SAFETY DATA SHEET

1. Identification

Product identifier

IMPROVAC FOR MALE PIGS (APVMA No. 70058)

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

australia.animalhealth@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

Contains 4-CHLORO-M-CRESOL. May produce an allergic reaction. 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>Mixture</th>
<th>Identity of chemical ingredients</th>
<th>CAS number and other unique identifiers</th>
<th>Concentration of ingredients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-CHLORO-M-CRESOL</td>
<td>59-50-7</td>
<td>&lt; 0.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gonadotropin Releasing Factor Analog - Diphtheria Toxoid Conjugate</td>
<td>Not assigned</td>
<td>0.02</td>
</tr>
<tr>
<td>Other components below reportable levels</td>
<td></td>
<td></td>
<td>90 - 100</td>
</tr>
</tbody>
</table>

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**
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. May cause allergic skin reaction. Dermatitis. Rash. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy.

**Symptoms caused by exposure**
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.

**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**
- Do not use water jet as an extinguisher, as this will spread the fire.
- During fire, gases hazardous to health may be formed.
- Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
- Move containers from fire area if you can do so without risk.

**Hazchem Code**
None.

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.
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.

Environmental precautions

Ensure adequate ventilation. Prevent product from entering drains.

Methods and materials for containment and cleaning up

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

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.

Precautions for safe handling

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.

Conditions for safe storage, including any incompatibilities

8. Exposure controls and personal protection

Follow standard monitoring procedures.

Control parameters

No exposure limits noted for ingredient(s).

Occupational exposure limits

No biological exposure limits noted for the ingredient(s).

Biological limit values

No exposure standards allocated.

Exposure guidelines

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

Control banding approach

Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.

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.

Appropriate engineering controls

If contact is likely, safety glasses with side shields are recommended.

Eye/face protection

Wear appropriate chemical resistant gloves.

Skin protection

Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Hand protection

No personal respiratory protective equipment normally required. 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. 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.

Respiratory protection

None known.

Thermal hazards

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.

Hygiene measures

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: Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride.

11. Toxicological information

Information on possible routes of exposure:

Inhalation: No adverse effects due to inhalation are expected.
Skin contact: May cause an allergic skin reaction.

4-CHLORO-M-CRESOL: Species: Rabbit
Severity: Slight
| Eye contact | Direct contact with eyes may cause temporary irritation. | Species: Rabbit | Severity: Severe |
| 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. May cause an allergic skin reaction. Dermatitis. Rash. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy. |

### Acute toxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-CHLORO-M-CRESOL (CAS 59-50-7)</td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>LOEL</td>
<td>Rat</td>
</tr>
<tr>
<td><strong>Subacute</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>NOEL</td>
<td>Rat</td>
</tr>
<tr>
<td><strong>Subchronic</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>NOEL</td>
<td>Rat</td>
</tr>
</tbody>
</table>

### Skin corrosion/irritation
Prolonged skin contact may cause temporary irritation.

### Serious eye damage/irritation
Direct contact with eyes may cause temporary irritation.

### Respiratory or skin sensitisation

#### Respiratory sensitisation
Not a respiratory sensitizer.

#### Skin sensitisation
Due to partial or complete lack of data the classification is not possible. May cause an allergic skin reaction.

| Skin sensitisation | Species: Guinea Pig | Severity: positive |

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

| Mutagenicity | In Vitro Bacterial Mutagenicity (Ames) | Result: negative |
| 4-CHLORO-M-CRESOL | Species: Salmonella |
| | In Vitro Unscheduled DNA Synthesis | Result: negative |
| | Species: Rat Hepatocyte |
Mutagenicity
4-CHLORO-M-CRESOL
In Vivo Micronucleus
Result: negative
Species: Mouse

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

Reproductive toxicity
May damage fertility or the unborn child.

Developmental effects
4-CHLORO-M-CRESOL
100 mg/kg/day Embryo / Fetal Development, Fetotoxicity
Developmental toxicity
Result: NOEL
Species: Rat
Organ: Oral

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.

Components

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-CHLORO-M-CRESOL (CAS 59-50-7)</td>
<td>Daphnia Magna (Water Flea)</td>
<td>4.4 mg/l, Hours</td>
</tr>
<tr>
<td></td>
<td>Scenedesmus subspicatus (Green Alga)</td>
<td>&gt; 10 mg/l, 72 Hours</td>
</tr>
<tr>
<td></td>
<td>Oncorhynchus mykiss (Rainbow Trout)</td>
<td>0.92 mg/l, 96 Hours</td>
</tr>
<tr>
<td></td>
<td>Pimephales promelas (Fathead Minnow)</td>
<td>4.2 mg/l, 96 Hours</td>
</tr>
</tbody>
</table>

Aquatic

Algae
EC50
12 mg/l, Hours ErC50

Crustacea
EC50
Water flea (Daphnia magna) 1.13 - 1.94 mg/l, 48 hours

Fish
LC50
Fathead minnow (Pimephales promelas) 1 - 10 mg/l, 96 hours

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

Bioaccumulative potential
No data available for this product.

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. 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).
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 Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA Number: 70058

Australia Medicines & Poisons Appendix E
Chlorocresol (CAS 59-50-7)

Australia Medicines & Poisons Schedule 5
Chlorocresol (CAS 59-50-7)

High Volume Industrial Chemicals (HVIC)
Not listed.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)
Not listed.

National Pollutant Inventory (NPI) substance reporting list
Not listed.

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
Not applicable.

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>Country(s) or region</td>
<td>Inventory name</td>
<td>On inventory (yes/no)*</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>------------------------</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>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**

10-July-2017

**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.