

PART I *What is the material and what do I need to know in an emergency?*

1. PRODUCT IDENTIFICATION

PRODUCT NAME (AS LABELED): DOXORUBICIN HYDROCHLORIDE FOR INJECTION

PRODUCT USE: Medical treatment of Leukemias and a Variety of Sarcomas, Lymphomas, and Carcinomas.

SUPPLIER/MANUFACTURER'S NAME: Sicor Pharmaceuticals, Inc.

ADDRESS: 19 Hughes
Irvine, CA 92618

CHEMTREC EMERGENCY NO.: 1-800-424-9300 (United States)**
1-202-483-7616 (International Collect)

BUSINESS PHONE: 1-800-729-9991

FAX: 1-949-855-8210

Common Names: Adriacin, Adriamycin Hydrochloride, Adriblastine

Chemical Name: Hydroxydaunorubicin Hydrochloride

Chemical Formula: C₂₇H₂₉NO₁₁•HCl

Chemical Family: Anthracycline Antibiotic

How Supplied: 2 mg/mL in 5, 25 and 100 mL vials.

DATE OF PREPARATION: March 20, 1998

2. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% by weight	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA		IDLH mg/m ³	OTHER mg/m ³
			TLV mg/m ³	STEL mg/m ³	PEL mg/m ³	STEL mg/m ³		
Doxorubicin Hydrochloride	25316-40-9	< 1	DOXORUBICIN HYDROCHLORIDE IS A CYTOTOXIC AGENT AND A POTENTIAL HUMAN CARCINOGEN. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.					
Sodium Chloride	7647-14-5	< 1	NE	NE	NE	NE	NE	NE
Water for injection	7732-18-5	Balance	NE	NE	NE	NE	NE	NE

NE = Not Established See Section 16 for definition of terms used.

NOTE: ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-1993 format.

**Chemtrec Number: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure, or accident involving this chemical.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: This product is a red, odorless solution. The primary health hazard associated with exposure to this product during an emergency response situation would be mild irritation of contaminated skin or eyes. Under certain circumstances of exposure, allergic reactions, nausea, vomiting, and other adverse effects may also occur. Doxorubicin Hydrochloride may reasonably be anticipated to be a carcinogen. This product is not flammable or reactive. Emergency responders must wear personal protective equipment appropriate to the situation to which they are responding.

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: This material is a powerful cytotoxic and antineoplastic agent. Doxorubicin Hydrochloride is generally intended for intravenous injection under the supervision of physicians experienced in cancer chemotherapy. The potential health effects of this product are as follows:

INHALATION: Inhalation of this product is not anticipated to be a significant route of overexposure. Inhalation of this product may cause symptoms as described in "Injection", depending on the dose upon exposure.

CONTACT WITH SKIN or EYES: Contact of this product with the skin may cause mild irritation. Contact of this product with the eyes may cause mild to moderate irritation, redness, and tearing.

SKIN ABSORPTION: Direct skin absorption is not reported to be a significant route of overexposure for any component of this product.

INGESTION: Ingestion is not anticipated to be a likely route of occupational exposure. If this product is swallowed it may cause gastrointestinal distress, nausea and vomiting. Symptoms such as those described for "Injection" may occur; however, non-predictable absorption by mouth and the gastrointestinal tract may lead to confused symptoms.



INJECTION: Accidental injection of this product, via laceration or puncture by a contaminated object, may be harmful, depending on dose. If injected in doses similar to those associated with chemotherapy, the following health effects may be observed: acute nausea, vomiting, damage to the heart tissue, depression of bone marrow cell production, effects on the kidneys, pulmonary edema, loss of hair, hyperpigmentation of nails and skin, phlebosclerosis (thickening of wall veins), facial flushing, cellulitis (inflammation of soft connective tissue), vesication (blistering of tissue), local tissue necrosis, gastrointestinal ulceration, loss of appetite, diarrhea, fever, chills, and allergic reactions (rashes, coughing, breathing difficulty and anaphylaxis).

HEALTH EFFECTS OR RISKS FROM EXPOSURE (An explanation in lay terms).

