A GensiaSicor Company

GensiaSicor™ PHARMACEUTICALS

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

PRODUCT NAME (AS LABELED):	**IFOSFAMIDE INJECTION**
PRODUCT USE:	Antineoplastic Agent
SUPPLIER/MANUFACTURER'S NAME:	**GensiaSicor 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:	1-714-855-8210
Common Names:	A 4942, ASTA Z 4942, Cyfos, Holoxan, Ifosfamid, Iphosphamide, Isoendoxan, Isofosfamide, Mitoxana, MJF 9325, Naxamide, NCI-C01638, NSC-109724, Z 4942
Chemical Name:	For Active Ingredient: *N*,3-Bis(2-chloroethyl)tetrahydro-2*H*-1,3,2-oxazaphosphorin-2-amine-2-oxide
Chemical Formula:	For Active Ingredient: $C_7H_{15}Cl_2N_2O_2P$
Chemical Family:	For Active Ingredient: Cyclophosphamide
How Supplied:	20 mL of a 50 mg/mL solution in a 30 mL vial 60 mL of a 50 mg/mL solution in a 100 mL vial
DATE OF PREPARATION:	January 8, 1999

2. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% by weight	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA			
			TLV mg/m^3	STEL mg/m^3	PEL mg/m^3	STEL mg/m^3	IDLH mg/m^3	OTHER
Ifosfamide	3778-73-2	5	NE	NE	NE	NE	NE	NE
Sodium Phosphate, Dibasic, Anhydrous	7558-79-4	0.4	NE	NE	NE	NE	NE	NE
Sodium Phosphate, Monobasic, Monohydrate	10049-21-5	0.1	NE	NE	NE	NE	NE	NE
Water for Injection	7732-18-5	Balance	NE	NE	NE	NE	NE	NE

NE = Not Established C = Ceiling Limit mppcf: Millions of Particles per Cubic Foot See Section 16 for Definitions of Terms Used

NOTE: All WHMIS required information is included. It is located 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 is a clear, colorless, odorless liquid. The primary health hazard associated with exposure to this product during an emergency response situation would be mild irritation of contaminated skin or eyes. Ifosfamide is a potential carcinogen and reproductive toxin, based on animal data. This product is neither flammable nor reactive. Emergency responders must wear adequate personal protective equipment 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 or chronic effects in humans, as described in the following paragraphs.

INHALATION: Inhalation of mists or sprays of this product may mildly irritate the nose and throat. Symptoms of such exposure may include coughing and sneezing. Symptoms of such overexposure may also include the toxic effects described in "Other Potential Health Effects".

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: Ifosfamide can be absorbed through the skin, but the extent of systemic effect is not known. Symptoms of such overexposure may include the toxic effects described in "Other Potential Health Effects".

INGESTION: Ingestion is not anticipated to be a likely route of occupational exposure. If this product is swallowed, it may cause gastrointestinal distress and diarrhea. Symptoms of such overexposure may also include the toxic effects described in "Other Potential Health Effects".

INJECTION: In terms of anticipated occupational overexposure effects, local redness and pain are the primary symptoms of accidental injection. Symptoms of such overexposure may also include the toxic effects described in "Other Potential Health Effects".

HAZARDOUS MATERIAL INFORMATION SYSTEM

HEALTH	(BLUE)	2
FLAMMABILITY	(RED)	0
REACTIVITY	(YELLOW)	0
PROTECTIVE EQUIPMENT		X

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For medical treatment of cancer.

See Section 16 for Definition of Ratings

OTHER POTENTIAL HEALTH EFFECTS: Ifosfamide is a pharmacological product used in the treatment of germ cell testicular cancer. The most common dose-dependent adverse effects associated with therapeutic treatments include hair loss, nausea, vomiting, blood in the urine, sleepiness, confusion, depressive psychosis, hallucinations, dizziness, disorientation, cranial nerve dysfunction, seizures, coma, infection, renal impairment, liver dysfunction, leukopenia, thrombocytopenia, vein inflammation, fever, and allergic reaction.

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, effects described in "Other Potential Health Effects" may result.

CHRONIC: Ifosfamide is a potential carcinogen and reproductive toxin, based on animal data. Refer to Section 11 (Toxicological Information) for additional information on this product.

