1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Buserelin 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
Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements
Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td>3-1011</td>
</tr>
<tr>
<td>Buserelin</td>
<td>68630-75-1</td>
<td>&lt; 0.1</td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact : Wash with water and soap as a precaution. Get medical attention if symptoms occur.
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 if symptoms occur.
5. FIREFIGHTING 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 firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : 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...
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: Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. 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.
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.

Storage
Conditions for safe storage: Keep in properly labelled containers.
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 environment

<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>Benzyl alcohol</td>
<td>100-51-6</td>
<td>OEL-C</td>
<td>25 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin sensitizing agent; Group 2 substances which probably induce allergic reactions in humans.</td>
<td></td>
</tr>
<tr>
<td>Buserelin</td>
<td>68630-75-1</td>
<td>TWA</td>
<td>0.1 µg/m³ OEB 5</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 1 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Organic vapour type

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: liquid

Colour: colourless

Odour: No data available

Odour Threshold: No data available

Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit: No data available
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Lower explosion limit / Lower flammability limit : No data available

Flash point : Not applicable

Decomposition temperature : No data available

pH : 5.7 - 6.3

Evaporation rate : No data available

Auto-ignition temperature : Not applicable

Viscosity
  Viscosity, kinematic : No data available

Solubility(ies)
  Water solubility : soluble

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

Vapour pressure : No data available

Density and / or relative density
  Relative density : No data available

Density : 1.004 g/cm³

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 : Can react with strong oxidizing agents.

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:**
- **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

**Buserelin:**
- **Acute oral toxicity**
  - LD50 (Rat): 400 mg/kg
  - LD50 (Mouse): > 1,000 mg/kg
- **Acute toxicity (other routes of administration)**
  - LD50 (Rat): 36 mg/kg
  - Application Route: Intravenous
  - LD50 (Rat): > 500 mg/kg
  - Application Route: Subcutaneous
  - LD50 (Mouse): 56 - 78 mg/kg
  - Application Route: Intravenous
  - LD50 (Dog): > 100 mg/kg
  - Application Route: Subcutaneous

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Benzyl alcohol:**
- **Species**: Rabbit
- **Method**: OECD Test Guideline 404
- **Result**: No skin irritation
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Version: 3.0   Revision Date: 2020/10/10   SDS Number: 641708-00012   Date of last issue: 2020/03/23
   Date of first issue: 2016/05/03

Buserelin:
Species: Rabbit
Result: No skin irritation

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

Buserelin:
Species: Rabbit
Result: No eye irritation

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

Buserelin:
Exposure routes: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

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

**Species:** Mouse

**Application Route:** Intraperitoneal injection

**Result:** negative

### Buserelin

#### Genotoxicity in vitro

**Test Type:** Bacterial reverse mutation assay (AMES)
**Result:** negative

**Test Type:** unscheduled DNA synthesis assay
**Result:** negative

#### Genotoxicity in vivo

**Test Type:** Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)

**Species:** Mouse

**Application Route:** Intraperitoneal injection

**Result:** negative

### Carcinogenicity

Not classified based on available information.

### Components:

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>103 weeks</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 451</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Buserelin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>24 Months</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Target Organs:** Uterus (including cervix), Pituitary gland, Testes

### Reproductive toxicity

Not classified based on available information.

### 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

**Effects on foetal development**

**Test Type:** Embryo-foetal development

**Species:** Mouse

**Application Route:** Ingestion

**Result:** negative
Buserelin :  
Effects on fertility :  Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Subcutaneous  
Fertility: LOAEL: 0.2 µg/kg  
Result: Effects on fertility

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

Test Type: Fertility/early embryonic development  
Species: Mouse, female  
Application Route: Subcutaneous  
Fertility: LOAEL: 100 µg/kg  
Result: Effects on fertility

Effects on foetal development :  Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intravenous injection  
Developmental Toxicity: LOAEL: 0.4 µg/kg body weight  
Result: Embryotoxic effects., Effects on early embryonic development

Test Type: Embryo-foetal development  
Species: Rabbit  
Developmental Toxicity: LOAEL: 0.1 µg/kg body weight  
Result: Embryotoxic effects., No specific developmental abnormalities

Test Type: Embryo-foetal development  
Species: Mouse  
Developmental Toxicity: NOAEL: 0.1 µg/kg body weight  
Result: Embryotoxic effects., No effects on F1 offspring

Reproductive toxicity - Assessment :  May damage fertility.

STOT - single exposure  
Not classified based on available information.

STOT - repeated exposure  
Not classified based on available information.

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
Buserelin Formulation

Species: Rat
LOAEL: 0.5 ug/kg/day
Application Route: Subcutaneous
Exposure time: 14 Days

Species: Rat
LOAEL: 0.05 ug/kg/day
Application Route: Subcutaneous
Exposure time: 28 Days

Target Organs: Testis

Species: Rabbit
NOAEL: 20 ug/kg/day
Exposure time: 4 Weeks

Target Organs: Testis, Prostate, Pituitary gland

Species: Monkey
LOAEL: 5 ug/kg/day
Exposure time: 1 yr

Target Organs: Ovary, Pituitary gland

Species: Dog
LOAEL: 0.05 mg/kg
Application Route: Subcutaneous
Exposure time: 30 Days

Target Organs: Testis, Pituitary gland

Species: Dog
LOAEL: 0.05 mg/kg
Application Route: Subcutaneous
Exposure time: 6 Months

Target Organs: Reproductive organs

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Buserelin:

Inhalation: Symptoms: male reproductive effects, female reproductive effects, reduced libido, Headache, Rash, Gastrointestinal disturbance, mental depression, Local irritation
Remarks: May damage fertility.
Based on Human Evidence
12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 460 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 230 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC (Daphnia magna (Water flea)): 51 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Buserelin:</th>
<th>Ecotoxicology Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute aquatic toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Chronic aquatic toxicity</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Persistence and degradability**

**Components:**

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>92 - 96 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>14 d</td>
</tr>
</tbody>
</table>

**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
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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

JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

AIIIC - 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; ENC - 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-
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.