SAFETY DATA SHEET

Buserelin Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Buserelin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@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 in accordance with ABNT NBR 14725 Standard
Not a hazardous substance or mixture.

GHS label elements in accordance with ABNT NBR 14725 Standard
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>Acute toxicity (Oral), Category 4</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute toxicity (Inhalation), Category 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye irritation, Category 2A</td>
<td></td>
</tr>
<tr>
<td>Buserelin</td>
<td>68630-75-1</td>
<td>Reproductive toxicity, Category 1A</td>
<td>&lt; 0,1</td>
</tr>
</tbody>
</table>

SECTION 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.

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 fire fighting: 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: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

SECTION 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 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: 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.

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.

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

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

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>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 vapor Type
- **Hand protection**: Chemical-resistant gloves

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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: liquid
- **Color**: colorless
- **Odor**: No data available
- **Odor Threshold**: No data available
- **pH**: 5.7 - 6.3
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: Not applicable
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Flammability (liquids)**: No data available
## SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

## SECTION 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Exposure Route</th>
<th>Acute Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Not classified based on available information.</td>
</tr>
<tr>
<td>Skin contact</td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td></td>
</tr>
</tbody>
</table>

### Information on likely routes of exposure

**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

**Relative density**: No data available

**Density**: 1,004 g/cm³

**Solubility(ies)**

- **Water solubility**: soluble

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

**Autoignition temperature**: Not applicable

**Decomposition temperature**: No data available

**Viscosity**

- **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
SAFETY DATA SHEET

Buserelin Formulation

Version 1.10
Revision Date: 23.03.2020
SDS Number: 641695-00011
Date of last issue: 13.09.2019
Date of first issue: 03.05.2016

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

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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

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

Buserelin:
Routes of exposure: 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

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

Test Type: unscheduled DNA synthesis assay
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 fetal development:
Test Type: Embryo-fetal 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 fetal development:
Test Type: Embryo-fetal 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-fetal development
Species: Rabbit
Developmental Toxicity: LOAEL: 0,1 µg/kg body weight
Result: Embryotoxic effects., No specific developmental abnormalities.

Test Type: Embryo-fetal 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
LOAEL: 0.5 ug/kg/day
Application Route: Subcutaneous
Exposure time: 14 Days
Species: Rat
**SAFETY DATA SHEET**

**Buserelin 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>
<tbody>
<tr>
<td>1.10</td>
<td>23.03.2020</td>
<td>641695-00011</td>
<td>13.09.2019</td>
<td>03.05.2016</td>
</tr>
</tbody>
</table>

**LOAEL**
- 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 y
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

**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

**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

**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.

Domestic regulation

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. List of chemicals controlled by the Federal Police: Sodium hydroxide

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


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 -
SAFETY DATA SHEET

Buserelin Formulation

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.

BR / Z8