

Version 4.4 Revision Date: 09.04.2021 SDS Number: 22225-00017 Date of last issue: 16.10.2020
Date of first issue: 15.10.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Ganirelix Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

| | |
|--|---|
| Reproductive toxicity, Category 1B | H360Fd: May damage fertility. Suspected of damaging the unborn child. |
| Specific target organ toxicity - repeated exposure, Category 1 | H372: Causes damage to organs through prolonged or repeated exposure. |

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H360Fd May damage fertility. Suspected of damaging the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.

Ganirelix Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 16.10.2020 |
| 4.4 | 09.04.2021 | 22225-00017 | Date of first issue: 15.10.2014 |

P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

Ganirelix

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------|---|---|--------------------------|
| Ganirelix | 124904-93-4 | Repr. 1B; H360Fd STOT RE 1; H372 (Bone marrow, Liver, Adrenal gland, spleen, Ovary) | >= 0,01 - < 0,1 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures**4.1 Description of 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.
- 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).
- 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.

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 16.10.2020 |
| 4.4 | 09.04.2021 | 22225-00017 | Date of first issue: 15.10.2014 |

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May damage fertility. Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 16.10.2020 |
| 4.4 | 09.04.2021 | 22225-00017 | Date of first issue: 15.10.2014 |

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.
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

Ganirelix Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 16.10.2020 |
| 4.4 | 09.04.2021 | 22225-00017 | Date of first issue: 15.10.2014 |

Hygiene measures : environment.
 : 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
 Strong oxidizing agents
 Organic peroxides
 Explosives
 Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

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

8.2 Exposure controls**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

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.

SAFETY DATA SHEET



Ganirelix Formulation



Version 4.4 Revision Date: 09.04.2021 SDS Number: 22225-00017 Date of last issue: 16.10.2020
Date of first issue: 15.10.2014

Hand protection : Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic 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

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

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

 Auto-ignition temperature : No data available

SAFETY DATA SHEET



Ganirelix Formulation



Version 4.4 Revision Date: 09.04.2021 SDS Number: 22225-00017 Date of last issue: 16.10.2020
Date of first issue: 15.10.2014

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.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Ganirelix:

Ganirelix Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 16.10.2020 |
| 4.4 | 09.04.2021 | 22225-00017 | Date of first issue: 15.10.2014 |

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 |
| Method | : | Draize Test |
| Result | : | Mild eye irritation |

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 |

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. |

Ganirelix Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 16.10.2020 |
| 4.4 | 09.04.2021 | 22225-00017 | Date of first issue: 15.10.2014 |

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

May damage fertility. Suspected of damaging the unborn child.

Components:**Ganirelix:**

- | | | |
|------------------------------------|---|---|
| Effects on fertility | : | <p>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</p> <p>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</p> <p>Test Type: Fertility Species: Monkey Application Route: Subcutaneous Fertility: NOAEL: 0,02 mg/kg body weight Result: Effects on fertility</p> |
| Effects on foetal development | : | <p>Test Type: Embryo-foetal development Species: Rat, female Application Route: Subcutaneous Embryo-foetal toxicity: LOAEL: 10 µg/kg Result: Embryo-foetal toxicity</p> <p>Test Type: Embryo-foetal development Species: Rabbit, female Application Route: Subcutaneous Embryo-foetal toxicity: LOAEL: 30 µg/kg Result: Embryo-foetal toxicity</p> |
| Reproductive toxicity - Assessment | : | <p>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.</p> |

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Ganirelix Formulation

Version 4.4 Revision Date: 09.04.2021 SDS Number: 22225-00017 Date of last issue: 16.10.2020
Date of first issue: 15.10.2014

Components:

Ganirelix:

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

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

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 16.10.2020 |
| 4.4 | 09.04.2021 | 22225-00017 | Date of first issue: 15.10.2014 |

SECTION 12: Ecological information

12.1 Toxicity

Components:

Ganirelix:

Ecotoxicology Assessment

Acute aquatic toxicity : No data available

Chronic aquatic toxicity : No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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.

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 16.10.2020 |
| 4.4 | 09.04.2021 | 22225-00017 | Date of first issue: 15.10.2014 |

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H360Fd : May damage fertility. Suspected of damaging the unborn child.

H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure

SAFETY DATA SHEET



Ganirelix Formulation



| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 16.10.2020 |
| 4.4 | 09.04.2021 | 22225-00017 | Date of first issue: 15.10.2014 |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

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, <http://echa.europa.eu/>

Classification of the mixture:

| | |
|-----------|--------|
| Repr. 1B | H360Fd |
| STOT RE 1 | H372 |

Classification procedure:

| |
|--------------------|
| Calculation method |
| Calculation method |

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 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.

SAFETY DATA SHEET



Ganirelix Formulation



| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 16.10.2020 |
| 4.4 | 09.04.2021 | 22225-00017 | Date of first issue: 15.10.2014 |

ZA / EN