

SAFETY DATA SHEET



1. Identification

Product identifier Factrel

Other means of identification
Synonyms Factrel® * Factrel® Injection * Gonadorelin for injection * Gonadorelin Hydrochloride Solution

Recommended use Veterinary product used for estrus synchronization

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 Reproductive toxicity Category 1B

Environmental hazards Not classified.

Label elements



Signal word Danger

Hazard statement 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. Wear protective gloves/protective clothing/eye protection/face protection.

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 None known.

Supplemental information

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.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Benzyl alcohol		100-51-6	2
Sodium chloride		7647-14-5	0.6
Gonadorelin hydrochloride		51952-41-1	50 µg / ml
Water for injection		7732-18-5	

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.

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. Do not induce vomiting without advice from poison control center. 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. 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

Provide general supportive measures and treat symptomatically. Symptoms may be delayed. Keep victim under observation.

General information

IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. 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.

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

Do not handle until all safety precautions have been read and understood. 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 accidental injection. Avoid prolonged exposure. Wash thoroughly after handling. When using, do not eat, drink or smoke. 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). 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

Gonadorelin hydrochloride: Zoetis OEB 5 (control exposure to <1 ug/m3)

Appropriate engineering controls

Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. 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, such as personal protective equipment

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. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

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 OEB, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB range. Respiratory protection should be worn to supplement engineering controls when handling this compound.

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.

9. Physical and chemical properties

Appearance

Liquid preparation.

Physical state

Liquid.

Form

Liquid.

Colour

Clear.

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)	Not available.
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.

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.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks. High temperatures. Exposure to light. Sunlight.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

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	Prolonged skin contact may cause temporary irritation.
Benzyl alcohol	Species: Guinea Pig Severity: Moderate
Sodium chloride	Species: Rabbit Severity: Mild
Benzyl alcohol	Species: Rabbit Severity: Minimal
Eye contact	Direct contact with eyes may cause temporary irritation.
Sodium chloride	Species: Rabbit Severity: Moderate

Eye contact
Benzyl alcohol

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, redness, or discomfort. 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

Components	Species	Test results
Benzyl alcohol (CAS 100-51-6)		
Acute		
Dermal		
LD50	Rabbit	2000 mg/kg
Inhalation		
LC50	Rat	> 4.178 mg/l 1000 mg/l, 8 Hours
Oral		
LD50	Mouse	1580 mg/kg
	Rat	1230 mg/kg
Gonadorelin hydrochloride (CAS 51952-41-1)		
Acute		
Intravenous		
LD50	Mouse	> 100 mg/kg
	Rat	> 150 mg/kg
Oral		
LD50	Rat	> 3000 mg/kg
Subacute		
Intravenous		
LOAEL	Rat	5 µg/kg/day, 28 days (Target organs: Male reproductive system)
NOAEL	Monkey	0.5 mg/kg/day, 28 days (No effects at maximum dose)
Sodium chloride (CAS 7647-14-5)		
Acute		
Oral		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
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		
Sodium chloride	Species: Rabbit Severity: Moderate	
Benzyl alcohol	Species: Rabbit Severity: Severe	

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** This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.**Reproductive toxicity** May damage fertility or the unborn child.**Developmental effects**Gonadorelin hydrochloride 100 ug/kg/day Embryo / Fetal Development, No effects at maximum dose
Result: NOAEL
Species: Mouse
Organ: Intravenous100 ug/kg/day Embryo / Fetal Development, No effects at maximum dose
Result: NOAEL
Species: Rat
Organ: Intravenous**Specific target organ toxicity - single exposure** Not classified.**Specific target organ toxicity - repeated exposure** Not classified.**Aspiration hazard** Not an aspiration hazard.**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
Benzyl alcohol (CAS 100-51-6)	EC50	Daphnia magna (Water Flea)	230 mg/l, 48 Hours
			66 mg/l, 21 day(s) Toxicity for reproduction
	LC50	Pseudokirchneriella subcapitata (Green Alga)	500 mg/l, 72 Hours
		Pimephales promelas (Fathead Minnow)	460 mg/l, 96 Hours
Aquatic Fish	LC50	Bluegill (Lepomis macrochirus)	10 mg/l, 96 hours
	Sodium chloride (CAS 7647-14-5)		
Aquatic Crustacea	EC50	Water flea (Daphnia magna)	340.7 - 469.2 mg/l, 48 hours
	Fish	Fathead minnow (Pimephales promelas)	6020 - 7070 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

Country(s) or region	Inventory name	On inventory (yes/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	Yes
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 20-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: Disclosure Overrides
GHS: Classification