

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

Catalogue Number	CS-L-00110
Product Name	Cetrorelix
CAS No.	120287-85-6
Category	API
Synonyms	Not available
Brand	Clearsynth Labs Ltd.
Identified uses	Laboratory Chemicals
Uses advised against	Not available
Company	Clearsynth Labs Ltd. Mumbai, India
Emergency Phone #	+91-22-245045900
REACH No.	Not available

SECTION 2: Hazards identification

Disclaimer: This is sample MSDS. Please email sales@clearsynth.com for more details.

2.1 Classification of the substance or mixture-Regulation (EC) No 1272/2008:

Serious eye damage/eye irritation (Category 2)

2.2 Label Elements

Signal Word: Warning



Hazard Statement(s)

Code	Statement
H360	Not available
H319	Causes serious eye irritation.

Precautionary Statement(s)

Code	Statement
P203	Not available
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P318	Not available
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation
P264+P265	Not available
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present
P337+P317	If eye irritation persists: Get medical help.

SECTION 3: Composition / information on ingredients

3.1 Substance

Component : Cetorelix

CAS Number : 120287-85-6

Molecular Formula : Not available

Molecular Weight : Not available

Parent Chemical : Cetorelix

Synonyms : Not available

Concentration : Not available

SECTION 4: First aid measures

SECTION 4: First-aid measures

4.1 Description of first aid measures

General advice: Seek medical attention if symptoms occur or persist. Show this SDS to the physician.

Inhalation: Move person to fresh air. If breathing is difficult, seek medical attention.

Skin contact: Wash with plenty of soap and water. Remove contaminated clothing and wash before reuse. Get medical attention if irritation develops.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Seek medical attention if irritation persists.

Ingestion: Rinse mouth. Do not induce vomiting unless directed by medical personnel. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically. Not available.

SECTION 5: Firefighting measures

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing measures appropriate to local circumstances and the surrounding environment (e.g., water spray, dry chemical, foam, carbon dioxide).

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance or mixture

Specific hazards: Not available.

Hazardous combustion products: Not available.

5.3 Advice for firefighters

Wear self-contained breathing apparatus and full protective gear. Use water spray to cool unopened containers exposed to heat. Avoid inhalation of combustion products.

SECTION 6: Accidental release measures

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6.1 Personal precautions, protective equipment and emergency procedures

Avoid breathing dust/aerosols. Avoid contact with skin and eyes. Use appropriate personal protective equipment (see Section 8). Ensure adequate ventilation.

6.2 Environmental precautions

Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Do not allow to enter drains/surface waters/groundwater.

6.3 Methods and material for containment and cleaning up

Contain spill. Collect spilled material using methods that minimize dust generation (e.g., damp wipe or HEPA-filtered vacuum). Place in a suitable, closed container for disposal. Clean contaminated area.

6.4 Reference to other sections

See Section 8 for personal protective equipment and Section 13 for disposal considerations.

SECTION-7: Handling and storage

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid formation of dust/aerosols. Avoid contact with skin, eyes, and clothing. Do not breathe dust. Use with adequate ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Store in a tightly closed container. Keep container properly labeled. Store in a cool, dry, well-ventilated place. Protect from moisture. Incompatibilities: Not available.

7.3 Specific end use(s)

API. Not available.

SECTION 8: Exposure controls / personal protection

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits: Not available.

Biological limit values: Not available.

8.2 Exposure controls

Engineering controls: Use local exhaust ventilation or other engineering controls to maintain airborne levels below applicable exposure limits (if established). Provide eyewash station and safety shower.

Personal protective equipment (PPE):

- Eye/face protection: Safety glasses with side shields or chemical splash goggles.
- Skin protection: Protective gloves (chemical-resistant). Protective clothing as appropriate.
- Respiratory protection: If dust/aerosols are generated or ventilation is inadequate, use a properly fitted particulate respirator in accordance with applicable regulations.
- Hygiene measures: Wash hands after handling. Do not eat, drink, or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Test	Result
Appearance	No data available
IR spectrum	No data available
pH	No data available
Solubility	No data available

Property	Value
a) Physical State	No data available
b) Color	No data available
c) Odor	No data available
d) pH	No data available
e) Vapour Pressure	No data available
f) Viscosity	No data available
g) Initial Boiling Point and boiling range	No data available
h) Melting Point / Freezing Point	No data available
i) Auto Ignition Temperature	No data available
j) Flash Point	No data available
k) Explosion Limit, Lower	No data available

