MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI and Canadian WHMIS Standards

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

1. PRODUCT IDENTIFICATION

TRADE NAME (AS LABELED):	**CYTOVENE® IV (500 MG/VIAL)**
CHEMICAL NAME:	For Active Ingredient: 9-[[2-Hydroxy-1-(hydroxymethyl)-ethoxy]methyl]guanine, Monosodium Salt
COMMON NAME:	For Active Ingredient: Ganciclovir Sodium
CHEMICAL FORMULA:	For Active Ingredient: $C_9H_{12}N_5NaO_4$
PRODUCT CODES:	46-2903-48
PRODUCT USE:	Cytomegalovirus Anti-viral
HOW SUPPLIED:	500 mg White to Off-white Lyophilized Powder
SUPPLIER/DISTRIBUTOR'S NAME:	**Hoffmann-La Roche Inc.**
ADDRESS:	340 Kingsland Street Nutley, NJ 07110-1199
EMERGENCY PHONE:	1-800-827-6243
INFORMATION NUMBER:	1-800-526-0189

2. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	%w/w	EXPOSURE LIMITS IN AIR					
			ACGIH-TLV		OSHA-PEL		NIOSH	OTHER
			TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Ganciclovir Sodium	84245-13-6	100	NE	NE	NE	NE	NE	Roche IOEL = 0.005

IN ANIMAL AND *IN VITRO* STUDIES GANCICLOVIR SODIUM (THE ACTIVE COMPONENT OF THIS PRODUCT) CAUSED ASPERMATOGENESIS, MUTAGENICITY, TERATOGENICITY AND CARCINOGENICITY; THEREFORE, IT SHOULD BE CONSIDERED A POTENTIAL TERATOGEN AND CARCINOGEN IN HUMANS. IT MAY CAUSE BIRTH DEFECTS AND/OR DEATH TO THE EXPOSED FETUS. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.

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

NOTE: ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-1998 format. This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: This product is a white to off-white lyophilized powder. The chief health hazard in an occupational setting in event of exposure is the potential for mild irritation of contaminated skin or eyes. In animal and *in vitro* studies Ganciclovir Sodium (the active component of this product) caused aspermatogenesis, mutagenicity, teratogenicity and carcinogenicity; therefore, it should be considered a potential teratogen and carcinogen in humans. This product must be substantially pre-heated before ignition can occur. If this product is ignited, the decomposition products generated will include irritating vapors and toxic gases (e.g., carbon oxides, nitrogen oxides, and sodium oxides). This product presents no significant reactivity hazards. Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The extent of entry into the body by most routes has not been fully investigated. Occupational exposures to this product may cause acute effects in humans, as described on the following page.

INHALATION: Inhalation of airborne dusts of this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Skin contact may cause mild irritation, which is alleviated upon rinsing. Eye contact with airborne dusts of this product may cause mild to moderate irritation, redness, and tearing.

SKIN ABSORPTION: The components of this product are not known to be absorbed through intact skin.

INGESTION: Ingestion is not anticipated to be a significant route of accidental exposure for this product. If this product is swallowed, it can cause effects as described in “Other Potential Health Effects”.

3. HAZARD IDENTIFICATION (Continued)

INJECTION: Accidental injection of this product can cause effects as described in "Other Potential Health Effects".

OTHER POTENTIAL HEALTH EFFECTS: Cytovene is a pharmacological product used for the treatment of cytomegalovirus retinitis in immunocompromised patients. The most common dose-dependent adverse effects associated with therapeutic treatments include decrease in the number of neutrophils in the blood, decrease in the number of platelets in the blood, and elevated serum creatinine levels. Less common side effects include enlarged abdomen, weakness, chest pain, swelling, headache, fatigue, pain, abnormal liver function test, canker sores in the mouth, constipation, indigestion, pancytopenia, increased cough, difficulty breathing, abnormal dreams, anxiety, confusion, depression, dizziness, dry mouth, insomnia, seizures, sleepiness, tremor, hair loss, dry skin, abnormal vision, abnormal taste, ringing in the ears, weight loss, increased SGOT, increased SGPT, high blood pressure, kidney failure, abnormal kidney function, increased urination, joint pain, leg cramps, muscle pain, muscle weakness, gastrointestinal perforation, multiple organ failure, pancreatitis, and sepsis. In animal and *in vitro* studies Ganciclovir Sodium (the active component of this product)caused aspermatogenesis, mutagenicity, teratogenicity and carcinogenicity; therefore, it should be considered a potential teratogen and carcinogen in humans.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in **Lay Terms**.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2
FLAMMABILITY HAZARD	(RED)	1
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Use and Handling Applications

See Section 16 for Definition of Ratings

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, and redness. In the event of exposures via ingestion and injection of therapeutic doses of this product, effects described in "Other Potential Health Effects" may result.

