

## SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Date of issue: 05/01/2015

Version 1.0

### SECTION 1. Identification

#### Product identifier

Product number	353028
Product code	F55A01A0
Product name	CETROTIDE 250 MCG VIAL

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

Identified uses	Use restricted under TSCA to research and development or as analytical reagent. Uses regulated under FDA or FIFRA are not affected.
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#### Details of the supplier of the safety data sheet

Company	EMD Serono, Inc. One Technology Place, Rockland, MA-02370 USA 1-800-283-8088 x5562 - Product Information
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Emergency telephone	800-424-9300 CHEMTREC (USA) +1-703-527-3887 CHEMTREC (International) 24 Hours/day; 7 Days/week
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### SECTION 2. Hazards identification

#### GHS Classification

Reproductive toxicity, Category 1B, H360

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

#### GHS-Labeling

*Hazard pictograms*



*Signal Word*  
Danger

*Hazard Statements*  
H360 May damage fertility or the unborn child.

*Precautionary Statements*

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P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P281 Use personal protective equipment as required.

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

P405 Store locked up.

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

## Other hazards

Pharmaceutical highly active substance

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## SECTION 3. Composition/information on ingredients

### Hazardous ingredients

*Chemical Name (Concentration)*

CAS-No.

*Cetrotirelix-Acetate ( $\geq 0.1\%$  -  $< 1\%$ )*

130143-01-0

Exact percentages are being withheld as a trade secret.

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## SECTION 4. First aid measures

### Description of first-aid measures

*Inhalation*

After inhalation: fresh air. Call in physician.

*Skin contact*

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.

*Eye contact*

After eye contact: rinse out with plenty of water. Call in ophthalmologist.

*Ingestion*

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

Never give anything by mouth to an unconscious person.

### Most important symptoms and effects, both acute and delayed

We have no description of any toxic symptoms.

### Indication of any immediate medical attention and special treatment needed

No information available.

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## SECTION 5. Fire-fighting measures

### Extinguishing media

*Suitable extinguishing media*

Water, Foam, Carbon dioxide (CO<sub>2</sub>), Dry powder

*Unsuitable extinguishing media*

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

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## Special hazards arising from the substance or mixture

Combustible.

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

## Advice for firefighters

*Special protective equipment for fire-fighters*

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

*Further information*

Prevent fire extinguishing water from contaminating surface water or the ground water system.

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## SECTION 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders:

Protective equipment see section 8.

### Environmental precautions

Do not let product enter drains.

### Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up carefully. Dispose of properly. Clean up affected area. Avoid generation of dusts.

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## SECTION 7. Handling and storage

### Precautions for safe handling

Work under hood. Do not inhale substance/mixture.

Pregnant women should not be exposed to this product.

Observe label precautions.

### Conditions for safe storage, including any incompatibilities

Keep locked up or in an area accessible only to qualified or authorized persons.

Locally Defined - only to be used for Pharma

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## SECTION 8. Exposure controls/personal protection

### Exposure limit(s)

Contains no substances with occupational exposure limit values.

### Engineering measures

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

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## Individual protection measures

Protective clothing should be selected specifically for the workplace, depending on concentration and quantity of the hazardous substances handled. The chemical resistance of the protective equipment should be inquired at the respective supplier.

### *Hygiene measures*

Change contaminated clothing. Wash hands after working with substance.

### *Eye/face protection*

Safety glasses

### *Hand protection*

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

### *Other protective equipment:*

protective clothing

### *Respiratory protection*

required when dusts are generated.

Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

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## SECTION 9. Physical and chemical properties

Physical state	powder (lyophilized)
Color	white
Odor	not significant
Odor Threshold	No information available.
pH	No information available.
Melting point	No information available.
Boiling point	No information available.
Flash point	Not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	Not applicable
Upper explosion limit	Not applicable
Vapor pressure	Not applicable

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Relative vapor density	Not applicable
Density	No information available.
Relative density	No information available.
Water solubility	soluble
Partition coefficient: n-octanol/water	Not applicable
Autoignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none
Viscosity, kinematic	Not applicable

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## SECTION 10. Stability and reactivity

### Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

### Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

### Possibility of hazardous reactions

Dangerous reactions are not expected handling the product according to its intended use.

