

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>IMPROVAC Vaccine</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	IMPROVAC * IMPROVAC for Male Pigs * Boar Taint Vaccine for Male Pigs
<b>Recommended use of the chemical and restrictions on use</b>	
<b>Recommended use</b>	Veterinary vaccine
<b>Restrictions on use</b>	Not for human use
<b>Details of manufacturer or importer</b>	
<b>Company Name (AU)</b>	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
<b>Tel</b>	1800 814 883
<b>Fax</b>	(02) 8876 0444
<b>Email</b>	australia.animalhealth@zoetis.com
<b>Emergency Phone</b>	1800 814 883 (all hours)
<b>Police and Fire Brigade</b>	Dial 000
<b>If ineffective</b>	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

## 2. Hazard(s) identification

### Classification of the hazardous chemical

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Reproductive toxicity	Category 1B
<b>Environmental hazards</b>	Not classified.	

### Label elements, including precautionary statements

#### Hazard symbol(s)



Health hazard

<b>Signal word</b>	Danger
<b>Hazard statement(s)</b>	May damage fertility or the unborn child.
<b>Precautionary statement(s)</b>	
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.
<b>Response</b>	IF exposed or concerned: Get medical advice/attention.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Other hazards which do not result in classification</b>	None known.

**Supplemental information** In the event of systemic exposure, this material may cause immune system reactions in humans. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy. Pregnant women should not administer this product. Women and men of childbearing age should exercise extreme caution when handling this product. In the event of accidental injection, an allergic reaction may occur. Accidental self injection could affect reproductive physiology of both men and women and may adversely affect pregnancy. After self injection or needle stick injury do not administer the product, and/or any other product with similar action, in the future.

### 3. Composition/information on ingredients

#### Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Gonadotropin Releasing Factor Analog - Diphtheria Toxoid Conjugate	Not assigned	0.02
Thimerosal	54-64-8	0.01
Synthetic adjuvant	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

**Inhalation** Under normal conditions of intended use, this material is not expected to be an inhalation hazard. If inhaled, remove to fresh air. Get medical attention immediately.

**Skin contact** In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.

**Eye contact** Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention immediately.

**Ingestion** IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician. Rinse mouth thoroughly. 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. Show this safety data sheet to the doctor in attendance. Accidental self injection could affect reproductive physiology of both men and women and may adversely affect pregnancy. After self injection or needle stick injury do not administer the product, and/or any other product with similar action, in the future.

**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. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy.

**Medical attention and special treatment** Accidental self injection could affect reproductive physiology of both men and women and may adversely affect pregnancy. After self injection or needle stick injury do not administer the product, and/or any other product with similar action, in the future.

### 5. Fire-fighting measures

#### Extinguishing media

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

**Unsuitable extinguishing media** Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the chemical** During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for fire fighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Fire fighting equipment/instructions** Move containers from fire area if you can do so without risk.

**Hazchem Code** None.

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

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

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel** Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.

**For emergency responders** Wear appropriate protective equipment and clothing during clean-up. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

**Environmental precautions** Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

**Methods and materials for containment and cleaning up** Ensure adequate ventilation. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Collect spill with an inert, non-combustible absorbent material and transfer to labeled container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment.

Small Spills: Wipe up with a damp cloth and place in container for disposal. 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** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Pregnant women should not administer this product. Women and men of childbearing age should exercise extreme caution when handling this product. Special care should be taken to avoid accidental self injection and needle stick injury when administering the product. Use a safety injector, preferably one which has a dual safety system providing both a needle guard and a mechanism to prevent accidental operation of the trigger. Handle and open container with care. Wear appropriate personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Wash thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment.

**Conditions for safe storage, including any incompatibilities** Store locked up. Store in original tightly closed container. Protect from light. Refrigeration recommended. 2 - 8°C (36 - 46°F). Do not freeze. Store away from incompatible materials (see Section 10 of the SDS). Use care in handling/storage.

## 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

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

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

#### 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.

<b>Control banding approach</b>	Gonadotropin Releasing Factor Analog - Diphtheria Toxoid Conjugate: Zoetis OEB 4 (control exposure to the range of 1ug/m3 to <10ug/m3)
<b>Appropriate engineering controls</b>	<p>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.</p> <p>Caution: To avoid accidental self-injection, Improvac should only be administered using the CSL Improvac-approved vaccinator with a dual safety system providing both a needle safety shield and a mechanism to prevent accidental operation of the trigger. Operators should be trained in procedures for safe use of this material.</p>
<b>Individual protection measures, for example personal protective equipment (PPE)</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear impervious gloves if skin contact is possible.
<b>Other</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. 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. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. Chemical respirator with organic vapour cartridge and full facepiece.
<b>Thermal hazards</b>	Not applicable.
<b>Hygiene measures</b>	Observe any medical surveillance requirements. 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>	
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Colour</b>	Clear, colorless
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	6.7
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<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>	1.05

## 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. Hazardous polymerisation does not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials. Exposure to light. Avoid high temperatures.
<b>Incompatible materials</b>	Strong oxidising agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known. Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

## 11. Toxicological information

### Information on possible routes of exposure

<b>Inhalation</b>	No adverse effects due to inhalation are expected.
<b>Skin contact</b>	No adverse effects due to skin contact are expected.
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
Thimerosal	Species: Rabbit Severity: Mild

**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. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy.

### Acute toxicity

Components	Species	Test results
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Thimerosal (CAS 54-64-8)

#### Acute

##### Oral

LD50	Mouse	91 mg/kg
	Rat	75 mg/kg

##### Subcutaneous

LD50	Rat	98 mg/kg
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**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
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### Respiratory or skin sensitisation

**Respiratory sensitisation** Not a respiratory sensitizer.

**Skin sensitisation** 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.
<b>Reproductive toxicity</b>	May damage fertility or the unborn child.
<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.
<b>Other information</b>	The toxicity of similar GnRF biologicals has been evaluated in several species. In all species tested, vaccination was associated with significant changes in sex hormone balance with severe consequences to reproduction and development.

## 12. Ecological information

<b>Ecotoxicity</b>	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.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available for this product.
<b>Other adverse effects</b>	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

<b>Disposal methods</b>	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. 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.
<b>Residual waste</b>	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).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Do not re-use empty containers.

## 14. Transport information

<b>ADG</b>	Not regulated as dangerous goods.
<b>RID</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not available.

## 15. Regulatory information

### Safety, health and environmental regulations

<b>National regulations</b>	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 4
	APVMA Registration Number: 50113

**Australia Medicines & Poisons Appendix E**

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 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)**

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
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>	31-August-2016
<b>Revision date</b>	05-July-2017
<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>	Product and Company Identification: Synonyms Exposure controls and personal protection: Appropriate engineering controls Disposal considerations: Disposal methods Regulatory information: National regulations