CHRONIC: In animal and *in vitro* studies Ganciclovir Sodium (the active component of this product) caused aspermatogenesis, mutagenicity, teratogenicity and carcinogenicity; therefore, it should be considered a potential teratogen and carcinogen in humans. Refer to Section 11 (Toxicological Information) for additional information on this product.

TARGET ORGANS: Skin, eyes (anticipated occupational exposures). Blood system (therapeutic doses).

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

4. FIRST-AID MEASURES

Victims of chemical exposure must be taken for medical attention. Rescuers should be taken for medical attention if necessary. Take a copy of label and MSDS to physician or health professional with victim.

SKIN EXPOSURE: Use of basic hygiene should prevent any problems. If the product contaminates the skin, immediately begin decontamination with running water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. The minimum recommended flushing time is 15 minutes. Victims must seek immediate medical attention, especially if an adverse reaction occurs.

EYE EXPOSURE: If airborne dusts generated by opened or damaged capsules 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. The contaminated individual must seek immediate medical attention after flushing if any adverse effect occurs.

INHALATION: If airborne dusts generated by opened or damaged capsules of this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

INGESTION: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. DO NOT INDUCE VOMITING, unless directed by medical personnel. If conscious, have victim rinse mouth with water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

INJECTION: Not a route of exposure due to method of administration.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing blood system conditions and other disorders involving the Target Organs of this product (see Section 3, Hazard Information) may be aggravated by exposures to this product (especially in doses approaching therapeutic levels for this product).

4. FIRST-AID MEASURES (Continued)

RECOMMENDATIONS TO PHYSICIANS: Treat symptoms and eliminate overexposure. Consult the Package Insert for additional information that can assist with treatment of overexposure.

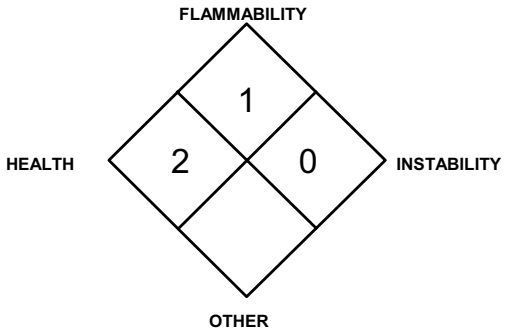
5. FIRE-FIGHTING MEASURES

FLASH POINT: Not applicable.
AUTOIGNITION TEMPERATURE: Not applicable.
FLAMMABLE LIMITS (in air by volume, %):
Lower (LEL): Not applicable.
Upper (UEL): Not applicable.

FIRE EXTINGUISHING MATERIALS: In the event of a fire, use suppression methods for surrounding materials.

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

NFPA RATING



See Section 16 for Definition of Ratings

UNUSUAL FIRE AND EXPLOSION HAZARDS: In animal and in vitro studies Ganciclovir Sodium (the active component of this product)caused aspermatogenesis, mutagenicity, teratogenicity and carcinogenicity; therefore, it should be considered a potential teratogen and carcinogen in humans. This product must be substantially pre-heated before ignition can occur. When involved in a fire, this product may decompose and produce irritating fumes and toxic gases (including carbon oxides, nitrogen oxides, and sodium oxides).

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

SPECIAL FIRE-FIGHTING PROCEDURES: Move containers from fire area if it can be done without risk to personnel. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Chemical resistant clothing may be necessary. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if any adverse effect occurs. 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), take basic hygiene precautions. Lightweight gloves, a lab coat, and eye protection should be worn. Sweep up spilled powder or absorb spilled liquid with paper towels or damp sponge. Wash contaminated area with soap and water, absorb with paper towels, and rinse with water. Trained personnel using pre-planned procedures should respond to large releases that are not immediately controlled. Proper protective equipment should be used. In case of a non-incidental spill, clear the affected area and protect people. Minimum Personal Protective Equipment should be **Level D: lab-gloves, chemical resistant apron, boots, and splash goggles. Respiratory protection should not be necessary.** Sweep up spilled powder or absorb spilled liquid with polypads or other suitable absorbent materials. Decontaminate the area thoroughly. Place all spill residue in a suitable container and seal. Dispose of in accordance with U.S. Federal, State, and local hazardous waste disposal regulations and those of Canada and its Provinces (see Section 13, Disposal Considerations).