### Conditions to avoid

no information available

### Incompatible materials

no information available

### Hazardous decomposition products

no information available

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## SECTION 11. Toxicological information

### Information on toxicological effects

*Likely route of exposure*

Inhalation, Eye contact, Skin contact, Ingestion

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### *CMR effects*

Teratogenicity:

May damage the unborn child.

Reproductive toxicity:

May damage the unborn child.

### *Specific target organ systemic toxicity - single exposure*

The substance or mixture is not classified as specific target organ toxicant, single exposure.

### *Specific target organ systemic toxicity - repeated exposure*

The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

### *Aspiration hazard*

Regarding the available data the classification criteria are not fulfilled.

## **Carcinogenicity**

IARC

No ingredient 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 ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

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

ACGIH

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

## **Further information**

Handle in accordance with good industrial hygiene and safety practice.

## **Ingredients**

### *Cetrorelix-Acetate*

#### *Acute oral toxicity*

LD50 Rat: > 2,150 mg/kg

OECD Test Guideline 401

#### *Eye irritation*

Rabbit

Result: slight irritation

OECD Test Guideline 405

#### *Sensitization*

Guinea pig

Result: negative

Method: OECD Test Guideline 406

#### *Repeated dose toxicity*

Rat

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NOAEL: > 0.5 mg/kg  
OECD Test Guideline 407

Dog  
NOAEL: > 0.5 mg/kg  
OECD Test Guideline 407

*Germ cell mutagenicity*  
*Genotoxicity in vitro*  
Ames test  
Salmonella typhimurium  
Result: negative

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## SECTION 12. Ecological information

### Ecotoxicity

No information available.

### Persistence and degradability

No information available.

### Bioaccumulative potential

*Partition coefficient: n-octanol/water*

Not applicable

### Mobility in soil

No information available.

### Ingredients

*Cetrorelix-Acetate*

*Partition coefficient: n-octanol/water*

log Pow: -1.1  
(experimental)

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## SECTION 13. Disposal considerations

The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

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## SECTION 14. Transport information

### Land transport (DOT)

Not classified as dangerous in the meaning of transport regulations.

### Air transport (IATA)

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Not classified as dangerous in the meaning of transport regulations.

## Sea transport (IMDG)

Not classified as dangerous in the meaning of transport regulations.

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## SECTION 15. Regulatory information

### United States of America

#### 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.

#### SARA 302

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

#### 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

#### DEA List I

Not listed

#### DEA List II

Not listed

### US State Regulations

#### Massachusetts Right To Know

Remarks

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

#### California Prop 65 Components

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

#### Notification status

TSCA:

This product is regulated under the Food, Drug, and Cosmetic Act and is exempt from TSCA.

DSL:

This product contains one or several components that are not on the Canadian DSL nor NDSL.

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## SECTION 16. Other information

### Training advice

Provide adequate information, instruction and training for operators.

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## Labeling

### *Hazard pictograms*



### *Signal Word*

Danger

### *Hazard Statements*

H360 May damage fertility or the unborn child.

### *Precautionary Statements*

#### Prevention

P201 Obtain special instructions before use.

#### Response

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

Restricted to professional users.

### **Full text of H-Statements referred to under sections 2 and 3.**

H360 May damage fertility or the unborn child.

### **Key or legend to abbreviations and acronyms used in the safety data sheet**

Used abbreviations and acronyms can be looked up at [www.wikipedia.org](http://www.wikipedia.org).

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The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to appropriate safety precautions. It does not represent a warranty of any product properties and we assume no liability for any loss or injury which may result from the use of this information. Users should conduct their own investigations to determine the suitability of the information.

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