SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ganirelix Formulation

Manufacturer or supplier’s details
Company : Organon & Co.
Address : 30 Hudson Street, 33rd 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

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/
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ganirelix</td>
<td>124904-93-4</td>
<td>&gt;= 0.01 -&lt; 0.3</td>
</tr>
</tbody>
</table>

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 (CO2)
Unsuitable extinguishing media: Dry chemical
None known.
Specific hazards during firefighting: 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.

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.

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 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 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**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ganirelix</td>
<td>124904-93-4</td>
<td>TWA</td>
<td>0.2 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Wipe limit 2 µg/100 cm² 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
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.

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
 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

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.

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
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:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Specie</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximisation</td>
<td>Guinea pig</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Chronic toxicity**

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Ganirelix:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test system</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>reverse mutation</td>
<td>Salmonella typhimurium</td>
<td>negative</td>
</tr>
<tr>
<td>reverse mutation</td>
<td>Escherichia coli</td>
<td>negative</td>
</tr>
<tr>
<td>in vitro assay</td>
<td>Chinese hamster ovary cells</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vivo micronucleus test</td>
<td>Mouse</td>
<td>Intravenous</td>
<td>negative</td>
</tr>
</tbody>
</table>

**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:**
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:**

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Target Organs</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Bone marrow, Liver, Adrenal gland, spleen, Ovary</td>
<td>Causes damage to organs through prolonged or repeated exposure</td>
</tr>
</tbody>
</table>
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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ganirelix:
Ecotoxicology Assessment
Acute aquatic toxicity : No data available
Chronic aquatic toxicity : No data available
Persistence and degradability
No data available

Bioaccumulative potential
No data available

Mobility in soil
No data available

Other adverse effects
No data available

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.

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

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:
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.

AU / EN