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

7. HANDLING and STORAGE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Avoid generating airborne dusts of this product. Do not eat or drink while administering or handling the product to patients. Follow SPECIFIC USE INSTRUCTIONS supplied with product. Particular care in working with this product must be practiced in pharmacies and other preparation areas and during manufacture of this product. Use of this product should meet the following provisions.

- Work should be performed in an appropriate, designated area;
- Contaminated waste must be properly handled; and,
- If necessary, work areas must be regularly decontaminated.

STORAGE AND HANDLING PRACTICES: All employees who handle this material should be trained to handle it safely. Contaminated waste must be properly handled. Work areas must be regularly decontaminated. Ensure

containers of this product are properly labeled. (continued on following page)

7. HANDLING and STORAGE (Continued)

STORAGE AND HANDLING PRACTICES (continued): Open containers slowly on a stable surface. Store vials as directed in the product insert. Keep vials tightly closed when not in use. Store away from incompatible materials. Store containers below 40°C (104°F). Protect from light. Inspect vials containing this product for leaks or damage. Read instructions provided with the product prior to use.

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, follow practices indicated in Section 6 (Accidental Release Measures). Make certain that application equipment is locked and tagged-out safely as applicable. Collect all rinsates and dispose of according to applicable Federal, State, or local procedures. All needles, syringes, vials, and other disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. Technicians should be aware of the risks associated with this drug via training and should use the same equipment recommended in Section 6 (Accidental Release Measures). Ensure eyewash/safety shower stations are available near areas where this product is used.

RESPIRATORY PROTECTION: Respiratory protection is not generally needed when using these products. Maintain airborne contaminant concentrations below limits listed in Section 2 (Composition and Information on Ingredients). If respiratory protection is needed, use only protection authorized in the U.S. Federal OSHA Standard (29 CFR 1910.134), applicable U.S. State regulations, or the Canadian CSA Standard Z94.4-93 and applicable standards of Canadian Provinces. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard (1910.134-1998).

EYE PROTECTION: None needed under normal circumstances of drug administration. For operations in which airborne dusts of these products will be generated, wear splash goggles or safety glasses. If necessary, refer to U.S. OSHA 29 CFR 1910.133, or Canadian Standards.

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. If necessary, refer to U.S. OSHA 29 CFR 1910.138 or appropriate Standards of Canada.

BODY PROTECTION: Use body protection appropriate for task, such as a lab coat. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR.

9. PHYSICAL and CHEMICAL PROPERTIES

RELATIVE VAPOR DENSITY (air = 1): Not established. EVAPORATION RATE (nBuAc = 1): Not applicable.
SPECIFIC GRAVITY (water = 1): Not established. FREEZING/MELTING POINT: Not established.
SOLUBILITY IN WATER: Soluble. BOILING POINT: Not established.
VAPOR PRESSURE, mm Hg @ 20°C: Not established. pH: Not available.
ODOR THRESHOLD: Not available.
LOG WATER/OIL DISTRIBUTION COEFFICIENT: Not available.
APPEARANCE, ODOR AND COLOR: White to off-white lyophilized powder.
HOW TO DETECT THIS SUBSTANCE: The appearance may act as a warning property associated with this product.

10. STABILITY and REACTIVITY

STABILITY: This product is stable, when stored at room temperature and protected from light.

DECOMPOSITION PRODUCTS: Thermal decomposition of this product may produce carbon oxides, nitrogen oxides, and sodium oxides.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Strong oxidizers, strong acids.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Extreme heat, any conditions that are incompatible with water, mixing this product with incompatible chemicals.

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

11. TOXICOLOGICAL INFORMATION

TOXICITY DATA: The following information is available for Ganciclovir, the physiologically active form of this product.

