SAFETY DATA SHEET

Buserelin Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Buserelin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   20 Spartan Road
   1619 Spartan, South Africa
   Telephone : +27119239300
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Not a hazardous substance or mixture.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Not a hazardous substance or mixture.

   Additional Labelling
   EUH210 Safety data sheet available on request.

2.3 Other hazards
   None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
</table>

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Buserelin Formulation

<table>
<thead>
<tr>
<th>Index-No.</th>
<th>Registration number</th>
<th>Acute Tox.4; H302</th>
<th>Acute Tox.4; H332</th>
<th>Eye Irrit.2; H319</th>
<th>&gt;= 1 - &lt; 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td></td>
<td></td>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
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<tr>
<td></td>
<td>202-859-9</td>
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<td>603-057-00-5</td>
<td></td>
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<td>&gt;= 1 - &lt; 10</td>
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<tr>
<td>Buserelin</td>
<td>68630-75-1</td>
<td>Repr.1A; H360F</td>
<td></td>
<td></td>
<td>&lt; 0,1</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

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.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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 as-
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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>
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</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>22 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>110 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>8 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>40 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5,4 mg/m³</td>
</tr>
<tr>
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<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>27 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Buserelin Formulation**

<table>
<thead>
<tr>
<th>Consumers</th>
<th>Ingestion</th>
<th>Long-term systemic effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>4 mg/kg bw/day</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance name</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
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<tr>
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</tr>
</tbody>
</table>

8.2 Exposure controls

**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**

**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.

**Hand protection**

**Material**

Chemical-resistant gloves

**Remarks**

Consider double gloving.

**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.

**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 (A)

**SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

**Appearance**

liquid

**Colour**

colourless
9.2 Other information

- Flammability (liquids): No data available
- Molecular weight: Not applicable
- Particle size: No data available
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

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

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
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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  
- **LOAEL:** 0.5 µg/kg/day  
- **Application Route:** Subcutaneous  
- **Exposure time:** 14 Days  
- **Species:** Rat  
- **LOAEL:** 0.05 µg/kg/day  
- **Application Route:** Subcutaneous  
- **Exposure time:** 28 Days  
- **Target Organs:** Testis  
- **Species:** Rabbit  
- **NOAEL:** 20 µg/kg/day  
- **Exposure time:** 4 Weeks  
- **Target Organs:** Testis, Prostate, Pituitary gland  
- **Species:** Monkey  
- **LOAEL:** 5 µg/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

SECTION 12: Ecological information

12.1 Toxicity

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: 51 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Buserelin:

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

12.2 Persistence and degradability

Components:

Benzyl alcohol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

12.3 Bioaccumulative potential

Components:

Benzyl alcohol:
Partition coefficient: n-octanol/water: log Pow: 1.05

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good
SAFETY DATA SHEET

Buserelin Formulation

Version 1.9  
Revision Date: 13.09.2019  
SDS Number: 641715-00010  
Date of last issue: 24.04.2019  
Date of first issue: 03.05.2016

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
The components of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H302: Harmful if swallowed.
H319: Causes serious eye irritation.
H332: Harmful if inhaled.
H360F: May damage fertility.

Full text of other abbreviations

Acute Tox.: Acute toxicity
Eye Irrit.: Eye irritation
Repr.: Reproductive toxicity

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx -
## Further information


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.

ZA / EN