Buserelin Formulation

**Section 1: Identification**

*Product name:* Buserelin Formulation

**Manufacturer or supplier's details**

*Company:* MSD

*Address:* 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

*Telephone:* +1-908-740-4000

*Emergency telephone number:* +1-908-423-6000

*E-mail address:* EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

*Recommended use:* Veterinary product

**Section 2: Hazard identification**

**GHS Classification**

Not a hazardous substance or mixture.

**GHS label elements**

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>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Buserelin</td>
<td>68630-75-1</td>
<td>&lt; 0.3</td>
</tr>
</tbody>
</table>

**Section 4: First-aid measures**

**If inhaled**

If inhaled, remove to fresh air.<br>
Get medical attention if symptoms occur.

**In case of skin contact**

Wash with water and soap as a precaution.<br>
Get medical attention if symptoms occur.

**In case of eye contact**

Flush eyes with water as a precaution.<br>
Get medical attention if irritation develops and persists.

**If swallowed**

If swallowed, DO NOT induce vomiting.<br>
Get medical attention if symptoms occur.<br>
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 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.

### Section 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 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 labelled 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

Components 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 rec-
**Section 9: Physical and chemical properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>colourless</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>pH</td>
<td>5.7 - 6.3</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</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>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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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Relative density : No data available
Density : 1.004 g/cm³
Solubility(ies) : soluble
Water solubility : soluble
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : Not applicable
Decomposition temperature : No data available
Viscosity : Not applicable
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

Section 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.

Section 11: Toxicological information

Exposure routes : 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
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Version: 1.10
Revision Date: 10.10.2020
SDS Number: 641712-00011
Date of last issue: 13.09.2019
Date of first issue: 03.05.2016

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:

Benzy 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.

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

Benzy 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
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:

Benzy1 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
LOAEL: 0.05 ug/kg/day
Application Route: Subcutaneous
Exposure time: 28 Days
Target Organs: Testis
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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

Section 12: Ecological information

Ecotoxicity

Components:

Benzy 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
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Buserelin Formulation

Version: 1.10  Revision Date: 10.10.2020  SDS Number: 641712-00011  Date of last issue: 13.09.2019

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

NZS 5433
Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number
Not applicable

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Report Status</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>

Section 16: Other information

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations

AIC - 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; 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 Organization 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 - Transport 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.

NZ / EN