GANCICLOVIR:

Sister Chromatid Exchange (lymphocyte, human) = 10 mg/L

LD_{50} (oral, mouse) > 2 g/kg

LD_{50} (intraperitoneal, mouse)= 1 g/kg

LD_{50} (intravenous, mouse) = 900 mg/kg

LD_{50} (oral, dog) > 1 g/kg

LD_{50} (intravenous, dog) > 150 mg/kg

TDLo (oral, rat) = 9100 mg/kg/13 weeks/intermittent; Brain and Coverings: other degenerative changes; Endocrine: other changes; Blood: changes in bone marrow (not otherwise specified)

GANCICLOVIR (continued):

TDLo (oral, mouse) = 91 g/kg/13 weeks/intermittent: Gastrointestinal: other changes; Endocrine: other changes; Blood: changes in bone marrow (not otherwise specified)

TDLo (oral, mouse) = 7300 mg/kg/1 years-intermittent: Blood: changes in bone marrow (not otherwise specified)

TDLo (intravenous, mouse) = 430 mg/kg/30 days/intermittent; Gastrointestinal: other changes; Endocrine: other changes; Blood: changes in bone marrow (not otherwise specified)

TDLo (intraperitoneal, mouse) = 1400 mg/kg/14 days/intermittent; Tumorigenic: protects against induction of experimental tumors

GANCICLOVIR (continued):

TDLo (oral, dog) = 18,200 μg/kg/13 weeks/intermittent; Gastrointestinal: other changes; Endocrine: other changes; Blood: changes in bone marrow (not otherwise specified)

TDLo (intraperitoneal, dog) = 12 mg/kg/30 days/intermittent; Gastrointestinal: other changes; Endocrine: other changes; Blood: changes in bone marrow (not otherwise specified)

Cytogenetic Analysis (ovary, hamster) = 0.4 μmol/L/14 hours

DNA Damage (ovary, hamster) = 1 μmol/L/14 hours

SUSPECTED CANCER AGENT: Ganciclovir Sodium was carcinogenic in the mouse at oral doses of 20 and 1000 mg/kg/day (approximately 0.1x and 1.4x, respectively, the mean drug exposure in humans following the recommended intravenous dose of 5 mg/kg, based on area under the plasma concentration curve [AUC] comparisons). At the dose of 1000 mg/kg/day, there was a significant increase in the incidence of tumors of the preputial gland in males, forestomach (nonglandular mucosa) in males and females, and reproductive tissues (ovaries, uterus, mammary gland, clitoral gland, and vagina) and liver in females. At the dose of 20 mg/kg/day, a slightly increased incidence of tumors was noted in the preputial and harderian glands in males, forestomach in males and females, and liver in females. No carcinogenic effect was observed in mice administered Ganciclovir Sodium at 1 mg/kg/day (estimated as 0.01x the human dose based on AUC comparison). Except for histocystic sarcoma of the liver, Ganciclovir Sodium-induced tumors were generally of epithelial or vascular origin. Although the preputial and clitoral glands, forestomach, and harderian glands of mice do not have human counterparts, Ganciclovir Sodium should be considered a potential carcinogen in humans. The remaining components of this product are not found on the following lists: FEDERAL OSHA Z LIST, NTP, CAL/OSHA, and therefore are neither considered to be nor suspected to be cancer causing agents by these agencies.

IRRITANCY OF PRODUCT: Contact with the skin or eyes may cause mild irritation, which is alleviated upon rinsing.

SENSITIZATION TO THE PRODUCT: Use of Ganciclovir Sodium is contraindicated in patients with a known hypersensitivity to Ganciclovir Sodium and acyclovir.

REPRODUCTIVE TOXICITY INFORMATION: The active component of this product, Ganciclovir Sodium is rated as Pregnancy Category C (RISK CANNOT BE RULED OUT, Human evidence is lacking, but animal evidence is positive). Adequate and well-controlled studies have not been carried out in pregnant women. Listed below is information concerning the effects of Ganciclovir Sodium on animal or human reproductive systems.

Mutagenicity: Ganciclovir Sodium increased mutations in mouse lymphoma cells and DNA damage in human lymphocytes *in vitro* at concentrations between 50 to 500 and 250 to 2000 μg/mL, respectively. In the mouse micronucleus assay, Ganciclovir Sodium was clastogenic at doses of 150 and 500 mg/kg (IV) (2.8 to 10x human exposure based on AUC) but not 50 mg/kg (exposure approximately comparable to the human based AUC). Ganciclovir Sodium was not mutagenic in the Ames Salmonella assay at concentrations of 500 to 5000 μg/plate.

