

# SAFETY DATA SHEET



## Ganirelix Formulation



Version 5.8      Revision Date: 16.10.2020      SDS Number: 22190-00016      Date of last issue: 13.09.2019  
Date of first issue: 15.10.2014

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ganirelix Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Bone marrow, Liver, Adrenal gland, spleen, Ovary)

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360Fd May damage fertility. Suspected of damaging the unborn child.  
H372 Causes damage to organs (Bone marrow, Liver, Adrenal gland, spleen, Ovary) through prolonged or repeated exposure.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe mist or vapours.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P281 Use personal protective equipment as required.

#### Response:

P308 + P313 IF exposed or concerned: Get medical advice/

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attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Ganirelix	124904-93-4	$\geq 0.01$ - $< 0.3$

### SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May damage fertility. Suspected of damaging the unborn child.  
Causes damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

### SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)

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- Unsuitable extinguishing media : Dry chemical  
: None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : No hazardous combustion products are known
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe the mist or vapours.  
Do not swallow.  
Avoid contact with eyes.
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- Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ganirelix	124904-93-4	TWA	0.2 µg/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	2 µg/100 cm <sup>2</sup>	Internal

- Engineering measures** : Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
No open handling permitted.  
Totally enclosed processes and materials transport systems are required.  
Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

**Personal protective equipment**

- Respiratory protection : No personal respiratory protective equipment normally required.
- Hand protection

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Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : 5

Melting point/freezing point : No data available

Initial boiling point and boiling range : 100 °C

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : 23 hPa (20 °C)

Relative vapour density : No data available

Relative density : 1

Solubility(ies)  
Water solubility : completely miscible

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Partition coefficient: n-octanol/water : No data available  
Auto-ignition temperature : No data available  
Decomposition temperature : No data available  
Viscosity  
  Viscosity, kinematic : No data available  
Explosive properties : Not explosive  
Oxidizing properties : The substance or mixture is not classified as oxidizing.  
Molecular weight : No data available  
Particle size : No data available

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Can react with strong oxidizing agents.  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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### SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Ganirelix:

Acute toxicity (other routes of administration) : LD50 (Rat): 40 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Ganirelix:

Species : Rabbit

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Result : Mild eye irritation  
Method : Draize Test

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Ganirelix:

Test Type : Maximisation Test  
Species : Guinea pig  
Result : negative

### Chronic toxicity

#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Ganirelix:

Genotoxicity in vitro : Test Type: reverse mutation assay  
Test system: Salmonella typhimurium  
Result: negative

Test Type: reverse mutation assay  
Test system: Escherichia coli  
Result: negative

Test Type: in vitro assay  
Test system: Chinese hamster ovary cells  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Application Route: Intravenous  
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

May damage fertility. Suspected of damaging the unborn child.

#### Components:

##### Ganirelix:

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- Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Subcutaneous  
Duration of Single Treatment: 13 Weeks  
Fertility: LOAEL: 0.1 µg/kg  
Result: Effects on fertility
- Test Type: Fertility/early embryonic development  
Species: Rat, female  
Application Route: Subcutaneous  
Duration of Single Treatment: 8 Weeks  
Fertility: LOAEL: 10 µg/kg  
Result: No effects on mating performance, Effects on fertility
- Test Type: Fertility  
Species: Monkey  
Application Route: Subcutaneous  
Fertility: NOAEL: 0.02 mg/kg body weight  
Result: Effects on fertility
- Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat, female  
Application Route: Subcutaneous  
Embryo-foetal toxicity: LOAEL: 10 µg/kg  
Result: Embryo-foetal toxicity
- Test Type: Embryo-foetal development  
Species: Rabbit, female  
Application Route: Subcutaneous  
Embryo-foetal toxicity: LOAEL: 30 µg/kg  
Result: Embryo-foetal toxicity
- Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Causes damage to organs (Bone marrow, Liver, Adrenal gland, spleen, Ovary) through prolonged or repeated exposure.

**Components:****Ganirelix:**

- Exposure routes : Ingestion  
Target Organs : Bone marrow, Liver, Adrenal gland, spleen, Ovary  
Assessment : Causes damage to organs through prolonged or repeated exposure.



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**Repeated dose toxicity****Components:****Ganirelix:**

Species	:	Rat
NOAEL	:	0.02 mg/kg
LOAEL	:	2 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	6 Months
Target Organs	:	Bone marrow
Species	:	Mouse, female
LOAEL	:	0.3 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	3 Months
Target Organs	:	Liver, Adrenal gland, spleen, Ovary
Species	:	Mouse, male
LOAEL	:	3 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	3 Months
Target Organs	:	Liver, Adrenal gland, spleen
Species	:	Monkey
NOAEL	:	2.5 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	6 Months
Remarks	:	No significant adverse effects were reported

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Ganirelix:**

Inhalation : Symptoms: The most common side effects are:, vaginal bleeding, Headache, Abdominal pain, Nausea, ectopic pregnancy, miscarriage

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Ganirelix:****Ecotoxicology Assessment**

Acute aquatic toxicity : No data available  
Chronic aquatic toxicity : No data available

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### **Persistence and degradability**

No data available

### **Bioaccumulative potential**

No data available

### **Mobility in soil**

No data available

### **Other adverse effects**

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

### **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

### **National Regulations**

#### **ADG**

Not regulated as a dangerous good

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## SECTION 15. REGULATORY INFORMATION

### **Safety, health and environmental regulations/legislation specific for the substance or mixture**

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

**The components of this product are reported in the following inventories:**

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AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

### SECTION 16. OTHER INFORMATION

#### Further information

Revision Date	:	16.10.2020
Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a>
Date format	:	dd.mm.yyyy

#### Full text of other abbreviations

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only

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to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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