

SAFETY DATA SHEETS

This SDS packet was issued with item:

078924760

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078385047

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.
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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 <1ug/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)		
<u>Acute</u>		
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)		
<u>Acute</u>		
Intravenous		
LD50	Mouse	> 100 mg/kg
	Rat	> 150 mg/kg
Oral		
LD50	Rat	> 3000 mg/kg
<u>Subacute</u>		
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)		
<u>Acute</u>		
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 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
	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

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.

SAFETY DATA SHEET



Revision date: 03-Jun-2015

Version: 2.2

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Gonadorelin Hydrochloride Solution

Trade Name: FACTREL

Chemical Family: Gonadotropin-releasing hormone

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used for estrus synchronization

Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.

100 Campus Drive, P.O. Box 651

Florham Park, New Jersey 07932 (USA)

Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896

Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.

Mercuriusstraat 20

1930 Zaventem

Belgium

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Liquid

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Signal Word: Not Classified

Hazard Statements: Non-hazardous in accordance with international standards for workplace safety.

Other Hazards

Short Term:

May cause eye irritation , May cause slight skin irritation. (based on components) 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. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy.

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Long Term:
Australian Hazard Classification (NOHSC):

Repeated exposure to dust or mist may produce allergic reactions.
Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox.4 (H302) Acute Tox.4 (H332)	2
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	0.6
Gonadorelin hydrochloride	51952-41-1	Not Listed	Repr.Cat.2;R60	Repr. 1B (H360F) Lact. (H362)	50 ug/ml

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	Not Listed	97.4

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

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5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Prevent exposure by any route. Ensure adequate ventilation. Avoid dust and mist generation. Personnel must wear appropriate protective equipment (see Section 8).

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Prevent discharge to drains.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Use with adequate ventilation. Avoid accidental injection. Restrict access to work area. Avoid open handling. Minimize generating airborne mists and vapors. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Protect from light. Store under refrigeration in closed container. Protect from freezing. Keep out of reach of children. Store as directed by product packaging.

Storage Temperature: 2-8°C (36-46°F)

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Benzyl Alcohol

Bulgaria OEL - TWA 5.0 mg/m³

Czech Republic OEL - TWA 40 mg/m³

Finland OEL - TWA 10 ppm

45 mg/m³

Latvia OEL - TWA 5 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

Sodium chloride

Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Gonadorelin hydrochloride

Zoetis OEB	OEB 5 (control exposure to <1ug/m ³)
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Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits or within the OEB range.
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Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
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Hands:	Wear impervious gloves if skin contact is possible.
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Eyes:	Safety glasses or goggles
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Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
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Respiratory protection:	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.
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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid preparation
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Odor:	No data available.
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Molecular Formula:	Mixture
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Color:	Clear
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Odor Threshold:	No data available.
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Molecular Weight:	Mixture
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Solvent Solubility:	No data available
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Water Solubility:	No data available
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Solubility:	Soluble: Water
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pH:	No data available.
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Melting/Freezing Point (°C):	No data available
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Boiling Point (°C):	No data available.
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Partition Coefficient: (Method, pH, Endpoint, Value)	
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No data available

Decomposition Temperature (°C):	No data available.
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Evaporation Rate (Gram/s):	No data available
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Vapor Pressure (kPa):	No data available
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Vapor Density (g/ml):	No data available
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Relative Density:	No data available
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Viscosity:	No data available
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Flammability:

Autoignition Temperature (Solid) (°C):	No data available
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Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information in this section describes the potential hazards of the individual ingredients and the formulation. The potential hazards have not been fully evaluated. Exposure by any route should be avoided. Routes of exposure: eye contact , skin contact

Acute Toxicity: (Species, Route, End Point, Dose)

Benzyl Alcohol

Rat	Oral	LD50	1230 mg/kg
Rat	Para-periosteal	LD50	53mg/kg
Rat	Inhalation	LC50	>4.178mg/L

Sodium chloride

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Gonadorelin hydrochloride

Rat	Oral	LD50	> 3000 mg/kg
Rat	IV	LD50	> 150mg/kg
Mouse	Intravenous	LD50	> 100mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Benzyl Alcohol

Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Minimal
Skin Irritation	Guinea Pig	Moderate

Sodium chloride

Eye Irritation	Rabbit	Moderate
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11. TOXICOLOGICAL INFORMATION

Skin Irritation Rabbit Mild

Irritation / Sensitization Comments: May cause eye irritation.
Skin Irritation / Sensitization May cause mild skin irritation.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Gonadorelin hydrochloride

28 Day(s) Monkey Intravenous 0.5 mg/kg/day NOAEL No effects at maximum dose
28 Day(s) Rat Intravenous 5 µg/kg/day LOAEL Male reproductive system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Gonadorelin hydrochloride

Embryo / Fetal Development Rat Intravenous 100 µg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Mouse Intravenous 100 µg/kg/day NOAEL No effects at maximum dose

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Product Level Toxicity Data

Acute Toxicity Estimate (ATE),
oral >5000 mg/kg

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12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Benzyl Alcohol

<i>Pimephales promelas</i> (Fathead Minnow)	EPA	LC50	96 Hours	460 mg/L
<i>Daphnia magna</i> (Water Flea)	OECD	EC50	48 Hours	230 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	OECD	EC50	72 Hours	500 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Benzyl Alcohol

<i>Daphnia magna</i> (Water Flea)	OECD	21 Day(s)	EC50 66 mg/L	Reproduction
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Persistence and Degradability:

Benzyl Alcohol

OECD	Activated sludge	Ready	92% After	14 Day(s)	Ready
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Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Should not be released into the environment. Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Gonadorelin hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1B; H360F - May damage fertility

Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

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Toxic to Reproduction: Category 2
Xn - Harmful

R60 - May impair fertility.
R20/22 - Harmful by inhalation and if swallowed.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 9 - Physical and Chemical Properties. Updated Section 11 - Toxicology Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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End of Safety Data Sheet