TARGET ORGANS: Skin, eyes (anticipated occupational exposures). Central nervous system, blood system, genital-urinary tract system, and reproductive system (therapeutic doses).

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

4. FIRST-AID MEASURES

SKIN EXPOSURE: 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 this product contaminates 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. If necessary, consult an ophthalmologist.

4. FIRST-AID MEASURES (Continued)

INHALATION: If this product is inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

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.

INJECTION: In the event of accidental injection, wash contaminated area with soap and water. Depending on the nature of the exposure, the Medical Surveillance requirements of the OSHA Bloodborne Pathogen standard (29 CFR 1910.1030) may be applicable.

Victims of chemical exposure must be taken for medical attention. Rescuers should be taken for medical attention, if they have been exposed 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.

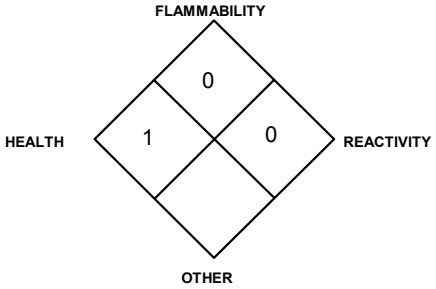
FIRE EXTINGUISHING EQUIPMENT:

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

UNUSUAL FIRE and EXPLOSION HAZARDS: At extremely high temperatures, this product will decompose to produce irritating vapors and toxic gases (carbon, nitrogen, and phosphorus oxides and hydrogen chloride).

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

NFPA RATING



See Section 16 for Definition of Ratings

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 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.

6. ACCIDENTAL RELEASE MEASURES

SPILL and LEAK RESPONSE: For small releases of this product (1 vial) wear double latex or nitrile gloves 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 and protect people. Clean up spilled liquid with a damp sponge, polypad, or other appropriate materials. If necessary, decontaminate area with a bleach solution. Decontaminate the area of the spill thoroughly by using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable U.S. Federal, State, and local waste disposal regulations (or those of Canada and its Provinces).

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

7. HANDLING and STORAGE

WORK and HYGIENE PRACTICES: As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat or drink while preparing or administering the product. Wash hands thoroughly after handling this product or equipment and containers which contain this product. 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. Precautions should be taken during the following activities:

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

7. HANDLING and STORAGE (Continued)

WORK and HYGIENE PRACTICES (continued): 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 an appropriate, designated area;
- Contaminated waste must be properly handled; and,
- If necessary, work areas must be regularly decontaminated.

STORAGE and HANDLING PRACTICES: Employees must be trained to properly use this product. Contaminated waste must be properly handled. Work areas must be regularly decontaminated. Ensure vials are properly labeled. Store this product away from incompatible materials. Store containers 2-8°C (36-46°F). Protect from light. Do not use discolored solutions.

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.

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) of this MSDS for the clean up of large spills.

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of drug administration. For operations in which mists or sprays of this product will be generated, a full-face respirator with a HEPA filter should be used until a Biological Safety Cabinet is installed.

EYE PROTECTION: None needed under normal circumstances of drug administration. For operations in which mists or sprays of this product will be generated, wear 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: None needed under normal circumstances of use. For operations in which mists or sprays of this product will be generated, a full body gown which is closed at the front and has long sleeves is recommended. The gown should be made of Tyvek™, PE-Coated Tyvek™, or SARANEX™.

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): Not determined.
EVAPORATION RATE (n-BuAc=1): > 1
SPECIFIC GRAVITY: Approximately 1.02
MELTING/FREEZING POINT: Not determined.
SOLUBILITY IN WATER: Soluble.
BOILING POINT: Approximately 100°C (212°F)
VAPOR PRESSURE, mm Hg @ 25°C: Not determined.
pH: 5.0 - 8.0
ODOR THRESHOLD: Not determined.
COEFFICIENT OF OIL/WATER DISTRIBUTION (Partition Coefficient): Not determined.
APPEARANCE and COLOR: This is a clear, colorless, odorless liquid.

HOW TO DETECT THIS SUBSTANCE (warning properties): There are no distinguishing characteristics associated with this product.

10. STABILITY and REACTIVITY

STABILITY: This product is stable, when refrigerated (NOT frozen) and protected from light.

