MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

TRADE/MATERIAL NAME: HYDROXOCOBALAMIN

Hydroxocobalamin Injection 1000 μg/mL 30mL Vial

DESCRIPTION: Solution Containing Hydroxocobalamin
OTHER DESIGNATIONS: NDC# 00591-2888-30
CHEMICAL NAME: Cobinamide, dihydroxide, dihydrogen phosphate (ester), mono (inner salt), 3'-ester with 5,6-dimethyl-1-α-D-ribofuranosylbenzimidazole
CHEMICAL FAMILY: B Vitamin
HOW SUPPLIED: 1000 μg/mL in 30 mL vials
FORMULA: $C_{62}H_{89}CoN_{13}O_{15}P$

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:	**WATSON PHARMACEUTICALS INC.**
U.S. ADDRESS:	400 Interpace Parkway Parsippany, NJ 07054, USA
U.S. BUSINESS PHONE/GENERAL MSDS INFORMATION:	1-800-272-5525
RESPONSIBLE PARTY EUROPE:	
EUROPEAN ADDRESS:	
e-mail: e-mail: SafetyDataSheets@Actavis.com	
EUROPEAN BUSINESS PHONE:	
EMERGENCY PHONE (U.S./NORTH AMERICA):	CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico
EMERGENCY PHONE (OUTSIDE U.S.):	CHEMTREC: +1-703-527-3887 (24 hours) Outside North America

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: November 5, 2004 **DATE OF REVISION:** February 13, 2013

2. HAZARD IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.
Classification: Not Applicable Signal Word: Not Applicable Hazard Statement Codes: Not Applicable

EU LABELING AND CLASSIFICATION 67/548/EEC: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.
Classification: Not Applicable Risk Phrases: Not Applicable Safety Phrases: Not Applicable

See Section 16 for full EU classification information of product and components and full text of hazard and precautionary statements.

EMERGENCY OVERVIEW:

EMERGENCY OVERVIEW:
Product Description: This product is a clear, red, odorless liquid.
Health Hazards: The chief health hazard associated with overexposures during normal use and handling is the potential for mild irritation of contaminated skin or eyes. Individuals who have had allergic reactions to prescription as well as to over-the-counter products containing Benzyl Alcohol or Hydroxocobalamine may experience allergic reactions to this product. Therapeutic use of Hydroxocobalamine can cause adverse symptoms on the skin and gastrointestinal system.
Flammability Hazards: When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, sodium oxides, and hydrogen chloride).
Reactivity Hazards: This product is not reactive.
Environmental Hazards: Large quantities released to the environment may have an adverse effect.
Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
Hydroxocobalamin	13422-51-0	236-533-2	0.1	SELF CLASSIFICATION EU 67/548 Classification: Harmful, Risk Phrases: R20, R22 Hazard Symbol:  EU/GHS 1272/2008 Signal word: Warning Classification: Acute Oral & Inhalation Toxicity, cat. 4; Hazard Statement Codes: H302, H332 Hazard Symbol/Pictogram: 
Benzyl Alcohol	100-51-6	202-859-9	1.5	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Sodium Chloride	7647-14-5	231-598-3	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Water	7732-18-5	231-791-2	Balance	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable

See Section 16 for full EU classification information of product and components.

4 FIRST-AID MEASURES

Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and MSDS to physician or health professional with the contaminated individual.

SKIN EXPOSURE: If adverse skin effects occur, discontinue use. Seek medical attention.

EYE EXPOSURE: If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 15 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

INHALATION: If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Remove or cover gross contamination to avoid exposure to rescuers.

INGESTION: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin conditions, Leber's disease, and folate deficiency may be aggravated by overexposures to this product.

RECOMMENDATIONS TO PHYSICIANS: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. In the event of an occupational overexposure, treat symptoms and eliminate overexposure.

5. FIRE-FIGHTING MEASURES

FLASH POINT (closed cup): Not flammable.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS (in air by volume, %):

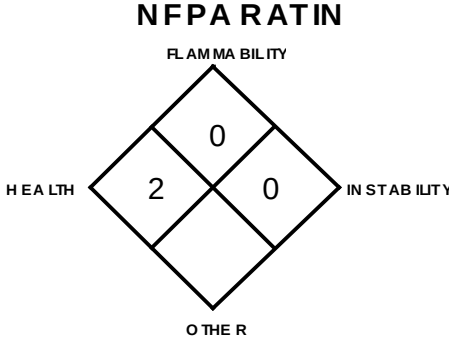
Lower (LEL): Not applicable.
Upper (UEL): Not applicable.

