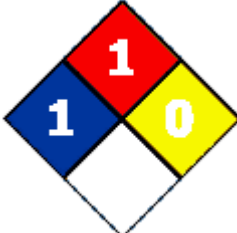



| NFPA | HMIS | PPE | Transport Symbol | | | | | | |
|---|--|---------------|------------------|-------------|---|------------|---|---|--|
|  | <table border="1"> <tr> <td>Health Hazard</td> <td align="center">1</td> </tr> <tr> <td>Fire Hazard</td> <td align="center">1</td> </tr> <tr> <td>Reactivity</td> <td align="center">0</td> </tr> </table> | Health Hazard | 1 | Fire Hazard | 1 | Reactivity | 0 |  | |
| Health Hazard | 1 | | | | | | | | |
| Fire Hazard | 1 | | | | | | | | |
| Reactivity | 0 | | | | | | | | |

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 ₂ 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

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid dust formation. Do not breathe vapors/dust. Do not eat, drink or smoke when using this product.

Storage Keep containers tightly closed in a dry, cool and well-ventilated place. Keep from freezing. Protect from light. Keep out of the reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Engineering Measures Showers, eyewash stations, and ventilation systems.

Personal Protective Equipment

Eye/Face Protection

Safety glasses with side-shields.

Skin and Body Protection

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

| | | | |
|--|-------------------|---------------------------------|---------------------|
| Appearance | White | Odor | Odorless |
| Odor Threshold | No data available | Physical State | Powder |
| pH | No data available | | |
| Flash Point | Not determined. | Autoignition Temperature | N/A |
| Decomposition Temperature | No data available | Boiling Point/Range | No data available |
| Melting Point/Range | No data available | | |
| Flammability Limits in Air | No data available | Explosion Limits | No data available |
| Molecular Weight | No data available | Water Solubility | Miscible with water |
| Evaporation Rate | No data available | Vapor Pressure | No data available |
| Vapor Density | No data available | VOC Content | N/A |
| Partition Coefficient (n-octanol/water) | No data available | | |

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.

14. TRANSPORT INFORMATION

| | |
|-----------------|----------------|
| <u>IATA</u> | Not regulated. |
| <u>IMDG/IMO</u> | Not regulated. |
| <u>RID</u> | Not regulated. |
| <u>ADR</u> | Not regulated. |
| <u>ADN</u> | 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

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