Embryotoxicity: Ganciclovir Sodium has been shown to be embryotoxic in rabbits and mice following intravenous administration. Fetal resorptions were present in at least 85% of rabbits and mice administered 60 mg/kg/day and 108 mg/kg/day (2x the human exposure based on AUC comparisons), respectively. Effects observed in rabbits and mice included embryo-lethality. Ganciclovir Sodium may be embryotoxic at does levels recommended for human use.

Teratogenicity: Ganciclovir Sodium has been shown to be teratogenic in rabbits. Teratogenic changes included cleft palate, anophthalmia/microphthalmia, aplastic organs (kidney and pancreas), hydrocephaly, and brachygnathia. Ganciclovir Sodium may be teratogenic at does levels recommended for human use.

Reproductive Toxicity: Effects observed in rabbits included fetal growth retardation and maternal toxicity. Effects observed in mice included fetal maternal toxicity. (continued on following page)

TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Reproductive Toxicity (continued): Daily intravenous doses of 90 mg/kg administered to female mice prior to mating, during gestation, and during lactation cause hypoplasia of the testes and seminal vesicles in the month-old male offspring, as well as pathologic changes in the nonglandular region of the stomach. The drug exposure in mice as estimated by the AUC was approximately 1.7x the human AUC. Ganciclovir Sodium caused decreased mating behavior, decreased fertility, and an increased incidence of embryo-lethality in female mice following intravenous doses of 90 mg/kg/day (approximately 1.7x the mean drug exposure in humans following the dose of 5 mg/kg, based on AUC comparisons). Ganciclovir Sodium caused decreased fertility in male mice and hypospermatogenesis in mice and dogs following daily oral or intravenous administration of doses ranging from 0.2 to 10 mg/kg. Systemic drug exposure (AUC) at the lowest dose showing toxicity in each species ranged from 0.03 to 0.1x the AUC of the recommended human intravenous dose.

A mutagen is a chemical that causes permanent changes to genetic material (DNA) such that the changes will propagate through generational lines. An embryotoxin is a chemical that 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 that causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance that interferes in any way with the reproductive process.

BIOLOGICAL EXPOSURE INDICES: Currently, there are no Biological Exposure Indices (BEIs) determined for the components of this product

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: The components of this product will degrade in the environment into organic and inorganic constituents, especially upon exposure to light.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: Due to the small product size, no unusual effects on plants are expected if this product is released into the environment.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available on the effect of the components of this product on aquatic plants or animals in the environment.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations and those of Canada and its Provinces. This product, if unaltered by use, 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. Reusable equipment should be cleaned with soap and water. Incineration is recommended.

U.S. EPA WASTE NUMBER: Not applicable.

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: Not applicable (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.

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

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

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

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

15. REGULATORY INFORMATION (Continued)

ADDITIONAL U.S. REGULATIONS (continued):

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: Not applicable.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No components of this product are on the California Proposition 65 lists.

ANSI LABELING (Z129.1; Provided to Summarize Occupational Hazard Information): **CAUTION!** POSSIBLE CARCINOGEN. POSSIBLE BIRTH DEFECT HAZARD. CONTAINS MATERIAL THAT MAY CAUSE CANCER BASED ON ANIMAL DATA. CONTAINS MATERIAL THAT MAY CAUSE BIRTH DEFECTS BASED ON ANIMAL DATA. MAY CAUSE RESPIRATORY TRACT, SKIN, AND EYE IRRITATION. MAY BE HARMFUL IF INGESTED IN LARGE QUANTITIES. Do not taste or swallow. Do not get on skin, in eyes, or on clothes. Avoid breathing dusts or particulates. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear gloves and goggles. FIRST-AID: In case of contact, immediately flush skin or eyes with plenty of water. If inhaled, remove to fresh air. If ingested, do not induce vomiting. Get medical attention if necessary. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Sweep up spill and place in suitable container. Consult Material Safety Data Sheet for additional information.

CANADIAN REGULATIONS:

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

OTHER CANADIAN REGULATIONS: Requirements under the Therapeutic Products Programme (TPP) of Health Canada.

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

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: **D2B:** Materials Causing Other Toxic Effects/Toxic Material (reproductive toxicity).