FIRE EXTINGUISHING MATERIALS: Use extinguishing media appropriate for surrounding fire.

Water Spray: OK Carbon Dioxide: OK
Foam: OK Dry Chemical: OK
Halon: OK Other: Any "ABC" Class

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product contains a known skin sensitizer, and so it presents a contact hazard to firefighters. At extremely high temperatures this product will decompose to produce irritating vapors and toxic gases (e.g., carbon oxides, sodium oxides, and hydrogen chloride).

Explosion Sensitivity to Mechanical Impact: Not sensitive.
Explosion Sensitivity to Static Discharge: Not sensitive.



Hazard Scale: **0** = Minimal **1** = Slight
2 = Moderate **3** = Serious **4** = Severe

5. FIRE-FIGHTING MEASURES (Continued)

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with soapy water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE: For small releases of this compound (1 vial), wear double latex or butyl rubber gloves and safety glasses. Clean up solution with a damp sponge, polypad, or other appropriate material for small spills and place in a bag and hold for waste disposal. Avoid producing sprays or mists of this product during cleanup. In case of a large spill, clear the affected area and protect people. Large or uncontrolled releases should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used, including double butyl rubber gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator in event of a large spill. Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of the EU and its member states or Canada and its Provinces.

7. HANDLING and USE

NOTE: Consistent with the OSHA Bloodborne Pathogen regulation (29 CFR 1910.1030), observe Universal Precautions while using this product. Place used or product-contaminated hypodermic needles and syringes in a rigid "Sharps" container. Do not recap or clip used or product-contaminated hypodermic needles.

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling Hydroxocobalamin. Wash hands thoroughly after handling Hydroxocobalamin or equipment and containers of this compound. Follow SPECIFIC USE INSTRUCTIONS supplied with compound. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Operations of high risk associated with the use of this product include:

- Manual manipulation (measuring, transferring, etc.) of reconstituted drug product; and
- Opening ampoules.

Use of this product should meet the following provisions:

- Work should be performed in a designated area for working with hazardous drugs or potent compounds;
- Containment devices, such as a Biological Safety Cabinet, Ventilated Enclosures should be used;
- Contaminated waste must be properly handled; and
- Work areas must be regularly decontaminated.

STORAGE AND HANDLING PRACTICES: Employees must be trained to properly use this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Operations associated with the use of this product include withdrawal of needles from drug vials, drug transfers using syringes and needles, and expulsion of air from drug-filled syringes. Use of this product should be performed in a designated area for working with drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated. Ensure vials are properly labeled. Store this product away from incompatible materials (see Section 10, Stability and Reactivity). Store this product in original container, at controlled room temperature of 15–30°C (59–86°F). Avoid freezing and excessive heat. Protect from light.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad. Collect all rinsates and dispose of according to applicable U.S. Federal, State, and local hazardous waste disposal regulations, those of Canada, those of the European Union, or those of European Union Member States. All needles, syringes, vials, and other disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

NOTE: Consistent with the OSHA Bloodborne Pathogen regulation (29 CFR 1910.1030), observe Universal Precautions while using this product. Place used or product-contaminated hypodermic needles and syringes in a rigid "Sharps" container. Do not recap or clip used or product-contaminated hypodermic needles.

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR									
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	AIHA WEELs		OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	TWA mg/m^3	STEL mg/m^3	$\mu g/m^3$
Hydroxocobalamin	13422-51-0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Benzyl Alcohol	100-51-6	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Sodium Chloride	7647-14-5	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established. See Section 16 for Definitions of Terms Used.

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: Currently there are no international exposure limits established for the components of this product.

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use of this product.

EYE PROTECTION: For situations in which excessive splashes or sprays may be generated, wear chemical splash goggles, or regular splash goggles.

HAND PROTECTION: For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff.

BODY PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: Not established.

FREEZING/MELTING POINT Not established.

