

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard

**CETROTIDE 250 MCG VIAL**

Version	Revision Date:	SDS Number:	Date of last issue: 04/11/2024
2.2	05/16/2024	90MDGM353028	Date of first issue: 01/30/2023

SECTION 1. IDENTIFICATION

Product name : CETROTIDE 250 MCG VIAL

Manufacturer or supplier's details

Company : EMD Serono, Inc.
One Technology Place
MA-02370 Rockland
United States of America

Responsible Department : e-mail: HealthcareSDS@emdgroup.com

Emergency telephone number : 800-424-9300 CHEMTREC (USA)
+1-703-527-3887 CHEMTREC (International)
613-996-6666 CANUTEC (Canada)
24 Hours/day; 7 Days/week

Recommended use of the chemical and restrictions on use

Recommended use : finished pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360F May damage fertility.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

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P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cetrorelix-Acetate	130143-01-0	$\geq 0.1 - < 1$

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
- If inhaled : Move to fresh air.
If symptoms persist, call a physician.
- In case of skin contact : Rinse with water.
Remove contaminated clothing.
If symptoms persist, call a physician.
- In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
- Most important symptoms and effects, both acute and delayed : Headache
Nausea
ovarian dysfunction
May damage fertility.
- Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water
Foam
Carbon dioxide (CO₂)

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Dry powder

Unsuitable extinguishing media : For this substance/mixture no limitations of extinguishing agents are given.

Specific hazards during fire-fighting : Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

Fire may cause evolution of:

Hydrogen chloride gas
nitrogen oxides

Hazardous combustion products : No hazardous combustion products are known

Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Suppress (knock down) gases/vapours/mists with a water spray jet.
(contamination risk)

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 : Advice for non-emergency personnel:
Avoid inhalation of dusts.
Evacuate the danger area, observe emergency procedures, consult an expert.
Advice for emergency responders:
Protective equipment see section 8.

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.
Cover drains. Collect, bind, and pump off spills.
Observe possible material restrictions (see sections 7 and 10).
Take up dry. Dispose of properly. Clean up affected area.
Avoid generation of dusts.

SECTION 7. HANDLING AND STORAGE

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- Technical measures : Install appropriate equipment and wear appropriate personal protective equipment (see "8. Exposure control/personal protection").
- Local/Total ventilation : Ensure adequate ventilation.
- Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Observe label precautions.
- Avoid formation of respirable particles.
Do not breathe vapours/dust.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Observe label precautions.
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage stability : No decomposition if stored and applied as directed.
-

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

- inert or nuisance dust 50 Million particles per cubic foot
Value type (Form of exposure): TWA (total dust)
Basis: OSHA Z-3
- 15 mg/m³
Value type (Form of exposure): TWA (total dust)
Basis: OSHA Z-3
- 5 mg/m³
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3
- 15 Million particles per cubic foot
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3
- Dust, nuisance dust and par- 10 mg/m³

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ticulates	Value type (Form of exposure): PEL (Total dust) Basis: CAL PEL
	5 mg/m ³ Value type (Form of exposure): PEL (respirable dust fraction) Basis: CAL PEL

Contains no substances with occupational exposure limit values.

L. Engineering measures : Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

P. Personal protective equipment

Respiratory protection	: required when dusts are generated.
Filter type	: Filter P 3 (acc. to DIN 3181) for solid and liquid particles of toxic and very toxic substances
Hand protection	
Material	: Nitrile rubber
Break through time	: > 480 min
Glove thickness	: 0.11 mm
Manufacturer	: KCL 741 Dermatril® L
Remarks	: The suitability for a specific workplace should be discussed with the producers of the protective gloves.
Eye protection	: Eye wash bottle with pure water Tightly fitting safety goggles
Skin and body protection	: Dust impervious protective suit Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Protective measures	: The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Hygiene measures	: Wash hands before breaks and at the end of workday. Change contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: powder, (lyophilised)
Colour	: white

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Odour : odourless
not significant

Odour Threshold : Not applicable

pH : No data available

Melting point : No data available

Boiling point : No data available

Flash point : Not applicable

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : Upper explosion limit
No data available

Lower explosion limit / Lower flammability limit : Lower explosion limit
No data available

Vapour pressure : No data available

Relative vapour density : No data available
Not applicable

Density : No data available

Solubility(ies)
Water solubility : soluble

Partition coefficient: n-octanol/water : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not classified as explosive.

Oxidizing properties : none

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No decomposition if stored and applied as directed.

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Chemical stability	:	The product is chemically stable under standard ambient conditions (room temperature) .
Possibility of hazardous reactions	:	Violent reactions possible with: Strong oxidizing agents
Conditions to avoid	:	no information available
Incompatible materials	:	Not applicable
Hazardous decomposition products	:	in the event of fire: See section 5.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Product:

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Components:

Cetrorelix-Acetate:

Acute oral toxicity : LD50 (Rat): > 2,150 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks : No data available

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:

Cetrorelix-Acetate:

Species : Rabbit
Result : slight irritation
Method : OECD Test Guideline 405

Assessment : No eye irritation

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Respiratory or skin sensitisation

Skin sensitisation

Not classified due to lack of data.

Respiratory sensitisation

Not classified due to lack of data.

Components:

Cetorelix-Acetate:

Exposure routes : dermal
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Germ cell mutagenicity

Not classified due to lack of data.

Product:

Genotoxicity in vivo : Remarks: No data available

Components:

Cetorelix-Acetate:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Result: negative
Remarks: (External MSDS)

Carcinogenicity

Not classified due to lack of data.

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.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

May damage fertility.

Product:

Reproductive toxicity - Assessment : May impair fertility.

Components:

Cetorelix-Acetate:

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertil-

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Toxicity to algae/aquatic plants : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to microorganisms : Remarks: No data available

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Cetrotirelix-Acetate:

Partition coefficient: n-octanol/water : log Pow: -1.1
Method: (experimental)

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : Discharge into the environment must be avoided.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

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Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Do not re-use empty containers.

SECTION 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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.
Not classified as dangerous in the meaning of transport regulations.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

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This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

D-mannitol 69-65-8

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

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

TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Cetorelix-Acetate
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
TECI	:	Not in compliance with the inventory

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TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Company internal Occupational Exposure Limit (MOEL)

(130143-01-0) : 0.15 µg/m³

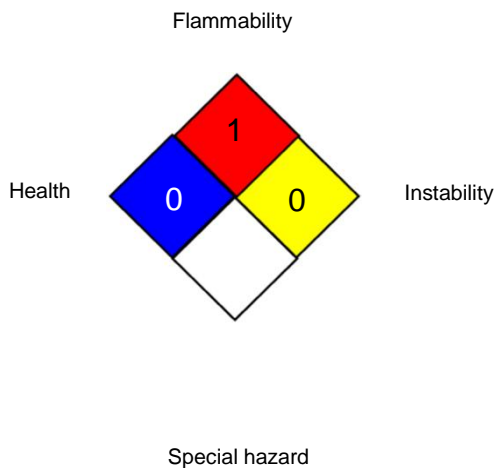
Short Term Exposure (15 min) Factor : 8

Pregnancy risk groups : C

There is no reason to fear damage to the embryo, or foetus when the company internal OEL value is observed.

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	0
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)
CAL PEL / PEL : Permissible exposure limit
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts

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AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Organisation 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; 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

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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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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