ACUTE: The primary health effects that may be experienced by medical personnel exposed to this product are mild irritation of contaminated skin and eyes, or pain, redness and local swelling after accidental injection. In the event of exposures via injection to therapeutic doses of this product, damage to the heart tissue, depression of bone marrow cell production, damage to the colon, bladder effects (pain, bleeding, diminished capacity) loss of hair, swelling of the tissues of the esophagus and stomach, gastrointestinal ulceration, loss of appetite, diarrhea, fever, and chills. Death may occur in the event of an accidental over-dose.

CHRONIC: Chronic exposure in therapeutic doses can result in heart damage. Doxorubicin Hydrochloride may reasonably be anticipated to be a carcinogen. Reproductive studies in rats and rabbits indicated some effects on the reproductive system. Other chronic effects include hypersensitization and changes in skin pigmentation. See Section 11 (Toxicological Information) for further information.

TARGET ORGANS: Skin, eyes (anticipated occupational exposures). Heart tissue, bone marrow, colon, bladder, kidneys (therapeutic doses).

HAZARDOUS MATERIAL INFORMATION SYSTEM			
HEALTH		(BLUE)	3
FLAMMABILITY		(RED)	0
REACTIVITY		(YELLOW)	0
PROTECTIVE EQUIPMENT			X
EYES	RESPIRATORY	HANDS	BODY
	See Section 8		See Section 8
For medical treatment of viral infections			

See Section 16 for Definition of Ratings

PART II *What should I do if a hazardous situation occurs?*

4. FIRST-AID MEASURES

PERSONS ACCIDENTALLY EXPOSED TO DOXORUBICIN HYDROCHLORIDE MUST RECEIVE PROMPT MEDICAL ATTENTION!

SKIN EXPOSURE: If this product contaminates the skin, immediately begin decontamination with warm, running water. Minimum flushing is for 15 minutes. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Victim must seek medical attention, especially if any adverse effect occurs.

EYE EXPOSURE: If sprays, splashes or mists of this product enter the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 15 minutes. Victim must seek medical attention.

INHALATION: If sprays, splashes or mists of this product are inhaled, 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 the product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, **DO NOT** induce vomiting. Victim should drink milk, egg whites, or large quantities of water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

Victims of chemical exposure must be taken for medical attention. Rescuers should be taken for medical attention, if they have been overexposed to this product. Take copy of label and MSDS to physician or health professional with victim.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not applicable.

AUTOIGNITION TEMPERATURE: Not applicable.

FLAMMABLE LIMITS (in air by volume, %): Lower: Not applicable.
Upper: Not applicable.

FIRE EXTINGUISHING EQUIPMENT:

<u>Water Spray:</u> YES	<u>Carbon Dioxide:</u> YES
<u>Foam:</u> YES	<u>Dry Chemical:</u> YES
<u>Halon:</u> YES	<u>Other:</u> Any "ABC" Class

UNUSUAL FIRE and EXPLOSION HAZARDS: When heated to decomposition, this product may emit toxic vapors containing hydrochloric acid, oxides of nitrogen and carbon monoxide.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

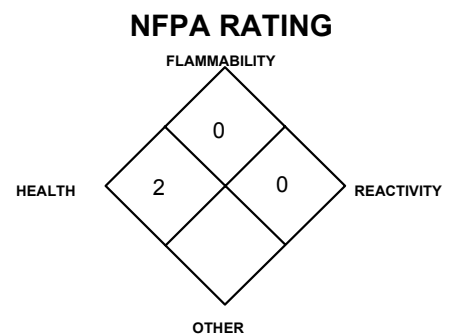
Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL FIRE-FIGHTING PROCEDURES: Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. . Move fire-exposed containers if it can be done without risk to firefighters. If protective equipment is contaminated by this product, it should be thoroughly washed with running 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. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water before being returned to service. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

6. ACCIDENTAL RELEASE MEASURES

SPILL and LEAK RESPONSE: For small releases of this product (1 vial) wear double latex or nitrile gloves, full body gown, and safety glasses. Large or uncontrolled releases should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used, including double latex or nitrile 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 case of a spill, clear the affected area, protect people, and respond with trained personnel. Clean up spilled solid with a damp sponge, polypad, or other appropriate materials. Avoid generating airborne dusts of this product. Decontaminate the area of the spill thoroughly by using bleach or detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with U.S. Federal, State, and local or Canadian waste disposal regulations.