EVAPORATION RATE (nBuAc = 1): Not established.

SOLUBILITY IN WATER: Slightly soluble.

VAPOR PRESSURE (air = 1): Not established.

SPECIFIC GRAVITY (water = 1): Not established.

ODOR THRESHOLD: Odorless.

pH: Not established.

COEFFICIENT WATER/OIL DISTRIBUTION: Not established.

APPEARANCE AND COLOR: This product is a clear, red, odorless liquid.

HOW TO DETECT THIS SUBSTANCE: The appearance and viscosity of this product is a distinguishing characteristic.

10. STABILITY and REACTIVITY

STABILITY: This product is stable when properly stored (see Section 7, Handling and Storage).

DECOMPOSITION PRODUCTS: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides, sodium oxides, and hydrogen chloride).

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to prescription as well as to over-the-counter products containing Benzyl Alcohol or Hydroxocobalamine may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following:

For Males and Females: Skin rash, itching, wheezing, diarrhea, itching exanthema, chills, fever, hot flushes, nausea, dizziness, anaphylaxis, acneiform and bullous eruptions, polycythemia vera, peripheral vascular thrombosis, transitory exanthema, feeling of swelling of entire body, pulmonary edema and congestive heart failure early in treatment, and death.

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. This product is designed to be administered via intramuscular injections. The following paragraphs describe the symptoms of exposure by route of exposure.

INHALATION: Inhalation of mist or sprays containing Hydroxocobalamin may mildly irritate the mucous membranes and upper respiratory tract. Symptoms of such overexposure can include coughing, sneezing, and a runny nose. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Skin contact may cause mild irritation, which is alleviated upon rinsing with soap and water. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). The Benzyl Alcohol component of this product is a weak skin sensitizer; prolonged or repeated skin contact may cause an allergic response (redness, rash, or swelling) to future exposures to Benzyl Alcohol. Eye contact with this product may cause transient irritation.

SKIN ABSORPTION: The Benzyl Alcohol component of this product can be absorbed through the skin. Skin absorption is not reported to contribute significantly to overall exposure.

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause nausea, vomiting, and symptoms described for “Other Potential Health Effects”.

11. TOXICOLOGICAL INFORMATION (Continued)

INJECTION: Depending on the dose of injection, this product may cause redness at the site of injection. Symptoms may include those described for "Other Potential Health Effects".

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: Employees administering the product should not experience adverse effects if handled properly. Adverse effects from therapeutic doses have included:

- Skin rash, itching, wheezing, and diarrhea.
- Sensitization to Hydroxocobalamin is rare but may manifest itself as itching exanthema, chills, fever, hot flushes, nausea, dizziness, and exceptionally, anaphylaxis. Acneiform and bullous eruptions have been reported rarely.
- Mild transient diarrhea, polycythemia vera, peripheral vascular thrombosis, itching, transitory exanthema, feeling of swelling of entire body, pulmonary edema and congestive heart failure early in treatment, anaphylactic shock, and death have been reported following vitamin B12 administration.
- Doses in excess of 10 micrograms daily may produce a haematological response in persons with folate deficiency.
- Persons who have early Leber's disease (hereditary optic nerve atrophy) have been found to suffer severe and swift optic atrophy when treated with vitamin B12.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
FLAMMABILITY HAZARD	(RED)	0
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate
3 = Serious **4** = Severe * = Chronic hazard

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Overexposure to this product may cause the following health effects:

ACUTE: Mild irritation of contaminated tissue is the primary health effect anticipated for occupational exposures to this product.

CHRONIC: Individuals who have had allergic reactions to prescription as well as to over-the-counter products containing Benzyl Alcohol or Hydroxocobalamine may experience allergic reactions to this product. See Section 11 (Toxicological Information) for additional information.

TARGET ORGANS: ACUTE: Industrial Exposure: Skin, eyes. Therapeutic Doses: Skin, eyes, gastrointestinal system. CHRONIC: Industrial Exposure: Skin. Therapeutic Doses: Skin, gastrointestinal system.

IRRITANCY OF PRODUCT: This product may mildly irritate contaminated tissue.

