

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 (US)	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 (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 1B
Environmental hazards	Not classified.	
OSHA defined 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.
Hazard(s) not otherwise classified (HNOC)	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	

Composition comments In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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 CENTER 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 vapor. 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 vapor. 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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value
Benzyl Alcohol (CAS 100-51-6)	TWA	44.2 mg/m3
		10 ppm

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.
Color	Clear.
Odor	Not available.
Odor 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.
Vapor pressure	Not available.
Vapor 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.
Oxidizing properties	Not oxidizing.

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 oxidizing 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

Skin contact
Benzyl Alcohol

Species: Rabbit
Severity: Minimal

Eye contact
Sodium chloride

Direct contact with eyes may cause temporary irritation.
Species: Rabbit
Severity: Moderate

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. 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.

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
Serious eye damage/eye irritation

Prolonged skin contact may cause temporary 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 sensitization****Respiratory sensitization** Not a respiratory sensitizer.**Skin sensitization** This product is not expected to cause skin sensitization.**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.**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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.**Chronic effects** Prolonged inhalation may be harmful.**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) Reproduction
		Pseudokirchneriella subcapitata (Green Alga) 500 mg/L, 72 Hours
	LC50	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

Components	Species	Test Results
Fish	LC50	Fathead minnow (<i>Pimephales promelas</i>) 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

DOT

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

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No
 Delayed Hazard - Yes
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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	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, including date of preparation or last revision**Issue date** 05-20-2017**Version #** 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** This document has undergone significant changes and should be reviewed in its entirety.