See Section 16 for Definition of Ratings

PART III *How can I prevent hazardous situations from occurring?*

7. HANDLING and STORAGE

WORK and HYGIENE PRACTICES: **DOXORUBICIN HYDROCHLORIDE IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.** As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat or drink while handling this product. Wash thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with 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 of high risk associated with the use of this product include:

- Withdrawal of needles from drug vials;
- Drug transfers using syringes and needles or filter straws;
- Opening ampoules; and
- Expulsion of air from drug-filled syringes.

DO NOT CLIP OR CRUSH NEEDLE WITH WHICH THIS PRODUCT WAS IN CONTACT. Use of this product should meet the following provisions:

- Work should be performed in a designated area for working with hazardous drugs;
- Containment devices, such as a Biological Safety Cabinet, 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. Ensure vials are properly labeled. Store this product away from incompatible materials (see Section 10, Stability and Reactivity). Refrigerate this product in original container at 2–8°C (36–46°F). Protect from light.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials, and other disposable items contaminated with this product should be disposed of properly. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean-up of equipment.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION and ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. Admixtures or manipulations of this drug should be carried out in a cytotoxic drug safety cabinet. The cabinet should be regularly cleaned following the manufacturer's recommendations, but no less frequently than weekly. All surfaces should be thoroughly washed with water and detergent and triple rinsed. During decontamination, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS for the clean up of a large spill. HEPA filters on the cytotoxic drug safety cabinet should be changed every six months. The safety cabinet should be tested and certified as recommended by the National Sanitation Foundation in Standard Number 49.

RESPIRATORY PROTECTION: A full-face respirator with a HEPA filter should be used until a Biological Safety Cabinet is installed. A respirator is not required for routine conditions of use with a Biological Safety Cabinet.

EYE PROTECTION: Chemical splash goggles, or regular splash goggles, with a full face-shield.

HAND PROTECTION: 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: A full body gown which is closed at the front and has long sleeves. The gown should be made of Tyvek^(TM), PE-Coated Tyvek^(TM), or SARANEX^(TM).

Product Preparation Instructions for Medical Personnel: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

9. PHYSICAL and CHEMICAL PROPERTIES

RELATIVE VAPOR DENSITY (air = 1): > 1

SPECIFIC GRAVITY: Approximately 1

SOLUBILITY IN WATER: Soluble.

EVAPORATION RATE (n-BuAc=1): > 1

MELTING/FREEZING POINT: Not determined.

BOILING POINT: 100-105°C (212-221°F)

9. PHYSICAL and CHEMICAL PROPERTIES (Continued)

VAPOR PRESSURE, mm Hg @ 25°C: 18.

pH: 2.5-4.5

ODOR THRESHOLD: Odorless.

COEFFICIENT OF OIL/WATER DISTRIBUTION (Partition Coefficient): Not determined.

APPEARANCE and COLOR: This is a red solution, which is packaged in vials.

HOW TO DETECT THIS SUBSTANCE (warning properties): The color of this product may be a distinguishing characteristic.

10. STABILITY and REACTIVITY

STABILITY: Stable when stored under ambient conditions up to the shelf-life of the product when stored properly [see Section 7 (Storage and Handling)]. The recommended storage temperature is 2-8°C (36-46°F).

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Strong oxidizers, strong bases, water reactive chemicals, and other compounds that could affect its performance should be avoided.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Heat may cause this product to decompose, destroy the product, and produce irritating vapors and toxic gases. Avoid contact with heat and incompatible chemicals.

PART IV *Is there any other useful information about this material?*

11. TOXICOLOGICAL INFORMATION

TOXICITY DATA: The following toxicological data are available for Doxorubicin Hydrochloride, the active ingredient of this product.

