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.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
- None known.

Protection of first-aiders:
- No special precautions are necessary for first aid responders.

Notes to physician:
- Treat symptomatically and supportively.

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 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 dyeing or other appropriate containment to keep material from spreading. If dyed 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.
- Avoid contact with 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>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>Wipe limit</td>
<td>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
  - **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**: No data available
  - **Lower explosion 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

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:** Mouse
  - **Application Route:** Intraperitoneal injection
  - **Result:** negative
SAFETY DATA SHEET

Buserelin Formulation

Version 2.0  Revision Date: 2020/03/23  SDS Number: 641708-00011  Date of last issue: 2019/09/13
Date of first issue: 2016/05/03

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

Buserelin:
- Species: Rat
- Application Route: Subcutaneous
- Exposure time: 24 Months
- Result: negative
- 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:**
Species: Rat
SAFETY DATA SHEET

Buserelin Formulation

Version 2.0  Revision Date: 2020/03/23  SDS Number: 641708-00011  Date of last issue: 2019/09/13

10 / 15

| 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**: 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**: Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Toxicity to daphnia and other aquatic invertebrates:

Exposure time: 96 h

EC50 (Daphnia magna (Water flea)): 230 mg/l
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:

Exposure time: 48 h

EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Method: OECD Test Guideline 202

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):

Exposure time: 21 d

NOEC (Daphnia magna (Water flea)): 51 mg/l
Method: OECD Test Guideline 211

Buserelin:

Ecotoxicology Assessment

Acute aquatic toxicity: No data available
Chronic aquatic toxicity: No data available

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
SAFETY DATA SHEET

Buserelin Formulation

<table>
<thead>
<tr>
<th>Version</th>
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<td>641708-00011</td>
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<td>2016/05/03</td>
</tr>
</tbody>
</table>

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

AICS - Australian Inventory of Chemical Substances; 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.

JP / EN