AMPHASTAR PHARMACEUTICALS, INC.
11570 SIXTH STREET, RANCHO CUCAMONGE, CALIFORNIA 91730
AREA CODE (800) 423-4136, (909) 980-9484 (INTERNATIONAL)
FAX (909) 980-8296

MATERIAL SAFETY DATA SHEET

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	Not applicable
	Classification according to EC Directive 1272/2008	Not applicable
	Classification according to EC Directives 64/548/EEC (substances) or 1999/45/EC (mixtures)	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	Not applicable
	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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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	
ADR	Agreement on Dangerous Goods by Road
CAS	Chemical Abstracts Service Number
DOT	US Department of Transportation Regulations
IATA	International Air Transport Association
IMO	International Maritime Organization
LD50	Dosage producing 50% mortality
LEL	Lower Exposure Limit
N/A	Not applicable
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
TSCA	Toxic Substance Control Act
UEL	Upper Exposure Limit
Hazard Symbols	
	Irritant
Revision Date	07/11/14
Supersedes Date	07/22/03

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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