

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Ganirelix Acetate Injection

1.2. Intended Use of the Product

Injection indicated for the inhibition of premature LH surges in women.

1.3. Name, Address, and Telephone of the Responsible Party

Manufacturer

Gland Pharma Limited
Surney No. 143-148/150 And 151,
Dp Pally, Near Gandhi maisamma Cross Road,
Qutbullapur, 4-190/1, Gandhi Maisamma,
Hyderabad, Telangana 500043, India
+91-891-2747657 or +91-891-2548313

Distributor

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
<http://www.fresenius-kabi.com/us/>

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
(800)255-3924 (North America)
+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Not classified

2.2. Label Elements

GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	water / AQUA	(CAS-No.) 7732-18-5	95-100	Not classified
D-Mannitol	1,2,3,4,5,6-Hexanehexol / Mannitol, D- / Hexanehexol / MANNITOL / Mannite / Mannitol	(CAS-No.) 69-65-8	4.7	Comb. Dust
Acetic acid	ACETIC ACID / Acetic acid solution / Vinegar acid / Ethylic acid / Ethanoic acid / Acetic acid, glacial / Acetic acid ...%	(CAS-No.) 64-19-7	≤ 0.1	Flam. Liq. 3, H226 Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Sodium hydroxide	SODIUM HYDROXIDE / Sodium hydroxide (Na(OH)) / Caustic soda / LYE	(CAS-No.) 1310-73-2	≤ 0.1	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318

Ganirelix Acetate Injection

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

				STOT SE 1, H370 Aquatic Acute 3, H402
Ganirelix acetate	D-Alaninamide,N-acetyl-3-(2-naphthalenyl)-D-alanyl-4-chloro-D-phenylalanyl-3-(3-pyridinyl)-D-alanyl-L-seryl-L-tyrosyl-N6-[bis(ethylamino) methylene]-D-lysyl-L-leucyl-N6-[bis(ethylamino) methylene]-L-lysyl-L-prolyl-, diacetate (salt)	(CAS-No.) 129311-55-3	0.05	Repr. 1A, H360 STOT RE 1, H372

Full text of H-statements: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. Product is designed to be injected. In the event of accidental injection, immediately call a poison center or seek medical advice.

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Wash immediately with plenty of soap and water. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media suitable for surrounding type of fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: None expected under normal conditions of use.

Other Information: No additional information available.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

Ganirelix Acetate Injection

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Use closed systems only; open handling of product forbidden. Provide appropriate containment methods to prevent the leakage of product or its components into the workplace. Material may be biologically contaminated after use.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Storage Area: Keep cool. Protect from sunlight.

7.3. Specific End Use(s)

Ganirelix Acetate is a subcutaneous injection indicated for the inhibition of premature LR surges in women undergoing controlled ovarian hyperstimulation

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Acetic acid (64-19-7)		
USA ACGIH	ACGIH OEL TWA [ppm]	10 ppm
USA ACGIH	ACGIH OEL STEL [ppm]	15 ppm
USA OSHA	OSHA PEL (TWA) [1]	25 mg/m ³
USA OSHA	OSHA PEL (TWA) [2]	10 ppm
USA NIOSH	NIOSH REL (TWA)	25 mg/m ³
USA NIOSH	NIOSH REL TWA [ppm]	10 ppm
USA NIOSH	NIOSH REL (STEL)	37 mg/m ³
USA NIOSH	NIOSH REL STEL [ppm]	15 ppm
USA IDLH	IDLH [ppm]	50 ppm
Alberta	OEL STEL	37 mg/m ³
Alberta	OEL STEL [ppm]	15 ppm
Alberta	OEL TWA	25 mg/m ³
Alberta	OEL TWA [ppm]	10 ppm
British Columbia	OEL STEL [ppm]	15 ppm
British Columbia	OEL TWA [ppm]	10 ppm

Ganirelix Acetate Injection

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Manitoba	OEL STEL [ppm]	15 ppm
Manitoba	OEL TWA [ppm]	10 ppm
New Brunswick	OEL STEL	37 mg/m ³
New Brunswick	OEL STEL [ppm]	15 ppm
New Brunswick	OEL TWA	25 mg/m ³
New Brunswick	OEL TWA [ppm]	10 ppm
Newfoundland & Labrador	OEL STEL [ppm]	15 ppm
Newfoundland & Labrador	OEL TWA [ppm]	10 ppm
Nova Scotia	OEL STEL [ppm]	15 ppm
Nova Scotia	OEL TWA [ppm]	10 ppm
Nunavut	OEL STEL [ppm]	15 ppm
Nunavut	OEL TWA [ppm]	10 ppm
Northwest Territories	OEL STEL [ppm]	15 ppm
Northwest Territories	OEL TWA [ppm]	10 ppm
Ontario	OEL STEL [ppm]	15 ppm
Ontario	OEL TWA [ppm]	10 ppm
Prince Edward Island	OEL STEL [ppm]	15 ppm
Prince Edward Island	OEL TWA [ppm]	10 ppm
Québec	VECD (OEL STEL)	37 mg/m ³
Québec	VECD (OEL STEL) [ppm]	15 ppm
Québec	VEMP (OEL TWA)	25 mg/m ³
Québec	VEMP (OEL TWA) [ppm]	10 ppm
Saskatchewan	OEL STEL [ppm]	15 ppm
Saskatchewan	OEL TWA [ppm]	10 ppm
Yukon	OEL STEL	43 mg/m ³
Yukon	OEL STEL [ppm]	25 ppm
Yukon	OEL TWA	25 mg/m ³
Yukon	OEL TWA [ppm]	10 ppm
Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH OEL Ceiling	2 mg/m ³
USA OSHA	OSHA PEL (TWA) [1]	2 mg/m ³
USA NIOSH	NIOSH REL (Ceiling)	2 mg/m ³
USA IDLH	IDLH	10 mg/m ³
Alberta	OEL C	2 mg/m ³
British Columbia	OEL C	2 mg/m ³
Manitoba	OEL C	2 mg/m ³
New Brunswick	OEL C	2 mg/m ³
Newfoundland & Labrador	OEL C	2 mg/m ³
Nova Scotia	OEL C	2 mg/m ³
Nunavut	OEL C	2 mg/m ³
Northwest Territories	OEL C	2 mg/m ³
Ontario	OEL C	2 mg/m ³
Prince Edward Island	OEL C	2 mg/m ³
Québec	Plafond (OEL Ceiling)	2 mg/m ³
Saskatchewan	OEL C	2 mg/m ³
Yukon	OEL C	2 mg/m ³

