


**SAFETY DATA SHEET (SDS)****Product name:** Arsenic Trioxide Injection**1 – PRODUCT INFORMATION**

Product Name : Arsenic Trioxide Injection
Strength : 10 mg/10 mL (1 mg/mL), 12 mg/6 mL (2 mg/mL)
Product Use : Pharmaceutical
Product Type : Regulated Prescription Drug
Container Information : Single dose glass vials
Manufacturer : MSN Laboratories Private Limited, Formulation Division,
Unit-II, Sy. No. 1277 & 1319 to 1324, Nandigama (Village),
Kothur (Mandal), Rangareddy District -509216, Telangana,
INDIA

2 – COMPOSITION / INFORMATION ON INGREDIENTS

Common Name	Composition	CAS-No	Molecular formula	Molecular mass
Arsenic Trioxide	1 mg/ mL or 2 mg/mL	1327-53-3	As ₂ O ₃	197.84 g/mol
Sodium Hydroxide	<1 %	1310-73-2	NaOH	40 g/mol
Sodium Hydroxide	q.s to pH	1310-73-2	NaOH	40 g/mol
Hydrochloric Acid	q.s to pH	7647-01-0	HCl	36.46 g/mol

3 – HAZARDS IDENTIFICATION

Classification: : GHS Class: Carcinogenicity, Category 1
Signal Word, : 
Hazard statement(s),
Symbol(s), and/or
Precautionary statement(s)
DANGER!
H350 May cause cancer
P201 Obtain special instructions 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 regulations

Description of Hazards : May cause severe eye damage. May cause severe skin burns. May cause irritation of respiratory tract. If ingested, substance is considered toxic

Unknown Acute Toxicity : N/A



4 - FIRST AID MEASURES

- Eye Exposure : Flush eyes with large volumes of water for 15 minutes or more. Get medical attention if irritation or signs of exposure are noted
- Skin Exposure : Remove contaminated clothing, wash skin with water and soap for 15 minutes. Get medical attention if irritation or signs of exposure are noted
- Ingestion : If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person
- Injection : In cases of accidental injection, wash and disinfect area, get medical attention
- Inhalation : If difficulty with breathing, remove from exposure, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration
- Notes to Physician : See patient package insert in shipping carton for complete information

5 - FIRE-FIGHTING MEASURES

- 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
- Hazardous Combustion Products : Thermal decomposition can lead to release of irritating gases and vapors. Combustible material
- Special Protective Equipment / Precautions : As with all fires, evacuate personnel to a safe area. Fire fighters should wear full protective gear and self-contained breathing apparatus to avoid inhalation of smoke

6 - ACCIDENTAL RELEASE MEASURES

- Spill : Use the appropriate personal protective equipment, see Section 8. Absorb Drug Injection with absorbent materials and dispose according to local, state, and federal guidelines
- Release to Air : If aerosolized, reduce exposures by ventilating area. Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation
- Release to Water : Avoid runoff into storm sewers, ditches, and waterways. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines

7 - HANDLING AND STORAGE

- General Handling : When handling pharmaceutical products, avoid all contact with skin, eyes, nostrils, and mouth. Avoid inhalation of dust, fumes, mist, and/or vapors associated with the product. Arsenic trioxide injection is a hazardous drug. Follow applicable special handling and disposal procedures
- Storage Conditions : Store at controlled room temperature 20°-25°C (68°-77°F); excursions permitted to 15° to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. Do not freeze

8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

- Engineering Controls : Good general ventilation should be 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
- Personal Protection Measures



- Respiratory Protection : Not required for the normal use of the product. If the applicable Occupational Exposure limit
- Eye Protection : Chemical splash goggles; face shield when splash hazard exists
- Skin Protection : Work uniform, laboratory coat or disposable garment is recommended
- Hands : Protective Latex or Nitrile gloves
- Hygiene measures : Wash hands following use. No eating, drinking, or smoking while handling this product

9 - PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : Clear, colorless solution
- pH : Between 7.5 to 8.5
- Specific gravity : About 1

10 - STABILITY AND REACTIVITY

- Reactivity : Not Reactive
- Chemical Stability : Stable under normal conditions
- Possibility of Hazardous Reactions : N/A
- 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 : Avoid storage strong acids, strong bases, products incompatible with water
- Hazardous Decomposition Products : May emit fumes under fire conditions

11 - TOXICOLOGICAL INFORMATION

- Acute Toxicity : 10 mg/kg
- Inhalation: LD50 Oral
- Sodium hydroxide : Oral- Rabbit LD Lo: 500 m g/kg [Details of toxic effects not reported other than lethal dose value]
- Hydrochloric acid : Oral - Rabbit LD50: 900 m g/k g [Details of toxic effects not reported other than lethal dose value] (RTECS)
- Carcinogenesis : Carcinogenicity studies have not been conducted with arsenic trioxide.
- Mutagenesis : Arsenic trioxide and trivalent arsenite salts have not been demonstrated to be mutagenic to bacteria, yeast, or mammalian cells. Arsenite salts are clastogenic in vitro (human fibroblast, human lymphocytes, Chinese hamster ovary cells, Chinese hamster V79 lung cells). Trivalent arsenic was genotoxic in the chromosome aberrations assay and micronucleus bone marrow assay in mice.
- Impairment of Fertility : The effect of arsenic on fertility has not been adequately studied in humans. Decreased testicular weight and impaired spermatogenesis have been reported in animal studies. Male Wistar rat pups were administered 1.5 mg/kg sodium arsenite solution via the intraperitoneal route from postnatal days 1 to 14 and testes were collected for evaluation on postnatal days 15, 21, and 50. Results of this study revealed an altered morphology of the seminiferous tubules along with degeneration of spermatogenic cells, increased number of sperm with abnormal morphology, and decreased sperm counts. In beagle dogs administered intravenous arsenic trioxide for 90 days, reduced inner cell layers within



semiferous tubules and significantly decreased numbers of spermatocytes, spermatozoa, and sperm cells were observed at doses of 1 mg/kg/day and higher. The 1 mg/kg/day dose is approximately 3 times the recommended human daily dose on a mg/m² basis

12 - ECOLOGICAL INFORMATION

Ecotoxicity	: Not available
Persistence and degradability	: Not available
Bio accumulative potential	: Not available
Mobility in soil	: Not available
Other Adverse Effects	: Not available

13 - DISPOSAL CONSIDERATIONS

Dispose of in accordance with local, state, and federal regulations

14 - TRANSPORT INFORMATION

UN Number	: Not hazardous for transport
Transport Hazard Class(es) (ADR / RID / ADN (land transport)	: Not hazardous for transport
IMDG (sea transport)	: Not hazardous for transport
IATA / ICAO (air transport)	: Not hazardous for transport
Environmental Hazards (Marine Pollutant)	: No information available

15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture:

TSCA	: Listed
CERCLA	: Listed
SARA 302	: Not on this list
SARA 313	: Not on this list
CA Prop 65	: Listed

16 - OTHER INFORMATION

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterways (adopted in 2000)
°C	Degree centigrade
F	Foreign heat
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CPR	Controlled Products Regulations
IARC	International Agency for Research on Cancer
ICAO	International Civil Aviation Organization



IATA	International Air Transport Association
IMO	International Maritime Organization
IMDG	International Maritime Dangerous Goods
Mg	Milligram
mL	Millilitre
MSDS	Material Safety Data Sheet
NA	Not Applicable, except in Section 14 where NA = North America
RID	Regulations concerning the international carriage of dangerous goods by rail (EU)
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TSCA	Toxic Substances Control Act
UN	United Nations
USA	United States of America
USP	United States Pharmacopeia