

PRODUCT SAFETY DATA SHEET

Product name: **FIRMAGON**



SDS Version: Draft 2.1
Revision date: 04/01/2015
Print date: 4/22/2015

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY

Product name: **FIRMAGON® (degarelix for injection)**

Finished Form: Lyocake in Sealed Vial

Trade Name: N/A

Synonyms: N/A

Intended Use: Finished pharmaceutical product

Ferring Pharmaceuticals Inc.
100 Interpace Parkway
Parsippany, NJ 07054
USA +1 973 796 1600

Emergency telephone number: (CHEMTEL)

Domestic: 1-800-255-3924

International: +01-813-248-0585

2. HAZARDS IDENTIFICATION

2.1 Substance or mixture classification

GHS Classification in accordance with 29 CFR 1910.1200(d)

Reproductive Toxicant (Category 1A)

2.2 GHS Label Elements

Pictogram



Signal Word

Danger

Hazard Statement(s)

May damage fertility or the unborn child.

Precautionary Statement(s)

Prevention

Review product insert instructions prior to use.
Do not handle until all safety precautions have been read and understood.
Wear nitrile gloves when handling.

Response

If exposed or concerned: Get medical advice/attention.

Storage

Store under access control conditions.

Disposal

Dispose of lyocake in accordance with local regulations.

2.3 Hazards not otherwise classified - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Components:

Chemical name	CAS No.	EC No.	Hazard classification:	Concentration in Product
Degarelix	214766-78-6	none	Repr. – 1A	25-30%

4. FIRST-AID MEASURES

Inhalation: Move injured person into fresh air and keep person calm under observation. If uncomfortable or breathing is difficult: Seek hospital and bring along these instructions.

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Skin contact: If on skin: Wash skin thoroughly with water.
If skin irritation occurs: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.

Eye contact: Do not rub eye. Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyelids widely. If irritation persists: Seek medical attention and bring these instructions.

Ingestion: Immediately rinse mouth and drink plenty of water. If ingestion is suspected after rinsing mouth, seek hospital and bring along these instructions.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use fire-extinguishing media appropriate for surrounding materials.

Special hazards: During fire, gases hazardous to health may be formed.
Wear a self-contained breathing apparatus in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

Under normal handling conditions an accidental release is highly unlikely.

Personal precautions: Keep unauthorized persons away. For personal protection, see section 8.
Avoid any exposure. Follow precautions for safe handling described in this safety data sheet.

Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

Methods for cleaning up: Collect spillage with a moist cloth. For waste disposal, see section 13.

7. HANDLING AND STORAGE

Safe handling advice: Observe good laboratory and manufacturing hygiene practices.

If Lyocake or container is broken: avoid inhalation or contact with eyes, skin, and clothing.
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Wash hands and any exposed skin after removal of PPE.

Technical measures: Work practice should minimize contact. Use work methods which minimize dust or aerosol production. Keep the workplace clean. Do not eat, drink or smoke when using the product. Do not store tobacco, food or beverage in work rooms or areas where the product is used.

Technical measures for safe storage: Store as directed by product packaging.

Storage conditions: Store under access controlled conditions as directed by product packaging.

Specific end use: None other than those listed in Section 1.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational exposure limit values: Ferring OEL for 8-hr TWA
Degarelix: 0.100 µg/m³

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During normal handling operations of the lyocake:

Exposure controls: Minimize the risk of eye contact with dust including inadvertent exposure from touching eyes with contaminated gloves or hands.

Respiratory protection: None needed during normal handling operations.

Hand protection: None needed during normal handling operations.
In the event of a broken Lyocake: chemical resistant gloves should be worn for clean-up (disposable nitrile gloves).

Eye protection: None needed during normal handling operations.

Skin protection: None needed during normal handling operations.

Hygiene measures: Wash hands after handling. When using do not eat, drink or smoke.
In the event of contact with the product. Remove contaminated clothing and wash the skin thoroughly with soap and water after work. Launder contaminated clothing prior to reuse.

Environmental Exposure Controls: None needed during normal handling operations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Lyocake - white

Odor: No data available

Odor threshold: No data available

pH: No data available

Melting point: No data available

Boiling point: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability: No data available

Explosion limits: No data available

Relative density: No data available

Solubility: Soluble in water

Partition coefficient: No data available
(n-octanol/water)

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Other information: None

10. STABILITY AND REACTIVITY

Reactivity and Chemical Stability: Stable under normal conditions of use.

Conditions/materials to avoid: No data available

Hazardous decomposition products: No data available

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11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the hazardous components listed in Section 2.

Inhalation: No data available

Skin contact: No data available

Eye contact: No data available

Ingestion: No data available

Specific effects: No information available

Carcinogenicity: No component of this product is present at levels greater than or equal to 0.1% is identified as a probable, possible or confirmed human carcinogen by IARC; or a known or anticipated carcinogen by NTP; or a carcinogen or potential carcinogen by ACGIH or OSHA.

12. ECOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the hazardous components listed in Section 2.

Toxicity: No information available.

Persistence and degradability: No information available.

Bioaccumulative potential: No information available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose of waste and residues in accordance with local authority requirements.

14. TRANSPORT INFORMATION

Transported as a pharmaceutical finished product.
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

NONE

16. OTHER INFORMATION

Date of SDS Preparation: **2/2/2015**
Current Version Preparation: **2/2/2015**

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions. The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.