16. OTHER INFORMATION

PREPARED BY:

CHEMICAL SAFETY ASSOCIATES, Inc.
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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 that uniquely identifies each component.

EXPOSURE LIMITS IN AIR:

CEILING LEVEL: The concentration that shall not be exceeded during any part of the working exposure.

DFG MAK Pregnancy Risk Group Classification: Group A: A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can lead to damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed. **Group B:** Currently available information indicates a risk of damage to the developing embryo or fetus must be considered to be probable. Damage to the developing organism cannot be excluded when pregnant women are exposed, even when MAK and BAT values are observed. **Group C:** There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are observed. **Group D:** Classification in one of the groups A-C is not yet possible because, although the data available may indicate a trend, they are not sufficient for final evaluation.

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.

LOQ: Limit of Quantitation.

EXPOSURE LIMITS IN AIR (continued):

MAK: Federal Republic of Germany Maximum Concentration Values in the workplace.

NE: Not Established. When no exposure guidelines are established, an entry of NE is made for reference.

NIC: Notice of Intended Change.

NIOSH CEILING: The exposure that shall not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling shall be assumed as a 15-minute TWA exposure (unless otherwise specified) that shall not be exceeded at any time during a workday.

NIOSH RELs: NIOSH's Recommended Exposure Limits.

PEL-Permissible Exposure Limit: OSHA's Permissible Exposure Limits. 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 that was vacated by Court Order.

SKIN: Used when a there is a danger of cutaneous absorption.

STEL-Short Term Exposure Limit: Short Term Exposure Limit, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA.

DEFINITIONS OF TERMS (Continued)

EXPOSURE LIMITS IN AIR (continued):

TLV-Threshold Limit Value: An airborne concentration of a substance that 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.

TWA-Time Weighted Average: Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS: This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.

HEALTH HAZARD:

0 (Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. *Skin Irritation*: Essentially non-irritating. PII or Draize = "0". *Eye Irritation*: Essentially non-irritating, or minimal effects which clear in < 24 hours [e.g. mechanical irritation]. Draize = "0". *Oral Toxicity LD_{50} Rat*: < 5000 mg/kg. *Dermal Toxicity LD_{50}Rat or Rabbit*: < 2000 mg/kg. *Inhalation Toxicity 4-hrs LC_{50} Rat*: < 20 mg/L.); **1** (Slight Hazard: Minor reversible Injury may occur; slightly or mildly irritating. *Skin Irritation*: Slightly or mildly irritating. *Eye Irritation*: Slightly or mildly irritating. *Oral Toxicity LD_{50} Rat*: > 500-5000 mg/kg. *Dermal Toxicity LD_{50}Rat or Rabbit*: > 1000-2000 mg/kg. *Inhalation Toxicity LC_{50}* 4-hrs *Rat*: > 2-20 mg/L); **2** (Moderate Hazard: Temporary or transitory injury may occur. *Skin Irritation*: Moderately irritating; primary irritant; sensitizer. PII or Draize > 0, < 5. *Eye Irritation*: Moderately to severely irritating and/or corrosive; reversible corneal opacity; corneal involvement or irritation clearing in 8-21 days. Draize > 0, ≤ 25. *Oral Toxicity LD_{50} Rat*: > 50-500 mg/kg. *Dermal Toxicity LD_{50}Rat or Rabbit*: > 200-1000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.5-2 mg/L.); **3** (Serious Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation*: Severely irritating and/or corrosive; may destroy dermal tissue, cause skin burns, dermal necrosis. PII or Draize > 5-8 with destruction of tissue. *Eye Irritation*: Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity LD_{50} Rat*: > 1-50 mg/kg. *Dermal Toxicity LD_{50}Rat or Rabbit*: > 20-200 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.05-0.5 mg/L.); **4** (Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposure. *Skin Irritation*: Not appropriate. Do not rate as a "4", based on skin irritation alone. *Eye Irritation*: Not appropriate. Do not rate as a "4", based on eye irritation alone. *Oral Toxicity LD_{50} Rat*: ≤ 1 mg/kg. *Dermal Toxicity LD_{50}Rat or Rabbit*: ≤ 20 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: ≤ 0.05 mg/L).

