

SAFETY DATA SHEET



1. Identification

Product identifier	IMPROVEST®
Other means of identification	
Synonyms	IMPROVEST Injection * Improvac * Gonadotropin Releasing Factor Analog - Diphtheria Toxoid Conjugate injection
Recommended use	Veterinary product
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

Supplier Not available.

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Sensitization, skin	Category 1
	Reproductive toxicity	Category 1B
Environmental hazards	Not classified.	

Label elements



Signal word	Danger
Hazard statement	May cause an allergic skin reaction. May damage fertility or the unborn child.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing mist or vapour. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.

Response	IF exposed or concerned: Get medical advice/attention. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards	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. Improved mode of action is immunological like a vaccine. The first exposure either by self injection or needle stick may prime the immune system. The risk of a physiological effect is greater after a second or subsequent injection than after a first. 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

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Chloro-m-cresol, All Isomers		59-50-7	0.1
Adjuvant plus water for injection		Mixture	
Gonadotropin Releasing Factor Analog - Diphtheria Toxoid Conjugate		Not assigned	0.2 mg/ml

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. 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. For breathing difficulties, oxygen may be necessary.
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. Review other important information below in this section regarding accidental injection.
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. Do not induce vomiting without advice from poison control center. Rinse mouth thoroughly. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause allergic skin reaction. Dermatitis. Rash. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy.
Indication of immediate medical attention and special treatment needed	Accidental self injection could affect reproductive physiology of both men and women and may adversely affect pregnancy. If self injection is suspected, even in the case of needle stick during the use of the product (loaded syringe with product), contact the Poison Control Center identified in section 1 of this document (Toll free: 1-866-531-8896) and refer to the product insert for further information. Improved mode of action is immunological like a vaccine. The first exposure either by self injection or needle stick may prime the immune system. The risk of a physiological effect is greater after a second or subsequent injection than after a first. After self injection or needle stick injury do not administer the product, and/or any other product with similar action, in the future.
General information	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.

5. Fire-fighting measures

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 firefighters	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.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Do not breathe mist or vapour. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

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.

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.

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. Observe good industrial hygiene practices. Wash contaminated clothing before reuse. Wash hands after handling and before eating. When using, do not eat, drink or smoke. 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. Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits No exposure limits noted for ingredient(s).

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

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

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses or goggles if eye contact is possible.

Skin protection

Hand protection Wear impervious gloves if skin contact is possible.

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. In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. 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.

Thermal hazards Not applicable.

General hygiene considerations 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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Liquid.

Colour Colorless

Odour Not available.

Odour threshold Not available.

pH Not available.

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) Soluble

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

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. Sunlight. Avoid high temperatures. Protect from freezing.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Carbon oxides. Nitrogen oxides (NOx). May include hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact May cause an allergic skin reaction.
Chloro-m-cresol, All Isomers Species: Rabbit
Severity: Slight

Eye contact Direct contact with eyes may cause temporary irritation.
Chloro-m-cresol, All Isomers Species: Rabbit
Severity: Severe

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause an allergic skin reaction. Dermatitis. Rash. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy.

Information on toxicological effects

Acute toxicity

Product	Species	Test results
IMPROVEST®		
<u>Subacute</u>		
Oral		
NOEL	Rat	0.066 mg/kg/day, 45 days (No effects at maximum dose)

Components	Species	Test results
Chloro-m-cresol, All Isomers (CAS 59-50-7)		
<u>Acute</u>		
Dermal		
LD50	Rat	> 5000 mg/kg
Oral		
LD50	Mouse	608 mg/kg
	Rat	3636 mg/kg
<u>Chronic</u>		
Oral		
LOEL	Rat	400 ppm, 24 months (Target organs: Brain, Kidney)
<u>Subacute</u>		
Oral		
NOEL	Rat	200 mg/kg/day, 28 days (Target organs: None identified)
<u>Subchronic</u>		
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/eye irritation Direct contact with eyes may cause temporary irritation.

Eye contact

Chloro-m-cresol, All Isomers

Species: Rabbit
Severity: Severe

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitizer.

Skin sensitisation May cause an allergic skin reaction.

Skin sensitisation

Chloro-m-cresol, All Isomers

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

Chloro-m-cresol, All Isomers

In Vitro Bacterial Mutagenicity (Ames)
Result: negative
Species: Salmonella

In Vitro Unscheduled DNA Synthesis
Result: negative
Species: Rat Hepatocyte

In Vivo Micronucleus
Result: negative
Species: Mouse

Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity

May damage fertility or the unborn child. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy.

Developmental effects

Chloro-m-cresol, All Isomers

100 mg/kg/day Embryo / Fetal Development, Fetotoxicity
Developmental toxicity
Result: NOEL
Species: Rat
Organ: Oral

Reproductivity

IMPROVEST®

0.066 mg/kg/day Reproductive & Fertility, NOEL
Result: No effects at maximum dose
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.

Chronic effects

Prolonged inhalation may be harmful.

Further 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

Avoid release to the environment. 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.

Components	Species	Test results
Chloro-m-cresol, All Isomers (CAS 59-50-7)		
EC50	Daphnia Magna (Water Flea)	4.4 mg/l, Hours

Components	Species	Test results
	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.	
Mobility in soil	No data available.	
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 instructions	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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	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

TDG	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

Canadian regulations	This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.
Controlled Drugs and Substances Act	Not regulated.
Export Control List (CEPA 1999, Schedule 3)	Not listed.
Greenhouse Gases	Not listed.
Precursor Control Regulations	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
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 21-May-2017

Version No. 01

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 Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Toxicological Information: Toxicological Property Data
GHS: Classification