DECOMPOSITION PRODUCTS: When heated to decomposition temperatures, this product will emit carbon, nitrogen, and phosphorus oxides and hydrogen chloride.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. This product would not be compatible with strong oxidizers and bleach.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid freezing. Heat may cause this product to decompose, destroying the product and producing irritating vapors and toxic gases (e.g., oxides of carbon , hydrogen chloride). Avoid contact with incompatible chemicals.

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

11. TOXICOLOGICAL INFORMATION

TOXICITY DATA: The following data are available for the components of this product present in greater than 1% concentration.

IFOSFAMIDE:

Microsomal Mutageniticity Assay (*Salmonella typhimurium*, bacteria) = 400 mg/plate

Cytogenetic Analysis (leukocyte, human) = 130 mg/L

Cytogenetic Analysis (lymphocyte, human) = 75 mg/L

Cytogenetic Analysis (lymphocyte, human) = 130 mg/L

Cytogenetic Analysis (intraperitoneal, hamster) = 3300 μg/kg

Mutation in Microorganisms (*Escherichia coli*, bacteria) = 10 mmol/L

DNA Repair (*Escherichia coli*, bacteria) = 9 mmol/L

Sex Chromosome Loss and Nondisjunction (oral, *Drosophila melanogaster*) = 2 mmol/L/24 hours

Body Fluid Assay (*Salmonella typhimurium*, rat) = 2 g/kg

Micronucleus Test (intraperitoneal, mouse) = 70 mg/kg/24 hours

Sperm Morphology (intraperitoneal, mouse) = 500 mg/kg/5 days/intermittent

DNA Damage (lymphocyte, mammal) = 5600 μmol/L

Mutation Test Systems (chicken cells) = 5 mg/kg

Sister Chromatid Exchange (chicken cells) = 1250 μg/kg

TDLo (intravenous, rat) = 10 mg/kg/ female 10 days after conception: Reproductive: Specific Developmental Abnormalities: musculoskeletal system

TDLo (intravenous, rat) = 13,750 mg/kg/ female 7–17 days post: Teratogenic

TDLo (intravenous, rat) = 27500 μg/kg/ female 7–17 days after conception: Reproductive: Specific Developmental Abnormalities: Central Nervous System; Reproductive: Specific Developmental Abnormalities: respiratory system; Reproductive: Specific Developmental Abnormalities: urogenital system

TDLo (intraperitoneal, rat) = 90 mg/kg/ male 30 days pre-mating: Reproductive: Paternal Effects: prostate, seminal vesicle, Cowper's gland, accessory glands

TDLo (intraperitoneal, rat) = 300 mg/kg/30 days/continuous: Endocrine: other changes; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

IFOSFAMIDE (continued):

TDLo (intravenous, rat) = 260 mg/kg/ female 17–21 days post: Reproductive

TDLo (intraperitoneal, rat) = 940 mg/kg/1 year/intermittent: Carcinogenic

TDLo (intraperitoneal, rat) = 300 mg/kg/ male 30 days pre-mating: Reproductive: Paternal Effects: testes, epididymis, sperm duct

TDLo (intraperitoneal, rat) = 480 mg/kg/10 weeks/intermittent: Kidney, Urethra, Bladder - other changes in urine composition; Nutritional and Gross Metabolic: changes in phosphorus; Related to Chronic Data: death

TDLo (intraperitoneal, rat) = 432 mg/kg/6 weeks/intermittent: Related to Chronic Data: death

TDLo (intraperitoneal, rat) = 810 mg/kg/ female 27 days pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina

TDLo (intraperitoneal, mouse) = 450 mg/kg/8 weeks/intermittent: Neoplastic

TDLo (intraperitoneal, mouse) = 10 mg/kg/ female 11 days after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Reproductive: Specific Developmental Abnormalities: musculoskeletal system

TDLo (intraperitoneal, mouse) = 360 mg/kg/6 weeks/intermittent: Related to Chronic Data: death

TDLo (intraperitoneal, mouse) = 20 mg/kg/ female 11 days after conception: Reproductive: Specific Developmental Abnormalities: Central Nervous System, eye/ear, urogenital system

TDLo (subcutaneous, mouse) = 2600 mg/kg/65 weeks/intermittent: Carcinogenic

TDLo (subcutaneous, mouse) = 540 mg/kg: Blood: changes in leukocyte (WBC) count

TDLo (subcutaneous, mouse) = 5220 mg/kg/87 weeks/intermittent: Blood: changes in leukocyte (WBC) count

