

# SAFETY DATA SHEET



## 1. Identification

**Product identifier** Neovac Vaccine

### Other means of identification

**Synonyms** Neovac \* E.coli vaccine

### 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. This product is an oil-adjuvanted emulsion. Oil-adjuvant containing products may cause severe vasospasm following accidental injection. In the event of accidental injection, an allergic reaction may occur.

## 3. Composition/information on ingredients

### Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Thimerosal	54-64-8	0.01
Escherichia coli antigens (K88ab, K88ac, K99, 987p)	Not assigned	*

**Composition comments** \*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

## 4. First-aid measures

### Description of necessary first aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
<b>Skin contact</b>	In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately. 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.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
<b>Ingestion</b>	Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
<b>Personal protection for first-aid responders</b>	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.

<b>Symptoms caused by exposure</b>	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. This product is an oil-adjuvanted emulsion. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.
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<b>Medical attention and special treatment</b>	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.
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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

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.

<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
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**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. 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 accidental injection. Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapour. 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** Refrigeration recommended. 2 - 8°C (36 - 46°F). Do not freeze. 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
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

**US. ACGIH Threshold Limit Values**

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

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

**Exposure guidelines**

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

Thimerosal (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 appropriate chemical resistant gloves.

<b>Other</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. If ventilation is insufficient, suitable respiratory protection must be provided. 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.
<b>Thermal hazards</b>	Not applicable.
<b>Hygiene measures</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

<b>Appearance</b>	Oily liquid.
<b>Physical state</b>	Liquid.
<b>Form</b>	Water-in-oil emulsion.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	0 °C (32 °F)
<b>Initial boiling point and boiling range</b>	100 °C (212 °F)
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	100 %
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other physical and chemical parameters</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidising properties</b>	Not oxidising.
<b>Specific gravity</b>	0.9

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.

<b>Conditions to avoid</b>	Contact with incompatible materials. Keep away from heat, sparks, flame and all other sources of ignition. Protect from sunlight. Protect from freezing.
<b>Incompatible materials</b>	Strong oxidising agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known. May include products of carbon, nitrogen.

## 11. Toxicological information

### Information on possible routes of exposure

<b>Inhalation</b>	Health injuries are not known or expected under normal use.
<b>Skin contact</b>	Prolonged skin contact may cause temporary irritation.
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
Thimerosal	Species: Rabbit Severity: Mild

**Ingestion** Health injuries are not known or expected under normal use.

**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 emulsion. 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
Thimerosal (CAS 54-64-8)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	91 mg/kg
	Rat	75 mg/kg
<b>Subcutaneous</b>		
LD50	Rat	98 mg/kg
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Serious eye damage/irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye contact</b>	Species: Rabbit	
Thimerosal	Severity: Mild	
<b>Respiratory or skin sensitisation</b>		
<b>Respiratory sensitisation</b>	Due to partial or complete lack of data the classification is not possible.	
<b>Skin sensitisation</b>	Due to partial or complete lack of data the classification is not possible. This product contains formaldehyde and merthiolate which are considered to be skin sensitizers. This product is not expected to cause skin sensitisation.	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Carcinogenicity</b>	Due to partial or complete lack of data the classification is not possible. No data available to indicate product or any components present at greater than 0.1% are carcinogenic.	
<b>Reproductive toxicity</b>	This product is not expected to cause reproductive or developmental effects.	
<b>Specific target organ toxicity - single exposure</b>	Not classified.	
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.	
<b>Aspiration hazard</b>	Not an aspiration hazard.	

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

## 12. Ecological information

**Ecotoxicity** Based on available data, the classification criteria are not met for hazardous to the aquatic 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. Avoid release to the environment.

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

**Bioaccumulative potential** No data available for this product. 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.

## 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).

APVMA No. 53610

#### **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**

Thimerosal (CAS 54-64-8)

#### **Australia Medicines & Poisons Appendix F**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix G**

Thimerosal (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**

Thimerosal (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**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 6**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 7**

Thimerosal (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**

Thimerosal (CAS 54-64-8)

5 kg Threshold Category: 1B

**High Volume Industrial Chemicals (HVIC)**

Not listed.

**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
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

<b>Issue date</b>	14-September-2016
<b>Revision date</b>	11-March-2020
<b>Disclaimer</b>	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.
<b>Revision information</b>	Identification: Restrictions on use Physical and chemical properties: Appearance Toxicological information: Carcinogenicity Toxicological information: Ingestion