

SAFETY DATA SHEET



1. Identification

Product identifier Silirum Vaccine (59642)

Other means of identification None.

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 australia.animalhealth@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 (%) |
|----------------------------------|---|----------------------------------|
| Mineral oil | 8042-47-5 | 50 |
| Mycobacterium paratuberculosis | NA | <1 |
| Thimerosal | 54-64-8 | 0.01 |

4. First-aid measures

Description of necessary first aid measures

| | |
|---------------------|---|
| Inhalation | Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary. |
| 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. Self Injection: In all instances of accidental self injection contact a doctor as soon as possible. Further information on treatment is available from Poisons Information Centre - Phone 131 126. Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. Check your tetanus immunisation status. |
| 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 IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. 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. 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. Symptoms may be delayed. Self Injection: 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.

Self Injection: In all instances of accidental self injection contact a doctor as soon as possible. Further information on treatment is available from Poisons Information Centre - Phone 131 126. Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. Check your tetanus immunisation status. The recommendations following self inoculation for medical management or surgical intervention are as follows: Category 1 injury (superficial skin exposure) Simply wash the contaminated area in warm soapy water. If vaccine material is splashed onto mucosal surfaces (e. g. eyes) there is greater risk and topical corticosteroids should be considered here. Category 2 injury (simple needle-stick injuries without injection) Allow the wound to bleed freely and do not squeeze or interfere with the injection site. Clean the wound thoroughly with soap and water, and keep it clean and dry. Treat symptomatically (e.g. ensure appropriate tetanus cover; prescribe topical corticosteroids and oral antibiotics to prevent opportunistic infection). If unsure whether or not product has been injected, monitor for 24 hours. If pain and swelling subside, injection is unlikely to have occurred. If pain and swelling persist after 24 hours, treatment should be as per Category 3. Category 3 injury (injection of vaccine material) Acute pain and inflammation is usually evident within 24 hours. Perform early surgery and drainage to remove the oil based vaccine material before it spreads or elicits a severe granulomatous reaction. Category 4 injury (lesion that has progressed to necrosis or granulomatous ulceration) Perform surgical debridement to remove any residual vaccine material. Skin grafting may ultimately be required.

5. Fire-fighting measures

Extinguishing media

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|---------------------------------------|--|
| Suitable extinguishing media | Foam. Dry chemicals. Carbon dioxide (CO ₂). |
| Unsuitable extinguishing media | Do not use water jet as an extinguisher, as this will spread the fire. |

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|---|--|
| 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 | Cool containers exposed to heat with water spray and remove container, if no risk is involved. |
| Hazchem Code | None. |
| General fire hazards | Combustible. Material will burn in a fire. |
| 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

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|------------------------------------|---|
| 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

Ensure adequate ventilation. Remove sources of ignition. Wear appropriate protective equipment and clothing during clean-up.

Large Spills: Stop the flow of material, if this is without risk. 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.

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapour. Avoid accidental injection. Do not taste or swallow. 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 - 8°C (36 - 46°F). Do not freeze. Protect from light. 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 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 |
|-----------------------------|------|------------------------|
| Mineral oil (CAS 8042-47-5) | TWA | 5 mg/m ³ |
| Thimerosal (CAS 54-64-8) | STEL | 0.03 mg/m ³ |
| | TWA | 0.01 mg/m ³ |

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

| Components | Type | Value | Form |
|-----------------------------|------|------------------------|-------|
| Mineral oil (CAS 8042-47-5) | TWA | 5 mg/m ³ | Mist. |
| Thimerosal (CAS 54-64-8) | STEL | 0.03 mg/m ³ | |
| | TWA | 0.01 mg/m ³ | |

US. ACGIH Threshold Limit Values

| Components | Type | Value | Form |
|-----------------------------|------|------------------------|---------------------|
| Mineral oil (CAS 8042-47-5) | TWA | 5 mg/m ³ | Inhalable fraction. |
| Thimerosal (CAS 54-64-8) | STEL | 0.03 mg/m ³ | |
| | TWA | 0.01 mg/m ³ | |

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 (CAS 8042-47-5) | TWA | 5 mg/m ³ | Respirable fraction. |

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

Exposure guidelines

Australia 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.

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas. 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 appropriate chemical resistant gloves.

Other Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment. No personal respiratory protective equipment normally required.

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 Milky pink oil-water emulsion.

Physical state Liquid.

Form Liquid.

Colour Not available.

Odour Not available.

