SECTION 1. IDENTIFICATION

Product name: Gonadorelin Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure (Oral): Category 1 (Endocrine system)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H372 Causes damage to organs (Endocrine system) through prolonged or repeated exposure if swallowed.

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 vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Gonadorelin Formulation

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Benzyl alcohol, Benzenemethanol, Gonadorelin</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Benzenemethanol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td>Gonadorelin</td>
<td>No data available</td>
<td>34973-08-5</td>
<td>&gt;= 0.001 - &lt; 0.1 *</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

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
Suspected of damaging fertility. Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure if swallowed.

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. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

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 fire-fighters: 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 diking or other appropriate containment to keep material from spreading. If diked 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**: Use only with adequate ventilation.

**Advice on safe handling**: Do not breathe mist or vapors.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

**Conditions for safe storage**: Keep in properly labeled containers.
Store locked up.
Store in accordance with the particular national regulations.

**Materials to avoid**: Do not store with the following product types:
- Strong oxidizing agents
- Self-reactive substances and mixtures
- Organic peroxides
- Explosives
- Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients 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>Gonadorelin</td>
<td>34973-08-5</td>
<td>TWA</td>
<td>0.2 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>2 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Engineering measures**: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

**Personal protective equipment**

- **Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
  - **Filter type**: Organic vapor Type
- **Hand protection**: Chemical-resistant gloves
- **Material**: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Eye protection: Wear the following personal protective equipment: Safety glasses

Skin and body protection: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Color</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-</td>
<td>No data available</td>
</tr>
</tbody>
</table>
octanol/water
Autoignition temperature : No data available
Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : No data available
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : Not applicable
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

**Information on likely routes of exposure**

- Inhalation
- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

**Acute oral toxicity**
- Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method

**Acute inhalation toxicity**
- Acute toxicity estimate: > 5 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method
Components:

Benzyl alcohol:
- Acute oral toxicity: LD50 (Rat): 1,620 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: OECD Test Guideline 403

Gonadorelin:
- Acute oral toxicity: LD50 (Rat): > 3,000 mg/kg
  LD50 (Mouse): > 4,000 mg/kg
- Acute inhalation toxicity: Remarks: No data available
- Acute dermal toxicity: Remarks: No data available

Skin corrosion/irritation
Not classified based on available information.

Components:

Benzyl alcohol:
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation

Gonadorelin:
- Remarks: No data available

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Benzyl alcohol:
- Species: Rabbit
- Result: Irritation to eyes, reversing within 21 days
- Method: OECD Test Guideline 405

Gonadorelin:
- Remarks: No data available

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:

Benzyl alcohol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Gonadorelin:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

Benzyl alcohol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Gonadorelin:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

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

Carcinogenicity
Not classified based on available information.
Components:

Benzyal alcohol:
Species: Mouse
Application Route: Ingestion
Exposure time: 103 weeks
Method: OECD Test Guideline 451
Result: negative

Gonadorelin:
Species: Mouse
Exposure time: 2 Years
LOAEL: 2.4 mg/kg body weight
Result: positive
Remarks: Based on data from similar materials

Species: Rat
Exposure time: 1 Years
LOAEL: 0.05 mg/kg body weight
Result: negative
Remarks: Benign tumor(s)
The mechanism or mode of action may not be relevant in humans.
Based on data from similar materials

Reproductive toxicity
Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

Benzyal alcohol:
 Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Embryo-fetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Gonadorelin:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat, female
Application Route: Subcutaneous
Fertility: LOAEL: 50 µg/kg
Result: Effects on fertility.
Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development
Species: Rat, male
Application Route: Subcutaneous
Fertility: LOAEL: 500 µg/kg
Result: Effects on fertility.
Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Subcutaneous
Fertility: LOAEL: 1,000 µg/kg
Result: Effects on fertility.

Test Type: Fertility/early embryonic development
Species: Dog, male and female
Application Route: Subcutaneous
Fertility: LOAEL: 107 - 214 µg/kg
Result: Effects on fertility.

Effects on fetal development:
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: >= 2 µg/kg
Result: Effects on fetal development.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: > 20 µg/kg
Result: Effects on fetal development.

Reproductive toxicity - Assessment:
Some 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 (Endocrine system) through prolonged or repeated exposure if swallowed.

**Components:**

**Gonadorelin:**
Target Organs: Endocrine system
Assessment: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Benzyl alcohol:**
Species: Rat
Gonadorelin Formulation

NOAEL: 1.072 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

Gonadorelin:
Species: Rat
NOAEL: 0.12 mg/kg
Application Route: Intramuscular
Exposure time: 15 Days
Remarks: No significant adverse effects were reported

Species: Rat
NOAEL: 0.072 mg/kg
Application Route: Intravenous
Exposure time: 15 Days
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 0.12 mg/kg
Application Route: Intramuscular
Exposure time: 15 Days
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 0.072 mg/kg
Application Route: Intravenous
Exposure time: 15 Days
Remarks: No significant adverse effects were reported

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Gonadorelin:
Ingestion: Symptoms: Nausea, Abdominal pain, Headache, Palpitation, acne, liver function change, bronchospasm, anaphylaxis

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Benzyl alcohol:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Persistence and degradability

Components:

Benzyl alcohol:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Bioaccumulative potential

Components:

Benzyl alcohol:

Partition coefficient: n-octanol/water: log Pow: 1.05

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues: Do not dispose of waste into sewer.
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
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Gonadorelin Formulation

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.

Domestic regulation

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AICL - 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, Bioaccumu-
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Gonadorelin Formulation

Revision Date: 09/30/2023
SDS Number: 613529-00016
Date of last issue: 04/04/2023
Date of first issue: 04/27/2016

Sources of key data used to compile the Material Safety Data Sheet:
- Date format: mm/dd/yyyy

Revision Date: 09/30/2023
Date format: mm/dd/yyyy

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.

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