

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

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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

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
4-CHLORO-M-CRESOL	59-50-7	< 0.2
Gonadotropin Releasing Factor Analog - Diphtheria Toxoid Conjugate	Not assigned	0.02
Other components below reportable levels		90 - 100

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. May cause allergic skin reaction. Dermatitis. Rash. 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 ₂).
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	<p>Ensure adequate ventilation. Prevent product from entering drains.</p> <p>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.</p> <p>Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.</p> <p>Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.</p>

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	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
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	<p>Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. 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>

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.
Other	Wear suitable protective clothing. 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 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.
Thermal hazards	None known.
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

Material name: IMPROVAC FOR MALE PIGS (APVMA No. 70058)
3385

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
4-CHLORO-M-CRESOL
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

Components	Species	Test results
4-CHLORO-M-CRESOL (CAS 59-50-7)		
Acute		
Dermal		
LD50	Rat	> 5000 mg/kg
Oral		
LD50	Mouse	608 mg/kg
	Rat	3636 mg/kg
Chronic		
Oral		
LOEL	Rat	400 ppm, 24 months (Target organs: Brain, Kidney)
Subacute		
Oral		
NOEL	Rat	200 mg/kg/day, 28 days (Target organs: None identified)
Subchronic		
Oral		
NOEL	Rat	> 120 mg/kg/day, 13 weeks (No effects at maximum dose)

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

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

Eye contact
4-CHLORO-M-CRESOL
Species: Rabbit
Severity: Severe

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
4-CHLORO-M-CRESOL
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
4-CHLORO-M-CRESOL
In Vitro Bacterial Mutagenicity (Ames)
Result: negative
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		Species	Test results
4-CHLORO-M-CRESOL (CAS 59-50-7)			
	EC50	Daphnia Magna (Water Flea)	4.4 mg/l, Hours
		Scenedesmus subspicatus (Green Alga)	> 10 mg/l, 72 Hours
	LC50	Oncorhynchus mykiss (Rainbow Trout)	0.92 mg/l, 96 Hours
		Pimephales promelas (Fathead Minnow)	4.2 mg/l, 96 Hours
Aquatic			
Algae	EC50	Algae	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).

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 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 Depleting 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

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

Country(s) or region	Inventory name	On inventory (yes/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

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.