Odour threshold Not available.

pH 6.5 - 7.5

Melting point/freezing point 0 °C (32 °F)

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

Flash point Not available.

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 0.94

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. Exposure to light. Keep away from heat, sparks and open flame. Protect from freezing.

Incompatible materials Strong oxidising agents.

Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on possible routes of exposure

Inhalation Health injuries are not known or expected under normal use.

Skin contact Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.
Mineral oil
Species: Rabbit
Severity: Non-irritating

Eye contact Direct contact with eyes may cause temporary irritation.
Thimerosal
Species: Rabbit
Severity: Mild

Mineral oil
Species: Rabbit
Severity: Non-irritating

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 |
|-----------------------------|---------|-------------------------------|
| Mineral oil (CAS 8042-47-5) | | |
| Acute | | |
| Oral | | |
| LD50 | Rat | > 5000 mg/kg |
| Chronic | | |
| Oral | | |
| NOAEL | Rat | 1800 mg/kg/day, 90 days Liver |

| Components | Species | Test results |
|---|---|---|
| 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 | Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis. | |
| Serious eye damage/irritation | Direct contact with eyes may cause temporary irritation. | |
| Eye contact | | |
| Thimerosal | | Species: Rabbit Severity: Mild |
| Mineral oil | | Species: Rabbit Severity: Non-irritating |
| Respiratory or skin sensitisation | | |
| Respiratory sensitisation | Due to partial or complete lack of data the classification is not possible. Allergic reactions are possible. | |
| Skin sensitisation | Due to partial or complete lack of data the classification is not possible. Allergic reactions are possible. | |
| Skin sensitisation | | |
| Mineral oil | | Species: Guinea Pig Severity: negative |
| Germ cell mutagenicity | No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. | |
| Mutagenicity | | |
| Mineral oil | | In Vitro Bacterial Mutagenicity (Ames) Result: negative Species: Salmonella |
| | | In Vitro Mammalian Cell Mutagenicity Result: negative Species: Mouse Lymphoma |
| Carcinogenicity | Due to partial or complete lack of data the classification is not possible. | |
| ACGIH Carcinogens | | |
| Mineral oil (CAS 8042-47-5) | | A4 Not classifiable as a human carcinogen. |
| IARC Monographs. Overall Evaluation of Carcinogenicity | | |
| Mineral oil (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 | Due to partial or complete lack of data the classification is not possible. | |
| Chronic effects | Prolonged exposure may cause chronic effects. | |
| 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

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| 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 |
|--------------------------------------|---|---|
| Mineral oil (CAS 8042-47-5) | LC50 | Lepomis macrochirus (Bluegill Sunfish) > 10000 mg/l, 96 Hours |
| Persistence and degradability | No data is available on the degradability of this product. | |
| Bioaccumulative potential | No data available. Not expected to bioaccumulate. | |
| Mobility in soil | This product is miscible in water. | |
| 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

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|-------------------------------|--|
| Disposal methods | Avoid release to the environment. 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

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|---|--|
| National regulations | This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011). Poison Schedule (Product) – Schedule 0 APVMA No. 59642 |
| Australia Medicines & Poisons Appendix E | HYDROCARBONS, LIQUID (CAS 8042-47-5) Mercury, organic compounds (CAS 54-64-8) |
| Australia Medicines & Poisons Appendix G | Mercury (CAS 54-64-8) |
| Australia Medicines & Poisons Schedule 2 | Mercury (CAS 54-64-8) |
| Australia Medicines & Poisons Schedule 5 | HYDROCARBONS, LIQUID, INCLUDING KEROSENE, DIESEL (DISTILLATE), MINERAL TURPENTINE, WHITE PETROLEUM SPIRIT, TOLUENE, XYLENE AND LIGHT MINERAL AND PARAFFIN OILS (BUT EXCLUDING THEIR DERIVATIVES) (CAS 8042-47-5) |
| Australia Medicines & Poisons Schedule 7 | MERCURY, EXCEPT WHEN SEPARATELY SPECIFIED IN THIS SCHEDULE (CAS 54-64-8) |

Australia National Pollutant Inventory (NPI): Threshold quantity

Thimerosal (CAS 54-64-8) 5 kg Threshold Category: 1B

High Volume Industrial Chemicals (HVIC)

Mineral oil (CAS 8042-47-5) 1000 - 9999 TONNES See the regulation for additional information.

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

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Thimerosal (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

Thimerosal (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 |
| 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** 07-August-2017**Revision date** 15-March-2018**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.