SENSITIZATION OF PRODUCT: The Benzyl Alcohol component of this product is a weak skin sensitizer; prolonged or repeated skin contact may cause an allergic response to future exposures to Benzyl Alcohol. Individuals who have had allergic reactions to prescription as well as to over-the-counter products containing Benzyl Alcohol or Hydroxocobalamine may experience allergic reactions to this product.

TOXICITY DATA: The following are toxicity data for the active component of this product, Hydroxocobalamin. This MSDS presents toxicity data currently available for the active component. Additional data are available for the other components of this product, but are not presented in this MSDS. Contact Watson Pharmaceuticals for more information.

HYDROXOCOBALAMIN:

LD_{50} (intravenous, mouse) > 50 mg/kg

SUSPECTED CANCER AGENT: The components of this product are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: Listed below is information concerning the effects Hydroxocobalamin on human and animal reproductive systems.

Mutagenicity: This product is not reported to be mutagenic to humans in therapeutic doses.

Embryotoxicity: This product is not reported to be embryotoxic to humans in therapeutic doses.

Teratogenicity: This product is not reported to be teratogenic to humans in therapeutic doses.

Reproductive Toxicity: This product is not reported to have reproductive effects in humans in therapeutic doses

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: Hydroxocobalamin will be relatively stable under ambient environmental conditions. There are data for the Benzyl Alcohol component, but these data are not presented in this MSDS.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated plant and animal life, especially in large quantities.

12. ECOLOGICAL INFORMATION (Continued)

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available on the effect of this product on aquatic plants or animals in the environment. Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities. There are no aquatic toxicity data currently available for the active component of this product. Aquatic toxicity data are available for the Benzyl Alcohol component of this product, but are not presented in this MSDS.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, with regulations of Canada, with regulations of the European Union, or with regulations of EU member states. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

14. TRANSPORTATION INFORMATION

THIS PRODUCT IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

PROPER SHIPPING NAME:	Not Regulated
HAZARD CLASS NUMBER and DESCRIPTION:	Not Applicable
UN IDENTIFICATION NUMBER:	Not Applicable
PACKING GROUP:	Not Applicable
DOT LABEL(S) REQUIRED:	Not Applicable

EMERGENCY RESPONSE GUIDEBOOK NUMBER (2000): Not Applicable

MARINE POLLUTANT: No component of this product is classified by the U.S. DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B).

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not considered as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not considered as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for any component of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The components of this product are not on the California Proposition 65 Lists.

OTHER U.S. FEDERAL REGULATIONS: Based on this compound's use, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) are applicable.

CANADIAN REGULATIONS:

CANADIAN DSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it excepted from requirements of the DSL/NDSL Inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN WHMIS CLASSIFICATION AND SYMBOL: Class D2A (Materials Causing Other Toxic Effects)

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY CAUSE SKIN AND EYE IRRITATION. MAY CAUSE ALLERGIC REACTION. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting-seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Material Safety Data Sheet for additional information.

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

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COMPONENT GLOBAL HARMONIZATION, EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION FULL TEXT:

Hydroxocobalamin:

Classification: Acute Oral Toxicity, cat. 4; Acute Inhalation Toxicity, cat. 4

Signal Word: Warning

Hazard Statements: H302, H332

Precautionary Statements: P280: Wear protective gloves/protective clothing/eye protection/face protection; P260: Do not breathe dust; P262: Do not get in eyes, on skin, or on clothing

Hazard Symbol/Pictograms: 

ALL OTHER COMPONENTS:

These components do not meet the criteria for classification of hazardous.

COMPONENT EU 67/548/EEC LABELING AND CLASSIFICATION FULL TEXT:

Hydroxocobalamin:

Hazard Classification: Harmful

Risk Phrases: R20, R22

Hazard Symbol: 

Safety Phrases: Keep out of reach of children. (*This safety phrase can be omitted from the label when the substance or preparation is sold for industrial use only.*) [S: 26] In case of contact with eyes, rinse immediately with water and seek medical advice.

ALL OTHER COMPONENTS:

EU Classification: An official classification for these substances has not been published in Commission Directives.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

REVISION DETAILS: Updated with GHS

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc.
PO Box 3519, La Mesa, CA 91944-3519
619/670-0609

DATE OF PRINTING: May 28, 2013