1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Buserelin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Briahnager - Off Pune Nagar Road, Wagholi - Pune - India  412 207
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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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.

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></th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 5</td>
<td></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.
## 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 certain local or national requirements.

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.

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

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 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Colour: colourless

Odour: No data available

Odour 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

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available
SAFETY DATA SHEET

Buserelin Formulation

5. Flammability limit
   Vapour pressure : No data available
   Relative vapour 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
   Auto-ignition temperature : Not applicable
   Decomposition temperature : 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: > 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:
SAFETY DATA SHEET

Buserelin Formulation

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
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
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:

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: 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

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

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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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>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>

16. OTHER INFORMATION

Further information


Date format: dd.mm.yyyy

Full text of other abbreviations:

AIIC - 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 Or-
SAFETY DATA SHEET

Buserelin Formulation

Version: 1.10  Revision Date: 10.10.2020  SDS Number: 658130-00011  Date of last issue: 13.09.2019

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.

IN / EN