

SAFETY DATA SHEET



1. Identification

Product identifier	BOPRIVA
Other means of identification	
Synonyms	BOPRIVA Vaccine for Cattle * Bopriva vaccine for cattle (63172)
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	Reproductive toxicity	Category 1B
Environmental hazards	Not classified.	

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard

Signal word	Danger
Hazard statement(s)	May damage fertility or the unborn child.
Precautionary statement(s)	

Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.
Response	IF exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards which do not result in classification	None known.
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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	0.04
Thimerosal	54-64-8	0.01
Proprietary non-hazardous ingredients	7732-18-5	*

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 (CO₂).

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. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders Wear appropriate protective equipment and clothing during clean-up. Use personal protection recommended in Section 8 of the SDS. 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.

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/m ³
	TWA	0.01 mg/m ³

US. ACGIH Threshold Limit Values

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m ³
	TWA	0.01 mg/m ³

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.

Control banding approach Gonadotropin Releasing Factor Analog - Diphtheria Toxoid Conjugate: Zoetis OEB 4 (control exposure to the range of 1ug/m³ to <10ug/m³)

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 impervious gloves if skin contact is possible.
Other	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection	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.
Thermal hazards	Not applicable.
Hygiene measures	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

Appearance

Physical state	Liquid.
Form	Liquid.
Colour	Clear, colorless
Odour	Not available.
Odour threshold	Not available.
pH	6.7
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
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)	100 %
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	1.05

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. Hazardous polymerisation does not occur.
Conditions to avoid	Contact with incompatible materials. Exposure to light. Avoid high temperatures.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	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

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	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.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity Due to partial or complete lack of data the classification is not possible.

Reproductive toxicity May damage fertility or the unborn child.

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 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

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.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
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 discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. Incinerate the material under controlled conditions in an approved incinerator. If no on-site incinerator is available, dispose of material in a licensed commercial chemical incinerator. Dispose of contents/container in accordance with local/regional/national/international regulations. Contract with a disposal operator licensed by the Law on Disposal and Cleaning.
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. Do not re-use empty containers.

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 the Australia Model Code of Practice for the preparation of safety data sheets for hazardous chemicals. APVMA No. 63172 Poison Schedule (Product) - Schedule 4
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)

Proprietary non-hazardous ingredients (CAS 7732-18-5)

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
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

Issue date	24-August-2016
Revision date	17-August-2021
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	Identification: Restrictions on use Regulatory information: National regulations