DNA Inhibition-Mouse: leukocyte 1500 nmol/L

oms-Mouse: leukocyte 580 nmol/L

DNA Inhibition-Chicken, adult: embryo 900 nmol/L

Intraperitoneal-Rat TDLo: 6 mg/kg (male 2 weeks pre): Reproductive effects

Intravenous-Monkey TDLo: 27 mg/kg/2 years - Intermittent: Equivocal tumorigenic agent

Intravenous-Man LDLo :2571 µg/kg/3 weeks - Intermittent; kidney effects

Intravenous-Man TDLo: 12 mg/kg/26 weeks - Intermittent: Cardiovascular effects, Pulmonary system effects

Intraperitoneal-Rat LD₅₀: 16,030 µg/kg

Subcutaneous-Rat LD₅₀: 21,800 µg/kg

Intravenous-Rat LD₅₀: 13,100 mg/kg

Intramuscular-Rat LD₅₀: 16 mg/kg

Oral-Mouse LD₅₀: 698 mg/kg

Intraperitoneal-Mouse LD₅₀: 11,160 µg/kg

Subcutaneous-Mouse LD₅₀: 7678 µg/kg

Intravenous-Mouse LD₅₀: 1245 µg/kg

Intramuscular-Mouse LD₅₀: 13,700 µg/kg

Intravenous-Rabbit, adult LD₅₀: 6 mg/kg

Intravenous - rabbit LD₅₀: 5980 µg/

Inhalation - rat TDLo: 12 mg/kg/6 weeks Intermittent; Cardiac and Biochemical Effects

Intraperitoneal - rat TDLo: 60 mg/kg/30 days - Continuous; Liver, Endocrine, Blood

Intraperitoneal - rat TDLo: 18900 µg/kg/21 days Intermittent; Biochemical Effects

Intraperitoneal - rat TDLo: 6300 µg/kg/3 days Intermittent; Biochemical Effects

Intraperitoneal - rat TDLo: 38 mg/kg/14 weeks Intermittent; Cardiac, Endocrine, Blood Effects

Intravenous - rat TDLo: 12480 µg/kg/13 weeks Intermittent: Cardiac, Endocrine, Biochemical Effects

Intravenous - rat TDLo: 15 mg/kg/5 weeks Intermittent Cardiac, Nutritional and Gross Metabolic Effects

Intravenous - rat TDLo: 9 mg/kg/3 weeks Intermittent Cardiac, Endocrine, Biochemical Effects/ Reproductive - Tumorigenic Effects

Intravenous - rat TDLo: 22400 µg/kg/4 weeks Intermittent: Kidney, Ureter, Bladder, Blood Effects

Inhalation - mouse TDLo: 40 mg/kg/7 weeks Intermittent; Cardiac, Nutritional and Gross Metabolic Effects

Intravenous - dog TDLo: 15600 µg/kg/13 weeks Intermittent; Blood and Biochemical Effects

Intravenous - rabbit TDLo: 18 mg/kg/30 days Continuous; Endocrine, Blood Reproductive - Tumorigenic effects

Intravenous - monkey TDLo: 27 mg/kg/2 years - Intermittent; Equivocal Tumorigenic Agent

Subcutaneous - mouse TDLo: 4500 µg/kg: male 5 week(s) pre-mating; Reproductive - Paternal Effects - spermatogenesis

Intraperitoneal - rabbit: 30 mg/kg: male 30 day(s) pre-mating Reproductive - Paternal Effects

Intraperitoneal - rabbit TDLo: 60 mg/kg: female 30 day(s) pre-mating; Reproductive - Maternal Effects

Intravenous - rabbit TDLo: 18 mg/kg: male 30 day(s) pre-mating; Reproductive - Paternal Effects

Intravenous - rabbit: 600 µg/kg: female 30 day(s) pre-mating; Reproductive - Maternal Effects

Mutation in microorganisms: Bacteria - Salmonella typhimurium: 700 ng/plate

Bacteria - Escherichia coli: 1250 ng/plate

Phage inhibition capacity: Bacteria - Escherichia coli: 350 µg/L

Specific locus test: Oral - Drosophila melanogaster: 1 mg/L

Specific locus test: Oral - Drosophila melanogaster: 500 ppm

Micronucleus test Testis: 2 umol/L

Cytogenetic analysis Testis: 2 umol/L

Cytogenetic analysis: Non-mammalian species Cells - not otherwise specified: 200 nmol/L

