SAFETY DATA SHEET
Gonadorelin Formulation

Version 5.0  Revision Date: 2020/03/23  SDS Number: 613538-00010  Date of last issue: 2019/09/13  Date of first issue: 2016/04/27

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Gonadorelin Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
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 vapours.
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/face protection.

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

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td>3-1011</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gonadorelin</td>
<td>34973-08-5</td>
<td>&gt;= 0.001 - &lt; 0.1</td>
<td></td>
</tr>
</tbody>
</table>

### 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.

### 5. FIREFIGHTING MEASURES
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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 firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
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.

7. HANDLING AND STORAGE

Handling
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: Use only with adequate ventilation.
Advice on safe handling: Avoid inhalation of vapour or mist.
do not swallow.
avoid contact with eyes.
avoid prolonged or repeated contact with skin.
handle in accordance with good industrial hygiene and safety
practice, based on the results of the workplace exposure as-
essment
take care to prevent spills, waste and minimize release to the
environment.

avoidance of contact:
oxidizing agents

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.

storage
conditions for safe storage:
keep in properly labelled 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

packaging material:
unsuitable material: none known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work en-
vironment

<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></td>
<td>Wipe limit</td>
<td>2 µg/100 cm²</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 expo-
sure assessment demonstrates exposures outside the rec-
ommended guidelines, use respiratory protection.

filter type:
organic vapour type

hand protection:
chemical-resistant gloves

material:
chemical-resistant gloves

remarks:
choose gloves to protect hands against chemicals depending
on the concentration and quantity of the hazardous sub-
stance and 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).

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</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>Lower explosion limit and upper explosion limit / flammability limit</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>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
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<tr>
<td>5.0</td>
<td>2020/03/23</td>
<td>613538-00010</td>
<td>2019/09/13</td>
<td>2016/04/27</td>
</tr>
</tbody>
</table>

- **Partition coefficient: n-octanol/water**: No data available
- **Vapour pressure**: No data available
- **Density and / or relative density**
  - **Density**: No data available
  - **Relative vapour density**: No data available
- **Explosive properties**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
- **Molecular weight**: Not applicable
- **Particle characteristics**
  - **Particle size**: No data available

### 10. STABILITY AND REACTIVITY

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

### 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:
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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 sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.
Components:

Benzyl alcohol:
- Test Type: Maximisation Test
- Exposure routes: 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:

Benzyl alcohol:
- Species: Mouse
- Application Route: Ingestion
- Exposure time: 103 weeks
- Method: OECD Test Guideline 451
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<table>
<thead>
<tr>
<th>Result</th>
<th>negative</th>
</tr>
</thead>
</table>

### 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:

#### 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
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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 foetal development:
: Test Type: Embryo-foetal development
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: >= 2 µg/kg
Result: Effects on foetal development

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

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

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

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.

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
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable
## Poisonous and Deleterious Substances Control Law
Not applicable

### Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

### High Pressure Gas Safety Act
Not applicable

### Explosive Control Law
Not applicable

### Vessel Safety Law
Not regulated as a dangerous good

### Aviation Law
Not regulated as a dangerous good

### Marine Pollution and Sea Disaster Prevention etc. Law
- **Bulk transportation**: Noxious liquid substance (Category Z)
- **Pack transportation**: Not classified as marine pollutant

### Narcotics and Psychotropics Control Act
- **Narcotic or Psychotropic Raw Material (Export / Import Permission)**: Not applicable
- **Specific Narcotic or Psychotropic Raw Material (Export / Import permission)**: Not applicable

### Waste Disposal and Public Cleansing Law
Industrial waste

### The components of this product are reported in the following inventories:
- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

## 16. OTHER INFORMATION

### Further information

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

**Date format**: yyyy/mm/dd

**Full text of other abbreviations**
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.