TDLo (intravenous, dog) = 140 mg/kg/35 days/intermittent: Blood: normocytic anemia; Blood: changes in leukocyte (WBC) count; Related to Chronic Data: death

TDLo (intravenous, rabbit) = 260 mg/kg/ female 6–18 days after conception: Reproductive: Fertility: other measures of fertility; Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)

IFOSFAMIDE (continued):

TDLo (intravenous, rabbit) = 65 mg/kg/ female 6–18 days after conception: Reproductive: Specific Developmental Abnormalities: musculoskeletal system

TD (intraperitoneal, rat) = 1872 mg/kg/1 year/intermittent: Carcinogenic

TD (intraperitoneal, mouse) = 3120 mg/kg/1 year/intermittent: Carcinogenic

TDLo (oral, human) = 150 mg/kg: Gastrointestinal tract, kidney, skin

TDLo (oral, human) = 100 mg/kg;: Blood

TDLo (intravenous, human) = 2298 mg/kg/3 days/intermittent: Kidney, blood

TDLo (intravenous, human) = 1915 mg/kg/2 weeks/intermittent: Kidney

TDLo (intravenous, human) = 130 mg/kg/13 days/intermittent: Kidney, gastrointestinal tract

TDLo (intravenous, woman) = 218 mg/kg; Brain and Coverings: demyelination; Brain and Coverings: changes in surface EEG

TDLo (intravenous, human) = 2873 mg/kg/5 days/continuous: Behavioral: hallucinations, distorted perceptions; Kidney, Urethra, Bladder: hematuria; Tumorigenic: active as anti-cancer agent

LD_{50} (oral, rat) = 143 mg/kg

LD_{50} (intraperitoneal, rat) = 140 mg/kg

LD_{50} (subcutaneous, rat) = 160 mg/kg

LD_{50} (intravenous, rat) = 190 mg/kg

LD_{50} (unreported, rat) = 325 mg/kg

LD_{50} (oral, mouse) = 1005 mg/kg

LD_{50} (intraperitoneal, mouse) = 397 mg/kg

LD_{50} (subcutaneous, mouse) = 656 mg/kg

LD_{50} (intravenous, mouse) = 338 mg/kg

LDLo (intraperitoneal, dog) = 50 mg/kg

LDLo (intraperitoneal, cat) = 100 mg/kg: Behavioral: ataxia; Lungs, Thorax, or Respiration: dyspnea; Nutritional and Gross Metabolic: body temperature decrease

LDLo (intraperitoneal, rabbit) = 200 mg/kg: Sense Organs and Special Senses (Eye): miosis (pupillary constriction); Behavioral; muscle weakness; Lungs, Thorax, or Respiration: respiratory depression

LDLo (intraperitoneal, guinea pig) = 400 mg/kg: Sense Organs and Special Senses (Eye): ptosis; Behavioral: muscle weakness; Behavioral: ataxia

SUSPECTED CANCER AGENT: Ifosfamide is rated by IARC as being “Unclassifiable as to Carcinogenicity to Humans”. In a 79–84 week study of Sprague-Dawley rats and B6C3F1 mice, the incidence of uterine, breast, and hematopoietic tumors was a significant in female animals. The rats were given 6 or 12 mg/kg Ifosfamide intraperitoneally and the mice were given 10 or 20 mg/kg Ifosfamide intraperitoneally.

11. TOXICOLOGICAL INFORMATION (Continued)

SUSPECTED CANCER AGENT (continued): This product's ingredients are not found on the following lists: U.S. FEDERAL OSHA Z LIST, NTP, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

IRRITANCY OF PRODUCT: This product is mildly irritating to contaminated skin, eyes, and other tissue.

SENSITIZATION TO THE PRODUCT: This product may cause allergic-type reactions in sensitive individuals.

REPRODUCTIVE TOXICITY INFORMATION: Ifosfamide is rated as Pregnancy Category D (Positive Evidence of Risk). Listed below is information concerning the effects of Ifosfamide, the active ingredient of this product, on animal or human reproductive systems.

