



AMPHASTAR PHA
11570 SIXTH STREET, RANCH
AREA CODE (800) 423-4136

FAX (909) 980-8296

MATERIAL SAFETY DATA SHEET

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|-------------------|--------------|---------|-----------|------------|---|
| Post-it® Fax Note | 7671 | Date | 4/10/18 | # of pages | 5 |
| To | Chris Huns | From | Matthew | | |
| Co./Dept | Henry Behm | Co. | Orf Szwed | | |
| Phone # | | Phone # | | | |
| Fax # | 614 659-1607 | Fax # | | | |

| SECTION I. IDENTIFICATION | |
|--------------------------------------|---|
| Identity/Material Name | CORTROSYN® (cosyntropin) for Injection (as a Diagnostic Agent) |
| Synonyms | α 1-24 corticotropin |
| Stock Number | 5900 |
| NDC Number | 0548-5900-00 |
| Unit Size | 0.25 mg Cortrosyn® (lyophilized powder for reconstitution in 1 mL 0.9% Sodium Chloride Injection USP), single dose vial. |
| Intended Use | Rx Only. A diagnostic agent in the screening of patients presumed to have adrenocortical insufficiency. |
| Company Information | |
| Manufacture | Amphastar Pharmaceuticals, Inc. 11570 Sixth Street, Rancho Cucamonga, California 91730 Tel (800) 423-4136 Fax (909) 980-8296 |
| Emergency Number | (800) 423-4136 (US Domestic), (909) 980-9484 (International) |
| SECTION II. HAZARD(S) IDENTIFICATION | |
| Emergency Overview | White lyophilized powder After reconstitution: clear, colorless, odorless solution. The physician should be prepared, prior to injection, to treat any possible acute hypersensitivity reaction. |
| Statement of Hazard | May cause irritation. Repeated contact may cause allergic reactions in very susceptible persons. |
| Potential Health Effect | Since CORTROSYN® (cosyntropin) for Injection is intended for diagnostic and not therapeutic use, adverse reactions other than a rare hypersensitivity reaction are not anticipated. A rare hypersensitivity reaction usually associated with a pre-existing allergic disease and/or previous reaction to natural ACTH is possible. The following adverse reactions have been reported in patients after the administration of CORTROSYN® and the association has been neither confirmed nor refuted: Bradycardia, Tachycardia, Hypertension, Peripheral edema, rash. |
| Hazard Class | Not applicable |
| Hazard Category | GHS Classification Classification according to EC Directive 1272/2008 Classification according to EC Directives 64/548/EEC (substances) or 1999/45/EC (mixtures) |
| | Not applicable Not applicable Not applicable |

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| SECTION III. COMPOSITION/INFORMATION ON INGREDIENTS | |
|--|--|
| Active Ingredient | Cosyntropin USP |
| | Approximate % by weight: .025% RTECS No. GM7915000 |
| | EC Number: 241-031-1 CAS #: 16960-16-0 |
| Inactive Ingredients | Glacial Acetic Acid USP Sodium Hydroxide NF Mannitol USP Sodium Chloride USP Water for Injection USP |
| Chemical Formula | $C_{136}H_{210}N_{40}O_{31}S$ |
| SECTION IV. FIRST-AID MEASURES | |
| Eye Contact | Flush eyes immediately with copious amounts of water. Seek medical attention if deemed necessary. |
| Skin Contact | Avoid direct skin contact. Wash affected skin surfaces immediately with mild soap and copious amounts of water. |
| Inhalation | Do not inhale the lyophilized Cosyntropin USP powder. May cause hypersensitivity reaction. Remove to fresh air. Get medical attention for any breathing difficulty. |
| Ingestion | If large amounts were swallowed, give water to drink and get medical advice. |
| Effect and Treatment of Overdosage | CORTROSYN® (cosyntropin) for Injection is intended for diagnostic and not therapeutic use; adverse reactions other than a rare hypersensitivity reaction are not anticipated. The physician should be prepared, prior to injection, to treat any possible acute hypersensitivity reaction. |
| SECTION V. FIRE-FIGHTING MEASURES | |
| Extinguishing Media | Water, carbon dioxide, dry chemical or foam. |
| Special Fire-Fighting Precautions | No special precautions determined for this product. |
| Flammability | |
| Fire/Explosion Hazards | Not applicable |
| Hazardous Combustion Products | Unknown |
| Flash Point | Unknown |
| Auto-Ignition Temperature | Not applicable |
| Flammable Limits | LEL |
| | UEL |
| | Not applicable |
| SECTION VI. ACCIDENTAL RELEASE MEASURES | |
| Personal Precautions | Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure. |
| Environmental Precautions | Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. |