FLAMMABILITY HAZARD:

0 (Minimal Hazard-Materials that will not burn in air when exposure to a temperature of 815.5°C [1500°F] for a period of 5 minutes.); **1** (Slight Hazard-Materials that must be pre-heated before ignition can occur. Material require considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur, Including: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C [200°F] (e.g. OSHA Class IIIB, or; Most ordinary combustible materials [e.g. wood, paper, etc.]; **2** (Moderate Hazard-Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres in air, Including: Liquids having a flash-point at or above 37.8°C [100°F]; Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp; Solids and semisolids that readily give off flammable vapors.); **3** (Serious Hazard- Liquids and solids that can be ignited under almost all ambient temperature conditions.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued):

3 (continued): Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions, including: Liquids having a flash point below 22.8°C [73°F] and having a boiling point at or above 38°C [100°F] and below 37.8°C [100°F] [e.g. OSHA Class IB and IC]; Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air [e.g., dusts of combustible solids, mists or droplets of flammable liquids]; Materials that burn extremely rapidly, usually by reason of self-contained oxygen [e.g. dry nitrocellulose and many organic peroxides]); **4** (Severe Hazard-Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and which will burn readily, including: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C [73°F] and a boiling point below 37.8°C [100°F] [e.g. OSHA Class IA; Material that ignite spontaneously when exposed to air at a temperature of 54.4°C [130°F] or below [e.g. pyrophoric]).

PHYSICAL HAZARD:

0 (*Water Reactivity*: Materials that do not react with water. *Organic Peroxides*: Materials that are normally stable, even under fire conditions and will not react with water. *Explosives*: Substances that are Non-Explosive. Unstable *Compressed Gases*: No Rating. *Pyrophorics*: No Rating. *Oxidizers*: No "0" rating allowed. *Unstable Reactives*: Substances that will not polymerize, decompose, condense or self-react.); **1** *Water Reactivity*: Materials that change or decompose upon exposure to moisture. *Organic Peroxides*: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy. *Explosives*: Division 1.5 & 1.6 substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases*: Pressure below OSHA definition. *Pyrophorics*: No Rating. *Oxidizers*: Packaging Group III; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. *Unstable Reactives*: Substances that may decompose, condense or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosive hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors.); **2** (*Water Reactivity*: Materials that may react violently with water. *Organic Peroxides*: Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. *Explosives*: Division 1.4 – Explosive substances where the explosive effect are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. *Compressed Gases*: Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group II Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature);

DEFINITIONS OF TERMS (Continued)

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

PHYSICAL HAZARD (continued):

3 (continued) 3 (*Water Reactivity*: Materials that may form explosive reactions with water. *Organic Peroxides*: Materials that are capable of detonation or explosive reaction, but require a strong initiating source, or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives*: Division 1.2 – Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases*: Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group I Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3.:2 potassium bromate/cellulose mixture. Liquids: Any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives*: Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a moderate potential to cause significant heat generation or explosion.); **4** (*Water Reactivity*: Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides*: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives*: Division 1.1 & 1.2-explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases*: No Rating. *Pyrophorics*: Add to the definition of Flammability "4". *Oxidizers*: No "4" rating. *Unstable Reactives*: Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a high potential to cause significant heat generation or explosion.).

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

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: **0** Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur **2** Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air. **3** Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions. **4** Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily.

INSTABILITY HAZARD: **0** Materials that in themselves are normally stable, even under fire conditions. **1** Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures. **2** Materials that readily undergo violent chemical change at elevated temperatures and pressures. **3** Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation. **4** Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures.

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the **N**ational **F**ire **P**rotection **A**ssociation (**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.

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. **TL_m** = median threshold limit; 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.

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: **LD_{50}** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC_{50}** - 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/m^3** 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.

REGULATORY INFORMATION:

U.S. and CANADA:

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

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. **O**ccupational **S**afety and **H**ealth **A**dministration (**OSHA**). **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively.

Superfund Amendments and Reauthorization Act **(SARA)**; the Canadian Domestic/Non-Domestic Substances List **(DSL/NDSL)**; the U.S. Toxic Substance Control Act **(TSCA)**; Marine Pollutant status according to the **DOT**; the Comprehensive Environmental Response, Compensation, and Liability Act **(CERCLA or Superfund)**; and various state regulations. This section also includes information on the precautionary warnings which appear on the material's package label. **OSHA** - U.S. Occupational Safety and Health Administration.