SAFETY DATA SHEET

1. Identification

Product identifier **GUDAIR VACCINE (53839)**

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 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	<40
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	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 unconsious 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

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.
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	No unusual fire or explosion hazards noted. 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

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. 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. 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/m3
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

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/m3	Mist.
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	

US. ACGIH Threshold Limit Values

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

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/m3	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 White 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. Heat, flames and sparks. Sunlight. Exposure to light. Protect from freezing.
Incompatible materials	Strong oxidising agents.
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	No adverse effects due to skin contact are expected.	
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	Expected to be a low ingestion hazard.	

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
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/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.

Skin sensitisation Due to partial or complete lack of data the classification is not 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 Not an aspiration hazard.

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.

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

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

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 Registration Number: 53839

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 Deleting 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.

Resricted 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	23-October-2017
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	First-aid measures: Medical attention and special treatment Regulatory information: National regulations