Sex chromosome loss and non-disjunction - Testis: 2 umol/L

Sex chromosome loss and non-disjunction: Non-mammalian species Cells - not otherwise specified: 200 nmol/L

DNA damage Human Cells - not otherwise specified : 1 umol/L

DNA inhibition: Human Cells - not otherwise specified: 400 nmol/L

Mutation test systems - not otherwise specified: Human Cells - not otherwise specified: 300 nmol/L

Body fluid assay: Human Bacteria - Salmonella typhimurium: 714 µg/kg

Sister chromatid exchange: Human Lymphocyte: 100 nmol/L

DNA damage - rat Liver: 300 nmol/L

DNA damage - mouse Leukocyte: 1 umol/L

DNA inhibition - mouse Leukocyte: 1500 nmol/L

Mutation test systems - not otherwise specified - mouse Leukocyte: 580 nmol/L

DNA inhibition: Intraperitoneal - mouse: 15 mg/kg

Mutation test systems - not otherwise specified - Intraperitoneal - mouse: 15 mg/kg

DNA damage - hamster Lung: 1500 µg/L

Cytogenetic analysis - hamster Lung: 5 µg/

Cytogenetic analysis - hamster: 1 umol/L;

DNA inhibition: chicken Embryo: 900 nmol/L

11. TOXICOLOGICAL INFORMATION (Continued)

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

NOTE: Formal long-term carcinogenicity studies have not been conducted for Doxorubicin Hydrochloride. This substance has been shown to have mutagenic and carcinogenic properties in experimental models (including bacterial systems, mammalian cells in culture, and female Sprague-Dawley rats).

IRRITANCY OF PRODUCT: This product can be mildly irritating to contaminated tissue, especially upon prolonged or repeated exposure.

SENSITIZATION TO THE PRODUCT: This product can cause allergic reactions, including rashes, coughing, breathing difficulty and anaphylaxis in sensitive individuals.

REPRODUCTIVE TOXICITY INFORMATION: Doxorubicin Hydrochloride has rating of Pregnancy Category D (Positive Evidence of Risk) and is a potential reproductive toxin, based on animal data. Listed below is information concerning the effects of Doxorubicin Hydrochloride, the active ingredient on this product, on the human reproductive system.

Mutagenicity: Doxorubicin Hydrochloride has been shown to have mutagenic properties in experimental models (including bacterial systems, mammalian cells in culture, and female Sprague-Dawley rats).

Embryotoxicity: This product is embryotoxic in rats and rabbits. Refer to "Teratogenicity" for additional data.

Teratogenicity: Doxorubicin Hydrochloride is teratogenic in rats. Doxorubicin Hydrochloride is an abortifacient in rabbits.

Reproductive Toxicity: The possible adverse effect on fertility in males and females in humans or experimental animals has not been adequately evaluated. Testicular atrophy was observed in rats and dogs.

A mutagen is a chemical which causes permanent changes to genetic material (DNA) such that the changes will propagate through generational lines. An embryotoxin is a chemical which causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical which causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance which interferes in any way with the reproductive process.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently there are no ACGIH Biological Exposure Indices (BEIs) associated with this compound.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin conditions, gastrointestinal disorders, kidney, bone marrow disorders may be aggravated by exposure to this product, depending on dose and route of exposure.

RECOMMENDATIONS TO PHYSICIANS: Doxorubicin Hydrochloride is a potent cytotoxic antineoplastic drug. It should only be administered under the supervision of physicians experienced in cancer chemotherapy. Employees should receive routine medical surveillance before job placement, periodically (especially following acute exposures) and the termination of job or transfer. If necessary, cardiac evaluations, blood tests, and kidney/liver function tests should be conducted.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: It is anticipated that this compound will decompose into a variety of organic compounds.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: This product may be harmful or fatal to contaminated plant and animal life. Refer to Section 11 (Toxicological Information) for additional information on this product's components and their effects on test animals.