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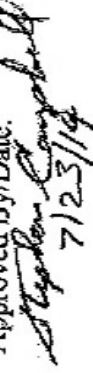
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| Steps to be Taken if Released or Spilled | Absorb onto paper. Wash spill site with copious amounts of water. |
| SECTION VII. HANDLING AND STORAGE | |
| Handling | Handle in accordance with good industrial hygiene and safety practice. Avoid contact 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 light and avoid freezing. Keep out of the reach of children. |
| SECTION VIII. EXPOSURE CONTROLS/PERSONAL PROTECTION | |
| Exposure Limits | Not applicable |
| Personal Protective Equipment (PPE) | |
| Eye Protection | Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance. |
| Skin Protection | Adequate skin protection recommended including gloves. Lab coats or additional precaution may be required based on procedure or level of exposure. Consult your site safety staff for guidance. |
| Respiratory Protection | Respiratory protection is not needed during normal product use. |
| Engineering Controls | Local ventilation adequate. |
| SECTION IX. PHYSICAL AND CHEMICAL PROPERTIES | |
| Appearance and Odor | White lyophilized powder After reconstitution: clear, colorless, odorless solution |
| Physical State | Powder |
| pH | 5.5-7.5 |
| Molecular Weight | Unknown |
| Melting Point(°C) | Unknown |
| Freezing Point(°C) | Unknown |
| Boiling Point(°C) | Not applicable |
| Evaporation Rate | Water solvent will slowly evaporate |
| Vapor Pressure | Not applicable |
| Vapor Density | Unknown |
| Relative Density | Unknown |
| Solubility(ies) | Solution miscible with water |
| Partition coefficient | Unknown |
| Decomposition Temperature | Unknown |
| Viscosity | Not applicable |
| Flammability | See Section V: Fire Fighting Measures for flammability/explosivity information. |

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| SECTION X. STABILITY AND REACTIVITY | |
|---|---|
| Stability/Reactivity | Stable under ordinary conditions of use and storage. Protection from light and freezing. Reconstituted Cortrosyn® (cosyntropin) for injection should not be retained. |
| Hazardous Reactions | Not determined. |
| Incompatibilities/ Conditions to Avoid | Temperature out side of 15 - 30°C (59 - 86°F), freezing, and light exposure. Injection is discolored or contains a precipitate. |
| Hazardous Decomposition Products | Not determined. |
| Hazardous Polymerization | Not anticipated to occur with this product. |
| SECTION XI. TOXICOLOGICAL INFORMATION | |
| The data presented below is for this product or for a structurally similar product. | |
| Acute Toxicity | Not applicable |
| Repeat Dose Toxicity Data | |
| Subchronic/ Chronic Toxicity | Not applicable |
| Reproductive/ Developmental Toxicity | Pregnancy Category C Animal reproduction studies have not been conducted with CORTROSYN® (cosyntropin) for Injection. It is also not known whether CORTROSYN® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. CORTROSYN® should be given to a pregnant woman only if clearly needed. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CORTROSYN® (cosyntropin) for Injection is administered to a nursing woman. |
| Mutagenicity/ Genotoxicity | Long term studies in animals have not been performed to evaluate carcinogenic or mutagenic potential or impairment of fertility. A study in rats noted inhibition of reproductive function like natural ACTH. |
| Carcinogenicity | Long term studies in animals have not been performed to evaluate carcinogenic or mutagenic potential or impairment of fertility. A study in rats noted inhibition of reproductive function like natural ACTH. |
| SECTION XII. ECOLOGICAL INFORMATION | |
| Ecotoxicity Data | Not determined for this product |
| Environmental Data | Not determined for this product |
| SECTION XIII. DISPOSAL CONSIDERATIONS | |
| Method of Disposal | Approved chemical waste incineration or approved aqueous discharge to municipal or on-site wastewater treatment systems. |
| Container Handling and Disposal | Dispose of container and unused contents in accordance with federal, state and local regulations. |
| SECTION XIV. TRANSPORT INFORMATION | |
| This material is not subject to the transportation regulation of USDOT, EUADR, IATA or IMDG/IMO | |

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| SECTION XV. REGULATORY INFORMATION | |
|------------------------------------|---|
| US State Regulations | Check state requirements for ingredient listing. |
| RCRA Status | Not listed |
| U.S. OSHA Classification | Unknown |
| TSCA Listing | Exempt |
| GHS Classification | Not applicable |
| Symbol |  |
| Response | See First Aid measures (Section IV) |
| SECTION XVI. OTHER INFORMATION | |
| Pharmaceutical Use | This product is Rx Only. Please follow instructions in the package insert. |
| Abbreviations | <p>Agreement on Dangerous Goods by Road Chemical Abstracts Service Number US Department of Transportation Regulations International Air Transport Association International Maritime Organization Dosage producing 50% mortality Lower Exposure Limit Not applicable US Occupational Safety and Health Administration - Permissible Exposure Limit US EPA, Resource Conservation and Recovery Act Registry of Toxic Effects of Chemical Substances Toxic Substance Control Act Upper Exposure Limit</p> |
| Hazard Symbols |  |
| Revision Date | 07/11/14 |
| Supersedes Date | 07/22/03 |
| | Irritant |

Rx Only. Refer to package insert for additional information.

The information contained herein is believed to be complete and accurate. However, it is the user's responsibility to determine the suitability of the information for their particular purpose. The company assumes no additional liability or responsibility resulting from the usage of, or reliance on this information.

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Approved By/Date:

Stephen Campbell
7/23/14