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PRODUCT AND COMPANY IDENTIFICATION

GHS Product Name: Buserelin acetate salt

Product code: p-104

Company: PharmSintez.Lab

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1.1 Product identifiers

Product name:	Buserelin acetate salt
Product Catalogue Number:	p-104
Band:	PharmSintez.Lab
CAS-No:	68630-75-1

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses:	Laboratory chemicals, Manufacture of substances
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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Acute toxicity, Oral (Category 4), H302
Reproductive toxicity (Category 1B), H360

For the full text of the H-Statements mentioned in this Section, see Section 16.

Classification according to EU Directives 67/548/EEC or 1999/45/EC

T Toxic R60

For the full text of the R-phrases mentioned in this Section, see Section 16.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram



Signal word

Danger

Hazard statement(s)

H302

Harmful if swallowed.

H360

May damage fertility or the unborn child.

Precautionary statement(s)

P201 Obtain special instructions before use.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Supplemental Hazard Statements none

2.3 Other hazards - none**SECTION 3: Composition/information on ingredients****3.1 Substances**

Synonyms : des-Gly10-[D-Ser[t-Bu]6]-LH-RH ethylamide
 pGlu-His-Trp-Ser-Tyr-D-Ser(t-Bu)-Leu-Arg-Pro-NHEt

Formula : C₆₀H₈₆N₁₆O₁₃ · C₂H₄O₂

Molecular Weight : 1,299.48 g/mol

CAS-No. : 68630-75-1

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component	Classification	Concentration
Buserelin acetate salt		
CAS-No. 68630-75-1	Acute Tox. 4; Repr. 1B; H302, H360	<= 100 %

Hazardous ingredients according to Directive 1999/45/EC

Component	Classification	Concentration
Buserelin acetate salt		
CAS-No. 68630-75-1	T, R60	<= 100 %

For the full text of the H-Statements and R-Phrases mentioned in this Section, see Section 16

SECTION 4: First aid measures**4.1 Description of first aid measures****General advice**

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

no data available

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, nitrogen oxides (NOx)

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information

no data available

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Avoid exposure - obtain special instructions before use.

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: -20 °C

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Appropriate engineering controls**

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- | | |
|---|---|
| a) Appearance | Form: solid |
| b) Odour | no data available |
| c) Odour Threshold | no data available |
| d) pH | no data available |
| e) Melting point/freezing point | no data available |
| f) Initial boiling point and boiling range | no data available |
| Flash point | no data available |
| g) Evaporation rate | no data available |
| h) Flammability (solid, gas) no data available | no data available |
| i) Upper/lower flammability or explosive limits | no data available |
| no data available | |
| j) Vapour pressure | no data available |
| k) Vapour density | no data available |
| l) Relative density | no data available |
| m) Water solubility | no data available Partition coefficient: n- octanol/water |
| n) Auto-ignition temperature | |

- p) Viscosity no data available
- q) Explosive properties no data available
- r) Oxidizing properties no data available

9.2 Other safety information

no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

no data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

no data available

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

Strong acids, Strong bases

10.6 Hazardous decomposition products

Other decomposition products - no data available

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - rat - > 400 mg/kg

Skin corrosion/irritation

no data available

Serious eye damage/eye irritation

no data available

Respiratory or skin sensitisation

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Presumed human reproductive toxicant

Specific target organ toxicity - single exposure

no data available

Specific target organ toxicity - repeated exposure

no data available

Aspiration hazard

no data available

Additional Information

RTECS: OK6370000

May have actions similar to luteinizing hormone releasing hormone (LH-RH) and gonadotropin releasing hormone (GN-RH) which are the key mediators in the neuroregulation of the secretion of gonadotropins,

lutinizing hormone (LH) and follicle stimulating hormone (FSH). LH-RH can modify sexual behavior by regulating plasma gonadotropin and sex steroid levels.

SECTION 12: Ecological information

- 12.1 Toxicity**
no data available
- 12.2 Persistence and degradability**
no data available
- 12.3 Bioaccumulative potential**
no data available
- 12.4 Mobility in soil**
no data available
- 12.5 Results of PBT and vPvB assessment**
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
- 12.6 Other adverse effects**
no data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods****Product**

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

- 14.1 UN number**
ADR/RID: - IMDG: - IATA: -
- 14.2 UN proper shipping name**
ADR/RID: Not dangerous goods
IMDG: Not dangerous goods

IATA: Not dangerous goods
- 14.3 Transport hazard class(es)**
ADR/RID: - IMDG: - IATA: -
- 14.4 Packaging group**
ADR/RID: - IMDG: - IATA: -
- 14.5 Environmental hazards**
ADR/RID: no IMDG Marine pollutant: no IATA: no
- 14.6 Special precautions for user**
no data available

SECTION 15: Regulatory information

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
no data available
- 15.2 Chemical Safety Assessment**

For this product a chemical safety assessment was not carried out

SECTION 16: Other information**Full text of H-Statements referred to under sections 2 and 3.**

Acute Tox.	Acute toxicity
H302	Harmful if swallowed.
H360	May damage fertility or the unborn child.
Repr.	Reproductive toxicity

Full text of R-phrases referred to under sections 2 and 3

T	Toxic
R60	May impair fertility.

Further information

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**Preparation
Information**

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multiple
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