected to cause reproductive or developmental effects.

**Specific target organ toxicity - single exposure** Not classified.

**Specific target organ toxicity - repeated exposure** Not classified.

**Aspiration hazard** Based on available data, the classification criteria are not met.

**Other information** The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms.

## **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.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available for this product.

**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 methods** 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. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

**Residual waste** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## **14. Transport information**

### **ADG**

Not regulated as dangerous goods.

### **RID**

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

### Safety, health and environmental regulations

**National regulations** This Safety Data Sheet was prepared in accordance with the Australia Model Code of Practice for the preparation of safety data sheets for hazardous chemicals.

This SDS replaces version: Issued July 2019

APVMA No. 54654

Poison Schedule (Product) – Schedule 0

**Australia Medicines & Poisons Appendix A**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix B**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix D**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix E**

Merthiolate (as mercury) (CAS 54-64-8)

Mineral oil, white (CAS 8042-47-5)

**Australia Medicines & Poisons Appendix F**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix G**

Merthiolate (as mercury) (CAS 54-64-8)

**Australia Medicines & Poisons Appendix H**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix I**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix J**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix K**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 10**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 2**

Merthiolate (as mercury) (CAS 54-64-8)

**Australia Medicines & Poisons Schedule 3**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 4**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 5**

Mineral oil, white (CAS 8042-47-5)

**Australia Medicines & Poisons Schedule 6**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 7**

Merthiolate (as mercury) (CAS 54-64-8)

**Australia Medicines & Poisons Schedule 8**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 9**

Poisons schedule number not allocated.

**Australia National Pollutant Inventory (NPI): Threshold quantity**

Merthiolate (as mercury) (CAS 54-64-8)

5 kg Threshold Category: 1B

**High Volume Industrial Chemicals (HVIC)**

Mineral oil, white (CAS 8042-47-5)

1000 - 9999 TONNES See the regulation for additional information.

**Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)**

Not listed.

**National Pollutant Inventory (NPI) substance reporting list**

Merthiolate (as mercury) (CAS 54-64-8)

2000 TONNES/YR Threshold Category: 2B

**Prohibited Carcinogenic Substances**

Not regulated.

**Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)**

Not listed.

**Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)**

Not listed.

**Restricted Carcinogenic Substances**

Not regulated.

**International regulations****Stockholm Convention**

Not applicable.

**Rotterdam Convention**

Merthiolate (as mercury) (CAS 54-64-8)

Pesticide

**Kyoto Protocol**

Not applicable.

**Montreal Protocol**

Not applicable.

**Basel Convention**

Not applicable.

**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
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** 15-May-2020**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** Product and Company Identification: Synonyms  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties: Multiple Properties