Mutagenicity: Mutagenicity data are available for Ifosfamide from studies involving bacterial and mammalian systems.
Embryotoxicity: Ifosfamide may cause embryotoxic effects. Refer to "Teratogenicity" for additional information.
Teratogenicity: Animal studies indicate that Ifosfamide is teratogenic in mice, rabbits, and rats. There are no adequate and well-controlled studies in pregnant women.
Reproductive Toxicity: Ifosfamide may adversely affect the male reproductive system..

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 the components of this product.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Disorders involving the Target Organs of this product (see Section 3, Hazard Information) can be aggravated by exposures to this product (especially in doses approaching therapeutic levels for this product).

RECOMMENDATIONS TO PHYSICIANS: In the event of an occupational exposure, treat symptoms and eliminate exposure. Consult the Package Insert for additional information which can assist with treatment of overexposure.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: This product will be relatively stable under ambient environmental conditions.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: No specific information is currently available on the effect of Ifosfamide on plants or animals in the environment. This product may be harmful or fatal to contaminated plant and animal life. Refer to Section 11 (Toxicological Information) for additional information on Ifosfamide and its effects on test animals.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available on the effect of Ifosfamide on aquatic plants or animals in the environment. This product may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal at medical facilities must be in accordance with appropriate U.S. Federal, State, and local regulations or those 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. Reusable equipment should be cleaned with soap and water. Incineration is recommended.

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

14. TRANSPORTATION INFORMATION

THIS MATERIAL IS NOT HAZARDOUS, PER THE U.S. DEPARTMENT OF TRANSPORTATION (49 CFR 172.101)

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. Refer to the above paragraph for additional information.

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product present in greater than 1% 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. TSCA STATUS: Ifosfamide is a "drug" as defined by the Federal Food, Drug and Cosmetic Act (21 USC 321 et. Seq.); therefore, it is not a chemical substance under TSCA (40 CFR 720.3 (e)).

U.S. SARA THRESHOLD PLANNING QUANTITY: Not applicable.

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

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

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): Ifosfamide is on the California Proposition 65 lists. **WARNING!** This compound is known to the State of California to cause reproductive toxicity.

U.S. STATE REGULATORY INFORMATION: The components of this product are 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: Ifosfamide.
Michigan - Critical Materials Register: None.
Minnesota - List of Hazardous Substances: None.
Missouri - Employer Information/Toxic Substance List: None.
New Jersey - Right to Know Hazardous Substance List: Sodium Phosphate, Dibasic, Anhydrous.
North Dakota - List of Hazardous Chemicals, Reportable Quantities: Sodium Phosphate, Dibasic, Anhydrous.
Pennsylvania - Hazardous Substance List: Sodium Phosphate, Dibasic, Anhydrous.
Rhode Island - Hazardous Substance List: Propylene Glycol.
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): **WARNING!** MAY BE HARMFUL IF ACCIDENTALLY INJECTED OR SWALLOWED. CAN CAUSE BLOOD AND CENTRAL NERVOUS SYSTEM EFFECTS. MAY CAUSE REPRODUCTIVE EFFECTS, BASED ON ANIMAL DATA. MAY CAUSE EYE OR SKIN IRRITATION. Do not taste or swallow. Do not accidentally get on skin, in eyes, or on clothes. Avoid prolonged or repeated skin contact. Avoid breathing mists or sprays. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling. If necessary, wear gloves, goggles, and appropriate body protection. Store containers in a cool location, tightly closed, away from direct light. **FIRST-AID:** In case of contact, immediately flush skin or eyes with plenty of water. If inhaled, remove to fresh air. If ingested, 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:** Absorb spill with polypads and place in suitable container. Consult Material Safety Data Sheet for additional information.

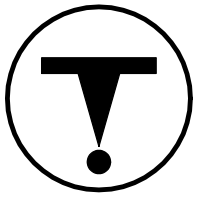
ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL STATUS: Ifosfamide 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:** 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

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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 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. **O**ccupational **S**afety and **H**ealth **A**dministration (**OSHA**). NIOSH issues exposure guidelines called **R**ecommended **E**xposure **L**evels (**REL**s). When no exposure guidelines are established, an entry of **NE** is made for reference.

HAZARD RATINGS:

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM: 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 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). PPE Rating X: Special attention should be given to PPE, based on product use.

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 **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.

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. **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.