EFFECT OF CHEMICAL ON AQUATIC LIFE: This product may be harmful or fatal to aquatic plant and animal life in contaminated bodies of water, especially if released in large quantities.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada and its Provinces. 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. Incineration is recommended for the product and disposable equipment. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable.

14. TRANSPORTATION INFORMATION

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

PROPER SHIPPING NAME: Not applicable.
HAZARD CLASS NUMBER and DESCRIPTION: Not applicable.
UN IDENTIFICATION NUMBER: Not applicable.
PACKING GROUP: Not applicable.
DOT LABEL(S) REQUIRED: Not applicable.
NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (1996): Not applicable.
MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B).
TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: THIS MATERIAL IS NOT CONSIDERED AS DANGEROUS GOODS.

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: This product is 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: Not applicable.

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

U.S. TSCA INVENTORY STATUS: This product is regulated by the Food and Drug Administration; it is exempt from the requirements of TSCA.

OTHER U.S. FEDERAL REGULATIONS: Based on this product's use as an injectable, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) are applicable. Employers should refer to OSHA Technical Instructions, TED 1.15, when employees are working with hazardous drugs.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): This product is not on the California Proposition 65 lists.

U.S. STATE REGULATORY INFORMATION: This product is not covered under the following specific State regulations (NONE indicates no special regulations were noted).

Alaska - Designated Toxic and Hazardous Substances: None.

California - Permissible Exposure Limits for Chemical Contaminants: None.

Florida - Substance List: None.

Illinois - Toxic Substance List: None.

Kansas - Section 302/313 List: None.

Massachusetts - Substance List: None.

Michigan - Critical Materials Register: None.

Minnesota - List of Hazardous Substances:

Missouri - Employer Information/Toxic

Substance List: None.

New Jersey - Right to Know Hazardous

Substance List: None.

North Dakota - List of Hazardous Chemicals,

Reportable Quantities: None.

Pennsylvania - Hazardous Substance List: None.

Rhode Island - Hazardous Substance List: None.

Texas - Hazardous Substance List: None.

West Virginia - Hazardous Substance List:

None.

Wisconsin - Toxic and Hazardous Substances: None.

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): **DANGER!** CYTOTOXIC AGENT. ACCIDENTAL INJECTION CAN BE FATAL. MAY BE HARMFUL IF SWALLOWED. CAN CAUSE DAMAGE TO THE HEART, LIVER, KIDNEYS AND BONE MARROW. MAY CAUSE SKIN IRRITATION. Doxorubicin Hydrochloride should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Avoid accidental injection. Avoid accidental ingestion. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Use in well-ventilated area. Use gloves, safety glasses, and appropriate respiratory and body protection. **FIRST-AID:** In case of skin or eye contact, flush with water for 15 minutes. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If ingested, do not induce vomiting. Get medical attention. **IN CASE OF FIRE:** Use water fog, dry chemical, CO₂, or "alcohol" foam. **IN CASE OF SPILL:** Absorb material with damp sponge and then place in a suitable container. Rinse area with water. Consult Material Safety Data Sheet before use.

In addition to standard pharmacy labeling practices, all syringes and IV bags containing this product should be labeled as follows:

SPECIAL HANDLING AND DISPOSAL REQUIRED

15. REGULATORY INFORMATION (Continued)

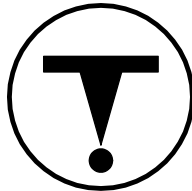
ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL/NDSL STATUS: This product is regulated by the Food and Drug Administration of Health Canada; it is exempt from the requirements of CEPA.

OTHER CANADIAN REGULATIONS: Not applicable.

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

CANADIAN WHMIS SYMBOLS: **Class D2A/B** Materials Causing Other Toxic Effects



16. OTHER INFORMATION

PREPARED BY:

CHEMICAL SAFETY ASSOCIATES, Inc.
9163 Chesapeake Drive, San Diego, CA 92123-1002
(619) 565 - 0302

DEFINITIONS OF TERMS

A large number of abbreviations and acronyms appear on a MSDS. Some of these which are commonly used include the following:

CAS #: This is the Chemical Abstract Service Number which uniquely identifies each constituent. It is used for computer-related searching.

