SAFETY DATA SHEET

Section 1 - Identification

Product identifier **GUDAIR VACCINE**

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 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)

Section 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.

Supplemental information This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm, significant pain and prolonged swelling at the injection site, scratch or wound (which will include tissue damage (necrosis) and may also involve draining lymph nodes) following accidental- or self-injection. In the event of accidental injection, an allergic reaction may occur.

Other hazards which do not result in classification None known.

Section 3 - Composition and information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
White mineral oil	8042-47-5	31.6
Mycobacterium paratuberculosis	NA	<1

Thimerosal	54-64-8	0.01

Composition comments Other components below reportable levels

Section 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. If irritation develops and persists, or if you are concerned, seek medical attention.

Eye contact Remove contact lenses, if present and easy to do. Rinse eyes thoroughly with saline solution or, if not available, clean and cool water from a running tap or a cup/jug. Continue to flush for at least 15 minutes and seek prompt medical attention.

Ingestion Rinse mouth with cool water. If irritation develops, you feel unwell, or if you are concerned, seek medical attention. 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. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. 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.

Symptoms caused by exposure This product is an oil-adjuvanted suspension. Direct contact with eyes may cause temporary irritation, redness, or discomfort. Oil-adjuvant containing products may cause severe vasospasm following accidental- or self-injection. Entry of Gudair into the human body through contact with the needle (accidental- or self-injection, needle stick, needle scratch, etc.) or entry through an open wound can cause significant pain and prolonged swelling at the injection site, scratch or wound, which will include tissue damage (necrosis) and may also involve the draining lymph nodes. Given the potential for serious side effects, prompt medical attention is required as surgical intervention may be needed. An allergic reaction may also occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal oedema, laryngeal mucosal oedema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

Medical attention and special treatment	Accidental- or self-injection: This product contains mineral oil. In the event of accidental self-administration or needle stick injury, allow the wound to bleed freely and do not squeeze or otherwise interfere with the wound or injection site. Gently wash the wound thoroughly with warm water, and after washing, keep it clean and dry. Check your tetanus immunisation status. Accidental- or self-injection without known injection of vaccine: If there is no pain or swelling 24 hours post exposure, continue to monitor for at least a month and seek medical attention if concerned. If there is any pain and swelling after 24 hours, it is likely that vaccine has entered the body. In such cases, follow the instructions below. Accidental- or self-injection with suspected injection of vaccine: Even if only a very small amount of vaccine is thought to have entered your body, seek prompt medical attention and take the product leaflet and packaging with you. Surgical intervention may be required. Accidental- or self-injection may lead to intense swelling and a persistent granulomatous inflammatory reaction, which 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, including debridement, may be required if Gudair enters the body, especially if the site of injection involves a finger joint or tendon sheath. If injected into a finger joint, the swelling and inflammation may compromise blood supply and result in necrosis that, in rare cases, may lead to the loss of a digit. If injected into a tendon sheath the product may track along the tendon and result in necrosis distant to the injection site. Timing of surgery is at the discretion of the medical practitioner. Cases of accidental- or self-injection should also be reported to Zoetis on 1800 814 883. 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 surgery and drainage to remove the oil based vaccine material – the timing of the surgical intervention is at the discretion of the medical practitioner. 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. Treat symptomatically. Symptoms may be delayed.

Section 5 - Firefighting measures

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	Will burn if involved in a fire. 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.
Extinguishing media	
Suitable extinguishing media	Foam. Dry chemicals. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

Section 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. Ensure adequate ventilation. Avoid breathing mist/vapours. Local authorities should be advised if significant spillages cannot be contained. 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. Avoid release to the environment. Large Spills: Stop the flow of material, if this is without risk. 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.

Section 7 - Handling and storage

Precautions for safe handling	Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Use only in well-ventilated areas. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. Avoid accidental- or self-injection. When vaccinating animals, administer using a Gudair Safety Vaccinator following instructions on the label.
Conditions for safe storage, including any incompatibilities	Store out of direct sunlight in dark, dry conditions. Store at 2-8°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. Protect from light. Keep out of the reach of children. Store away from incompatible materials (see Section 10 of the SDS).

Section 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
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
White mineral oil (CAS 8042-47-5)	TWA	5 mg/m3

US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value	Form
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3	
White mineral oil (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), as updated

Components	Type	Value	Form
White mineral oil (CAS 8042-47-5)	TWA	5 mg/m3	Respirable fraction.

Biological limit values

UK. BELs. Biological Monitoring Guidance Values (BMGVs) (EH40/2005 (Fourth Edition 2020)), Table 2

Components	Value	Determinant	Specimen	Sampling Time
Thimerosal (CAS 54-64-8)	20 umol/mol	Mercury	Creatinine in urine	*

* - For sampling details, please see the source document.

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas.

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. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Other	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. When vaccinating animals, administer using a Gudair Safety Vaccinator following instructions on the label.
Respiratory protection	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment.
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.

Section 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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water)	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	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

Section 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	Sunlight. Exposure to light. Heat, flames and sparks. Contact with incompatible materials. Protect from freezing.
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.

Section 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.
White mineral oil	Species: Rabbit Severity: Non-irritating
Eye contact	Direct contact with eyes may cause temporary irritation.
Thimerosal	Species: Rabbit Severity: Mild
White mineral oil	Species: Rabbit Severity: Non-irritating
Ingestion	Health injuries are not known or expected under normal use.

Symptoms related to exposure

Direct contact with eyes may cause temporary irritation, redness, or discomfort. Entry of Gudair into the human body through contact with the needle (accidental- or self-injection, needle stick, needle scratch, etc.) or entry through an open wound can cause significant pain and prolonged swelling at the injection site, scratch or wound, which will include tissue damage (necrosis) and may also involve the draining lymph nodes. Given the potential for serious side effects, prompt medical attention is required as surgical intervention may be needed. An allergic reaction may also occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal oedema, laryngeal mucosal oedema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. Oil-adjuvant containing products may cause severe vasospasm following accidental- or self-injection.

Acute toxicity

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

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

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
White 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

White 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

White 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

White mineral oil (CAS 8042-47-5)	A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

White 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.

Section 12 - Ecological information

Ecotoxicity 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.

Components		Species	Test Results
White mineral oil (CAS 8042-47-5)			
Aquatic			
Fish	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 Not expected to bioaccumulate.

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.

Section 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. 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.

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.

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

Section 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.

Section 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.

APVMA No.: 53839

Poison Schedule (Product) – Schedule 0

Australia Medicines & Poisons Appendix E

Thimerosal (CAS 54-64-8)
White mineral oil (CAS 8042-47-5)

Australia Medicines & Poisons Schedule 2

Thimerosal (CAS 54-64-8)

Australia Medicines & Poisons Schedule 5

White mineral oil (CAS 8042-47-5)

Australia Medicines & Poisons Schedule 7

Thimerosal (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)

White 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, as amended)

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 Carcinogenic Substances

Not regulated.

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

Not listed.

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 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
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).

Section 16 - Any other relevant information

Issue date	08-September-2022
Revision date	16-October-2024
Key abbreviations or acronyms used	AICIS: Australian Inventory of Industrial Chemicals.
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.