SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Gonadorelin Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASETWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
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 protec-
Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>Gonadorelin</td>
<td>34973-08-5</td>
<td>&gt;= 0,001 - &lt; 0,1</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 : 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
  - 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**
- Material: Chemical-resistant gloves
  - Remarks: 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

Appearance: liquid

Color: No data available

Odor: No data available

Odor Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

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

Vapor pressure: No data available

Relative vapor density: No data available

Density: No data available

Solubility(ies)

Water solubility: No data available

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

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 reac-
tions : 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: > 5,000 mg/kg
  Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 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
### Gonadorelin Formulation

| 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

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

Genotoxicity in vivo: 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:

#### Benzyl alcohol:

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

#### Gonadorelin:

Species: Mouse
Exposure time: 2 Years
**Reproductive toxicity**

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

**Components:**

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

**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.  
  Remarks: Based on data from similar materials

  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:
Test Type: Embryo-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
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
**SAFETY DATA SHEET**

**Gonadorelin Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

**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

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC (Daphnia magna (Water flea)): 51 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211
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: 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.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry: Not applicable
Control of precursors and essential chemicals for the preparation of drugs: Not applicable

### International Regulations

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### SECTION 16. OTHER INFORMATION

#### Further information

Sources of key data used to compile the Material Safety Data Sheet:

#### Full text of other abbreviations

- AIIC - 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 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.

AR / Z8