8.2. Exposure Controls

Appropriate Engineering Controls: Ensure all national/local regulations are observed. Use closed systems only; open handling of product forbidden. Minimize the risk of inhalation exposures to vapors and/or mists. Ensure adequate ventilation, especially in confined areas. Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Provide appropriate containment methods to prevent the leakage of product or its components into the workplace.

Ganirelix Acetate Injection

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Personal Protective Equipment: Gloves. Protective clothing. Safety glasses. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves. Double gloving may be recommended under certain conditions.

Eye and Face Protection: Chemical safety goggles or safety glasses with side shields.

Skin and Body Protection: Wear suitable protective clothing. When handling large quantities of material, wear additional protective clothing, using applicable industrial hygiene methods for selection of Personal Protective Equipment (PPE).

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection. In cases of uncontrolled release, use of respiratory protection is essential.

Environmental Exposure Controls: Avoid unnecessary release into the environment.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Colorless aqueous solution
Odor	: Not determined
Odor Threshold	: No data available
pH	: ≈ 5.0
Evaporation Rate	: No data available
Melting Point	: < 0 °C (32 °F) [Estimate]
Freezing Point	: < 0 °C (32 °F) [Estimate]
Boiling Point	: > 100 °C (212 °F) [Estimate]
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Specific Gravity	: No data available
Solubility	: Fully miscible in water.
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Ganirelix Acetate Injection

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Likely routes of exposure: Dermal, Eye Contact, Inhalation, Oral.

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified

pH: ≈ 5

Eye Damage/Irritation: Not classified

pH: ≈ 5

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Acetic acid (64-19-7)	
LD50 Oral Rat	3310 mg/kg
D-Mannitol (69-65-8)	
LD50 Oral Rat	13500 mg/kg
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Acetic acid (64-19-7)	
LC50 Fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	40 mg/l

12.2. Persistence and Degradability

Ganirelix Acetate Injection	
Persistence and Degradability	Expected to be biodegradable.

12.3. Bioaccumulative Potential

Ganirelix Acetate Injection	
Bioaccumulative Potential	Not expected to bioaccumulate.
Acetic acid (64-19-7)	
Partition coefficient n-octanol/water (Log Pow)	-0.17 (at 25 °C (at pH 7))

12.4. Mobility in Soil

Ganirelix Acetate Injection	
Ecology - Soil	Adsorbs into the soil. Leaches if exposed to water.

Ganirelix Acetate Injection

Safety Data Sheet

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12.5. Other Adverse Effects

Other Adverse Effects: None known.

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Treatment Methods: Incineration is the preferred method for disposal of waste product. Can be landfilled, when in compliance with local regulations.

Sewage Disposal Recommendations: Do not dispose of waste into sewer.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations

Additional Information: Biologically contaminated materials should be incinerated.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Acetic acid (64-19-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

CERCLA RQ	5000 lb
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D-Mannitol (69-65-8)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

CERCLA RQ	1000 lb
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Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

15.2. US State Regulations

Acetic acid (64-19-7)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

U.S. - Massachusetts - Right To Know List

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

Sodium hydroxide (1310-73-2)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

U.S. - Massachusetts - Right To Know List

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

15.3. Canadian Regulations

Acetic acid (64-19-7)

Listed on the Canadian DSL (Domestic Substances List)

Ganirelix Acetate Injection

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

D-Mannitol (69-65-8)
Listed on the Canadian DSL (Domestic Substances List)
Sodium hydroxide (1310-73-2)
Listed on the Canadian DSL (Domestic Substances List)
Water (7732-18-5)
Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest : 03/06/2023

Revision

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

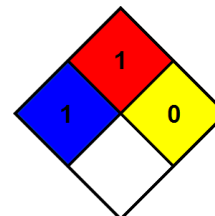
GHS Full Text Phrases:

H226	Flammable liquid and vapor
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H360	May damage fertility or the unborn child
H370	Causes damage to organs
H372	Causes damage to organs through prolonged or repeated exposure
H402	Harmful to aquatic life

NFPA Health Hazard : 1 - Materials that, under emergency conditions, can cause significant irritation.

NFPA Fire Hazard : 1 - Materials that must be preheated before ignition can occur.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health : 1 Slight Hazard - Irritation or minor reversible injury possible

Flammability : 1 Slight Hazard

Physical : 0 Minimal Hazard

Personal protection : C

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)