SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product identifier used on the label:

Product Name: **Arsenic Trioxide 1 mg/mL Solution for Infusion**

Other means of identification:

Recommended use of the chemical and restrictions on use:

Product Use/Restriction: Pharmaceutical

Chemical manufacturer address and telephone number:

Manufacturer Name: NerPharMa srl

Address: Viale Pasteur, 10 - 20014 Nerviano
Milan, Italy

Manufacturer e-mail: MDSD@nmsgroup.it

General Phone Number: +39 331 581111 - working hours (GTM +1)

Emergency phone number:

Emergency Phone Number: +39 331 581111 - working hours (GTM +1)

Chemical distributor, or other responsible party Name, address, and telephone number:

Distributor Name: Fresenius Kabi USA, LLC

Address: Three Corporate Drive
Lake Zurich, Illinois 60047

General Phone Number: (847) 550-2300

Health Issues Information: (800) 551-7176

SECTION 2 : HAZARD(S) IDENTIFICATION

Classification of the chemical in accordance with CFR 1910.1200(d)(f):

GHS Pictograms:

Signal Word: DANGER!

GHS Class: Carcinogenicity, Category 1.

Hazard Statements: H350 May cause cancer

Precautionary Statements: P201 Obtain special instruction before use
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up
P501 Dispense contents/container in accordance with local/regional/ national/ international regulations

Hazards not otherwise classified that have been identified during the classification process:

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

- Eye: May cause severe eye damage.
- Skin: May cause severe skin burns.
- Inhalation: May cause irritation of respiratory tract.
- Ingestion: If ingested, substance is considered toxic.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures:

Chemical Name	CAS#	Ingredient Percent	EC Num.
Arsenic trioxide	1327-53-3	1 mg/ml by weight	215-481-4

Water for Injection	7732-18-5	Proprietary by weight	231-791-2
Sodium hydroxide	1310-73-2	<1 by weight	215-185-5
Hydrochloric acid	7647-01-0	<1 by weight	

SECTION 4 : FIRST AID MEASURES

Description of necessary measures:

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed:

Other First Aid: For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Suitable and unsuitable extinguishing media:

Suitable Extinguishing Media: Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards arising from the chemical:

Hazardous Combustion Byproducts: Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

Special protective equipment and precautions for fire-fighters:

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Personal Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area.
Avoid dust/aerosol formation.
Avoid personal contact and breathing dust, vapors, mist, or gas. Use proper personal protective equipment as listed in Section 8.

Environmental precautions:

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Methods for cleanup: Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

SECTION 7 : HANDLING and STORAGE

Precautions for safe handling:

Handling: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

Hygiene Practices: Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

Conditions for safe storage, including any incompatibilities:

Storage: Keep container tightly closed in a dry and well-ventilated place. Keep away from direct sunlight. Avoid excessive heat. Keep in properly labelled containers. Recommended storage temperature 15 - 30 °C

Specific end use(s):

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety

shower.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE GUIDELINES:

Hydrochloric acid :

Guideline ACGIH:	TLV-STEL: 2 ppm(ceiling)
Guideline OSHA:	OSHA PEL-STEL 5 ppm Ceiling/Peak

Appropriate engineering controls:

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Individual protection measures:

Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.
General Hygiene Considerations:	Wash thoroughly after handling. Do not eat, drink, smoke or apply cosmetics while handling the 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. Work should be performed in a designated area for working with hazardous drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Aqueous solution.
Color:	Colorless.
Odor:	No information.
Odor Threshold:	No information.
Boiling Point:	100C
Melting Point:	Not established.
Density:	Similar to water.
Specific Gravity:	About 1
Solubility:	No information.
Vapor Density:	Similar to water.
Vapor Pressure:	Similar to water.
Percent Volatile:	Not established.
Evaporation Rate:	Similar to water.
pH:	7.0 - 9.0
Molecular Formula:	Mixture
Flash Point:	Not established.
Flash Point Method:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:

Chemical Stability:	Stable under normal temperatures and pressures.

Possibility of hazardous reactions:

Hazardous Polymerization:	Not reported.

Conditions To Avoid:

Conditions to Avoid:	Avoid direct sunlight, conditions that might generate heat, and sources of ignition. Avoid contact with incompatible materials. Do not expose to extreme temperatures.

Incompatible Materials:

Incompatible Materials:	Avoid storage strong acids, strong bases, products incompatible with water.

Hazardous Decomposition Products:

Special Decomposition Products:	May emit fumes under fire conditions.

SECTION 11 : TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Arsenic trioxide :

Inhalation:	LD50 Oral Rat - 10 mg/kg

Sodium hydroxide :

RTECS Number:	WB4900000
Ingestion:	Oral - Rabbit LDLo: 500 mg/kg [Details of toxic effects not reported other than lethal dose value]

Hydrochloric acid :

RTECS Number:	MW4025000
Eye:	Eye - Rabbit Total particulate/dust (T): 5 mg/30S (RTECS)
Skin:	Administration onto the skin - Human Standard Draize test.: 4 %/24H (RTECS)
Inhalation:	Inhalation - Rat LC50: 3124 ppm/1H [Sense Organs and Special Senses (Olfaction) - effect, not Otherwise specified Sense Organs and Special Senses (Eye) - Iritis] Inhalation - Mouse LC50: 1108 ppm/1H [Sense Organs and Special Senses (Eye) - effect, not Otherwise specified Lungs, Thorax, or Respiration - Respiratory stimulation Skin and Appendages - Dermatitis, other (After systemic exposure)] Inhalation - Rat LC50: 45000 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 8300 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 8300 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - LC50: 0.1 gm/m3 [Details of toxic effects not reported other than lethal dose value] Inhalation - Rat LC50: 60938 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 20487 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 7004 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 3940 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 3700 ppm/30M [Details of toxic effects not reported other than lethal dose value] Inhalation - Mouse LC50: 2644 ppm/30M [Details of toxic effects not reported other than lethal dose value] (RTECS)
Ingestion:	Oral - Rabbit LD50: 900 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:

Ecotoxicity:	No information.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Description of waste:

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.
IATA Shipping Name:	Non regulated.
IATA UN Number:	Non regulated.
IMDG UN Number :	Non regulated.
IMDG Shipping Name :	Non regulated.

SECTION 15 : REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product:

Arsenic trioxide :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	215-481-4

Water for Injection :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	231-791-2

Sodium hydroxide :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	215-185-5

Hydrochloric acid :

TSCA Inventory Status:	Listed
EINECS Number:	231-595-7
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.845(502)

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	3*
HMIS Fire Hazard:	1
HMIS Reactivity:	0
HMIS Personal Protection:	X

Health Hazard	**3***
Fire Hazard	**1**
Reactivity	**0**
Personal Protection	**X**

* **Chronic Health Effects**

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