PolyPeptide group

SAFETY DATA SHEET

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

Product Name: Deslorelin (Deslorelin Acetate)
Product Code: F1-0007-00
Synonyms: Des-Gly10, (D-Trp6)-Luteinizing Hormone Releasing Hormone; Gonadotropin Releasing Hormone; (D-Trp6-Pro9-NET)-; Somagard; D-Trp6-Pro9-N-Ethylamide-LHRH; (D-Trp6-Pro9)-LHRH Ethylamide; (D-Trp6-Pro9-NET)-GNRH; (D-Trp6-Pro9)-Luteinizing Hormone- Releasing Hormone Ethylamide, (D-Trp6-Pro9)-NET)-Gonadotropin Releasing Hormone
CAS No.: Deslorelin [57773-65-6]

Deslorelin Acetate [82318-06-7]

Form. : $C_{64}H_{83}N_{17}O_{12}\cdot(CH_3COOH)X\cdot(H_2O)Y$
Mol. Wt.: 1282.5 (free base)

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

Identified uses : For medical and veterinary research and/or commercial use. Restricted to professional users.

1.3. Details of the supplier of the safety data sheet:

Polypeptide Laboratories Pvt. Ltd.
Plot No. K-28,
Addl. MIDC, Phone: +91 251 3981900
Ambernath (E) Fax: +91 251 3981925
INDIA

1.4 Emergency telephone India:

+91 251 3981900.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
Reproductive toxicity (Category 1B), H360

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram	
Signal word	Danger
Hazard statement(s) H360	May damage fertility or the unborn child.
Precautionary statement(s) P201 P308 + P313	Obtain special instructions before use. IF exposed or concerned: Get medical advice/ attention.
Supplemental Hazard Statements	

PolyPeptide GROUP

SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms	:	Deslorelin
Formula	:	$C_{64}H_{83}N_{17}O_{12}$
Molecular weight	:	1282.5 (free base)
CAS No.	:	Deslorelin [57773-65-6] Deslorelin Acetate [82318-06-7]
Form.	:	C64H83N17O12·(CH3COOH)X·(H2O)Y

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 firefighting 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.

PolyPeptide GROUP

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 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.

Store at -20°C± 5°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

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. Use only in chemical fume hood

Personal protective equipment

Eye/face protection
Safety glasses 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.

Body Protection
Impervious clothing, 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

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

PolyPeptide GROUP

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a)	Appearance	White to off-white powder
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
g)	Flash point	No data available
h)	Evaporation rate	No data available
i)	Flammability (solid, gas)	No data available
j)	Upper/lower flammability or explosive limits	No data available
k)	Vapour pressure	No data available
l)	Vapour density	No data available
m)	Relative density	No data available
n)	Water solubility	No data available
o)	Partition coefficient: n-octanol/water	No data available
p)	Auto-ignition temperature	No data available
q)	Decomposition temperature	No data available
r)	Viscosity	No data available
s)	Explosive properties	No data available
t)	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 ordinary conditions of use and storage.

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
Hazardous decomposition products formed under fire conditions. - Carbon monoxide, carbon dioxide, nitrogen oxides

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Bioactive peptide with activity similar to that of gonadotropin releasing hormone (GnRH) , and will bind to GnRH receptors in the pituitary.
Peptide is rapidly degraded *in vivo*; mechanism of degradation is not fully understood. **Acute**

effects:

No symptoms associated with acute exposure

Increase in sex hormone levels [testosterone, estrogen, follicle stimulating hormone (FSH), and luteinizing hormone (LH)] within 48 hours, quickly returning to normal

May increase potential for pregnancy, or conversely, result in spontaneous abortion, depending on when during the menstrual cycle the exposure occurs

No evidence of fetal malformations in women exposed during pregnancy and who carried the infant to term.

Chronic Effects:

Chronic exposure (usually daily over several weeks) results in suppression of the pituitary axis with suppression of pituitary hormones, FSH, LH, as well as estrogen, testosterone, etc.

Symptoms of chronic exposure are due to hormone suppression and consist primarily of hot flashes in both men and women. Loss of libido and impotence have also been noted with chronic administration after several weeks.

Symptoms are completely reversible once exposure is stopped.

Additional information:

*Vale, W.W., Et Al., Peptides, Structure and Biological Function, Proceedings of the Sixth American peptide Symposium, Gross, E. and Meienhofer, M., Eds., 781 (1979).
Rtecs #: OK6755000
Luteinizing Hormone-Releasing Factor (Pig), 6-D-Tryptophan-9-(N-Ethyl-L-Prolinamide)-10-Deglycinamide-
Target Organ Data: Endocrine
(Change in LH) Endocrine
(Androgenic)
Paternal Effects (Spermatogenesis)
Paternal Effects (Prostrate, Seminal Vesicle, Cowper's, Accessory glands) Paternal Effects (Impotence)
Paternal Effects (Other effects on male)
Maternal Effects (Menstrual cycle changes or disorders)
Maternal Effects (Other effects on female)
Effects on Fertility (Female Fertility Index) Effects on Fertility (Pre-implantation mortality) Effects on Fertility (Other measures of fertility) Effects on Newborn (Live birth index)
Only selected registry of toxic effects of chemical substances (RTECS) data is presented here. See actual entry in RTECS for complete information.

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
No data available

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods Product
Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all Federal, State and Local Environmental Regulations.

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

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

European Information:

Caution: Substance not yet fully tested.
May impair fertility. S 45
In case of accident or if you feel unwell, seek medical advice immediately (Show the label where possible).
S 36/37/39
Wear suitable protective clothing, gloves and eye/face protection. S 22
Do not breathe dust.
Reviews, Standards, and Regulations
OEL=MAK
EPA Genetox Program 1988, Positive: Sperm Morphology-Human
Safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

The information presented herein is believed to be accurate and representative of currently accepted technical literature. However, PolyPeptide Laboratories does not mean to imply its completeness or comprehensiveness. Therefore, we suggest the use of this information solely as a guide in the use and handling of this product, and further urge the user to determine the suitability of this material for any particular purpose. PolyPeptide Laboratories shall not be held liable for any damages resulting from sole reliance on this information.