EXPOSURE LIMITS IN AIR:

ACGIH - American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

TLV - Threshold Limit Value - an airborne concentration of a substance which represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour **Time Weighted Average (TWA)**, the 15-minute **Short Term Exposure Limit**, and the instantaneous **Ceiling Level**. Skin absorption effects must also be considered.

OSHA - U.S. Occupational Safety and Health Administration.

PEL - Permissible Exposure Limit - This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL," is placed next to the PEL which was vacated by Court Order.

IDLH - Immediately Dangerous to Life and Health - This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury. **The DFG - MAK** is the Republic of Germany's Maximum Exposure Level, similar to the U.S. PEL. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (**OSHA**). NIOSH issues exposure guidelines called **Recommended Exposure Levels (RELs)**. When no exposure guidelines are established, an entry of **NE** is made for reference.

HAZARD RATINGS:

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM: Health

Hazard: **0** (minimal acute or chronic exposure hazard); **1** (slight acute or chronic exposure hazard); **2** (moderate acute or significant chronic exposure hazard); **3** (severe acute exposure hazard; onetime overexposure can result in permanent injury and may be fatal); **4** (extreme acute exposure hazard; onetime overexposure can be fatal). Flammability Hazard: **0** (minimal hazard); **1** (materials that require substantial pre-heating before burning); **2** (combustible liquid or solids; liquids with a flash point of 38-93°C [100-200°F]); **3** (Class IB and IC flammable liquids with flash points below 38°C [100°F]); **4** (Class IA flammable liquids with flash points below 23°C [73°F] and boiling points below 38°C [100°F]. Reactivity Hazard: **0** (normally stable); **1** (material that can become unstable at elevated temperatures or which can react slightly with water); **2** (materials that are unstable but do not detonate or which can react violently with water); **3** (materials that can detonate when initiated or which can react explosively with water); **4** (materials that can detonate at normal temperatures or pressures).

NATIONAL FIRE PROTECTION ASSOCIATION: Health Hazard: **0** (material that on exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials); **1** (materials that on exposure under fire conditions could cause irritation or minor residual injury); **2** (materials that on intense or continued exposure under fire conditions could cause temporary incapacitation or possible residual injury); **3** (materials that can on short exposure could cause serious temporary or residual injury); **4** (materials that under very short exposure could cause death or major residual injury). Flammability Hazard and Reactivity Hazard: Refer to definitions for "Hazardous Materials Identification System".

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the **National Fire Protection Association (NFPA)**. Flash Point - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air. Autoignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD₅₀** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC₅₀** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m³** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include **TDLo**, the lowest dose to cause a symptom and **TCLo** the lowest concentration to cause a symptom; **TDo**, **LDLo**, and **LDo**, or **TC**, **TCo**, **LCLo**, and **LCo**, the lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** The sources are: **IARC** - the International Agency for Research on Cancer; **NTP** - the National Toxicology Program, **RTECS** - the Registry of Toxic Effects of Chemical Substances, **OSHA** and **CAL/OSHA**. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** **BEI** - ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV. **Ecological Information:** EC is the effect concentration in water. **BCF** = Bioconcentration Factor, which is used to determine if a substance will concentrate in lifeforms which consume contaminated plant or animal matter. Coefficient of Oil/Water Distribution is represented by **log K_{ow}** or **log K_{oc}** and is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

This section explains the impact of various laws and regulations on the material. **U.S.:** **EPA** is the U.S. Environmental Protection Agency. **DOT** is the U.S. Department of Transportation. **SARA** is the Superfund Amendments and Reauthorization Act. **TSCA** is the U.S. Toxic Substance Control Act. **CERCLA (or Superfund)** refers to the Comprehensive Environmental Response, Compensation, and Liability Act. Labeling is per the American National Standards Institute (**ANSI Z129.1**). **CANADA:** **CEPA** is the Canadian Environmental Protection Act. **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **TC** is Transport Canada. **DSL/NDSL** are the Canadian Domestic/Non-Domestic Substances Lists.