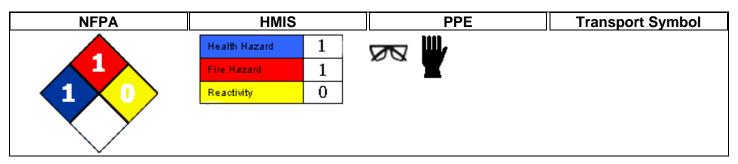


# **Material Safety Data Sheet**



Issuing Date 29-Oct-2008 Revision Date Revision Number 0

# 1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Cosyntropin for Injection, 0.25 mg

Product Code(s) 10139-905-02 - 0.25 mg Vial

10139-905-10 - Shelf Pack (0.25 mg Vials x 10)

Synonyms Cortrosyn

Recommended Use Diagnostic Agent

Supplier Address GeneraMedix Inc.

150 Allen Road

Liberty Corner, New Jersey 07938, USA

TEL: 908-504-1300

Chemical Emergency Phone Number Chemtrec 1-800-424-9300

# 2. HAZARDS IDENTIFICATION

# **Emergency Overview**

May cause skin irritation and/or dermatitis. May cause eye irritation. May cause irritation of respiratory tract. Repeated contact may cause allergic reactions in very susceptible persons.

Appearance White Physical State Powder Odor Odorless

**Potential Health Effects** 

Principle Routes of Exposure Skin contact. Eye contact.

**Acute Toxicity** 

**Eyes** May cause slight irritation.

Skin May cause skin irritation and/or dermatitis. Repeated or prolonged skin contact may cause

allergic reactions with susceptible persons.

**Inhalation** Not an expected route of exposure. May cause irritation of respiratory tract.

**Ingestion** May be harmful if swallowed.

Chronic Effects No known effect based on information supplied.

Aggravated Medical Conditions None known.

**Environmental Hazard** See Section 12 for additional Ecological Information.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
Mannitol	69-65-8	97.6
Cosyntropin	16960-16-0	2.4

Sodium hydroxide and/or acetic acid used to adjust pH.

#### 4. FIRST AID MEASURES

Eye Contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. If

symptoms persist, call a physician.

**Skin Contact** Wash off immediately with plenty of water for at least 15 minutes. In the case of skin irritation

or allergic reactions see a physician.

Inhalation Move victim to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give

oxygen. If symptoms persist, call a physician.

Ingestion Call a physician or Poison Control Center immediately. Do NOT induce vomiting. Drink 1 or 2

glasses of water. Never give anything by mouth to an unconscious person.

**Notes to Physician** See clinical drug insert information for treatment of overdose.

Protection of First-aiders Ensure that medical personnel are aware of the material(s) involved, and take precautions to

protect themselves. Avoid direct contact with skin. Use barrier to give mouth-to-mouth

resuscitation.

#### 5. FIRE-FIGHTING MEASURES

Flammable Properties Not flammable.

Flash Point Not determined.

Suitable Extinguishing Media Dry chemical, CO<sub>2</sub> or water spray. Move containers from fire area if you can do it without risk.

Dike fire control water for later disposal; do not scatter the material.

**Explosion Data** 

Sensitivity to Mechanical Impact None.
Sensitivity to Static Discharge None.

### **Protective Equipment and Precautions for Firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA Health Hazard 1 Flammability 1 Stability 0 Physical and Chemical

Hazards N/A

HMIS Health Hazard 1 Flammability 1 Stability 0 Personal Protection N/A

# **6. ACCIDENTAL RELEASE MEASURES**

Personal Precautions Use personal protective equipment. Do not touch damaged containers or spilled material

unless wearing appropriate protective clothing.

**Methods for Containment** Prevent further leakage or spillage if safe to do so. Absorb with earth, sand or other non-

combustible material and transfer to containers for later disposal.

**Methods for Cleaning Up** Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin Handling

and eyes. Avoid dust formation. Do not breathe vapors/dust. Do not eat, drink or smoke when

using this product.

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep from freezing. Storage

Protect from light. Keep out of the reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

This product does not contain any hazardous materials with occupational exposure limits **Exposure Guidelines** 

established by the region specific regulatory bodies.

**Engineering Measures** Showers, eyewash stations, and ventilation systems.

**Personal Protective Equipment** 

**Eye/Face Protection** Skin and Body Protection Safety glasses with side-shields. Wear protective gloves/clothing.

**Respiratory Protection** No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

**Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

White Odor Odorless **Appearance Odor Threshold** No data available **Physical State** Powder

Ha No data available

Not determined. N/A **Flash Point Autoignition Temperature** 

**Decomposition Temperature** No data available **Boiling Point/Range** No data available

Melting Point/Range No data available No data available Flammability Limits in Air No data available **Explosion Limits** 

No data available **Water Solubility** Miscible with water **Molecular Weight** No data available No data available **Evaporation Rate** Vapor Pressure

**Vapor Density** No data available **VOC Content** N/A No data available

**Partition Coefficient** (n-octanol/water)

10. STABILITY AND REACTIVITY

Stability Stable under recommended storage conditions.

**Incompatible Products** None known based on information supplied.

**Conditions to Avoid** Extremes of temperature and direct sunlight.

Hazardous Decomposition Products None known based on information supplied.

**Hazardous Polymerization** Hazardous polymerization does not occur.

# 11. TOXICOLOGICAL INFORMATION

# **Acute Toxicity**

**Product Information**No acute toxicity information is available for this product.

**Component Information** 

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Mannitol	13500 mg/kg (Rat)		

**Chronic Toxicity** 

Chronic Toxicity No known effect based on information supplied.

**Carcinogenicity** There are no known carcinogenic chemicals in this product.

**Sensitization** No data available. May cause sensitization of susceptible persons.

Mutagenic Effects No information available.

Reproductive Toxicity Reproductive effects are unknown.

**Developmental Toxicity** No information available.

Target Organ Effects No known effects under normal use conditions.

# 12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

**Ecotoxicity Effects**The environmental impact of this product has not been fully investigated.

# 13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR

261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local

regulations for additional requirements.

**Contaminated Packaging** Dispose of in accordance with local regulations.

# 14. TRANSPORT INFORMATION

**DOT** Not regulated.

TDG Not regulated.

MEX Not regulated.

ICAO Not regulated.

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14. TRANSPORT INFORMATION

IATA Not regulated.

IMDG/IMO Not regulated.

RID Not regulated.

ADR Not regulated.

ADN Not regulated.

# 15. REGULATORY INFORMATION

#### **International Inventories**

TSCA Exempt

DSL Does not Comply
EINECS/ELINCS Does not Comply
ENCS Does not Comply
IECSC Does not Comply
KECL Does not Comply
PICCS Does not Comply
AICS Does not Comply

#### **U.S. Federal Regulations**

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

# SARA 311/312 Hazard Categories

Acute Health Hazard Yes
Chronic Health Hazard No
Fire Hazard No
Sudden Release of Pressure Hazard No
Reactive Hazard No

#### **Clean Water Act**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

#### **U.S. State Regulations**

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### U.S. State Right-to-Know Regulations

# International Regulations

#### Canada

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This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.

#### **WHMIS Hazard Class**

Non-controlled. Not regulated under CEPA.

# **16. OTHER INFORMATION**

Issuing Date 29-Oct-2008

Revision Date

No data available.

Revision Note

No data available.

#### Disclaimer

The information provided on this MSDS 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text

**End of Safety Data Sheet** 

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