Property	Value
l) Explosion Limit, Upper	No data available
m) Decomposition Temperature	No data available
n) Loss on Drying	No data available
o) Relative Density	No data available
p) Solubility (in DMSO)	No data available
q) Oxidizing Properties	No data available

SECTION 10: Stability and reactivity

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10.1 Reactivity

Not available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Avoid dust formation. Avoid heat and moisture. Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Acute toxicity: /LABORATORY ANIMALS: Acute Exposure/ Single dose toxicity of cetorelix after oral and ip administration was studied in rats and mice. The acute oral toxicity was low. After ip injection, doses greater than or equal to 21.5 mg/kg caused reduced or slow movement, sunken sides, cyanosis of the skin and co-ordination disturbances. 68.1 mg/kg was determined as the minimal lethal dose. /LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ In the five repeated-dose toxicity studies of up to 26 weeks, performed on rats and dogs, daily sc injections of up to 0.5 mg/kg of cetorelix were well tolerated. No particular organ toxicity was determined. All observed changes appeared to be related to the pharmacological action of cetorelix and, thus are secondary to suppression of hormone levels. Minimal local irritant effects at the injection sites are partially related to a deposition and an accumulation of the drug in macrophages. All the findings were reversible or tended to be reversed during off-dose.

- Skin corrosion/irritation: No data available.
- Serious eye damage/eye irritation: No data available.
- Respiratory or skin sensitization: No data available.

- Germ cell mutagenicity: No data available.
- Carcinogenicity: No data available.
- Reproductive toxicity: /SIGNS AND SYMPTOMS/ Cases of hypersensitivity reactions, including anaphylactoid reactions with the first dose, have been reported during post-marketing surveillance. A severe anaphylactic reaction associated with cough, rash, and hypotension, was observed in one patient after seven months of treatment with Cetrotide (10 mg/day) in a study for an indication unrelated to infertility. /CASE REPORTS/ Clinical follow-up studies of 316 newborns of women administered Cetrotide were reviewed. One infant of a set of twin neonates was found to have anencephaly at birth and died after four days. The other twin was normal. Developmental findings from ongoing baby follow-up included a child with a ventricular septal defect and another child with bilateral congenital glaucoma.
- STOT-single exposure: No data available.
- STOT-repeated exposure: /LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ In the five repeated-dose toxicity studies of up to 26 weeks, performed on rats and dogs, daily sc injections of up to 0.5 mg/kg of cetorelix were well tolerated. No particular organ toxicity was determined. All observed changes appeared to be related to the pharmacological action of cetorelix and, thus are secondary to suppression of hormone levels. Minimal local irritant effects at the injection sites are partially related to a deposition and an accumulation of the drug in macrophages. All the findings were reversible or tended to be reversed during off-dose.
- Aspiration hazard: No data available.

Likely routes of exposure

- No data available.

Symptoms related to the physical, chemical and toxicological characteristics

- /SIGNS AND SYMPTOMS/ Cases of hypersensitivity reactions, including anaphylactoid reactions with the first dose, have been reported during post-marketing surveillance. A severe anaphylactic reaction associated with cough, rash, and hypotension, was observed in one patient after seven months of treatment with Cetrotide (10 mg/day) in a study for an indication unrelated to infertility.

SECTION 12: Ecological information

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12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Endocrine disrupting properties

Not available.

12.7 Other adverse effects

Not available.

SECTION 13: Disposal considerations

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13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulations. Do not discharge to drains.

Product: Dispose of as hazardous or special waste as applicable. Not available.

Contaminated packaging: Dispose of as unused product. Empty containers may retain residues.

SECTION 14: Transport information

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14.1 UN number

Not available.

14.2 UN proper shipping name

Not available.

14.3 Transport hazard class(es)

Not available.

14.4 Packing group

Not available.

14.5 Environmental hazards

Not available.

14.6 Special precautions for user

Not available.

14.7 Maritime transport in bulk according to IMO instruments

Not available.

SECTION 15: Regulatory information

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

Not available.

15.2 Chemical safety assessment

Not available.

SECTION 16: Other information

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Catalog No.: CS-L-00110

CAS No.: 120287-85-6

Supplier: Clearsynth Labs Ltd., Mumbai, India

Emergency phone: +91-22-245045900

Revision date: Not available.

Disclaimer: The information provided is believed to be accurate based on available data; however, it is provided without warranty. Users are responsible for determining suitability for their particular application and for compliance with applicable laws and regulations.

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