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.
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

<table>
<thead>
<tr>
<th>Identity of chemical ingredients</th>
<th>CAS number and other unique identifiers</th>
<th>Concentration of ingredients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gonadotropin Releasing Factor Analog - Diphtheria Toxoid Conjugate</td>
<td>Not assigned</td>
<td>0.04</td>
</tr>
<tr>
<td>Thimerosal</td>
<td>54-64-8</td>
<td>0.01</td>
</tr>
<tr>
<td>Proprietary non-hazardous ingredients</td>
<td>7732-18-5</td>
<td>*</td>
</tr>
</tbody>
</table>

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)**

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thimerosal (CAS 54-64-8)</td>
<td>STEL</td>
<td>0.03 mg/m3</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>0.01 mg/m3</td>
</tr>
</tbody>
</table>

**US. ACGIH Threshold Limit Values**

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
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</tr>
<tr>
<td></td>
<td>TWA</td>
<td>0.01 mg/m3</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thimerosal (CAS 54-64-8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>91 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>75 mg/kg</td>
</tr>
<tr>
<td>Subcutaneous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>98 mg/kg</td>
</tr>
<tr>
<td><strong>Skin corrosion/irritation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prolonged skin contact may cause temporary irritation.</td>
<td></td>
</tr>
<tr>
<td><strong>Serious eye damage/irritation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Direct contact with eyes may cause temporary irritation.</td>
<td></td>
</tr>
<tr>
<td><strong>Eye contact</strong></td>
<td>Thimerosal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severity: Mild</td>
<td></td>
</tr>
</tbody>
</table>

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**

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 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.

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

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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