

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name	Arsenic Trioxide 1 mg/ml concentrate for solution for infusion
CAS	-
EINECS	No information available
Index No	No information available
Reach Registration Number	No information available

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use	Pharmaceutical
Uses advised against	No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer	Alidac Pharmaceuticals Ltd, Matoda, Ahmedabad:382213, INDIA
Supplier	Zydus Pharmaceuticals USA Inc. 73 Route 31 North Pennington, NJ 08534

For further information, please contact

E-mail Address	pshah@zydususa.com
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1.4. Emergency Telephone Number

Emergency Telephone Number	(609) 730-1900 Ext. 109
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SECTION 2: Hazards identification

2.1. - Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008
Exempt from requirements - regulated as a medicinal product.

2.2. Label Elements

Exempt from requirements - regulated as a medicinal product

2.3. Other hazards

None known

SECTION 3: Composition/information on ingredients

3.1. Substances

N.A.

3.2. Mixtures

Chemical Name	EC No.	REACH Reg. No.	CAS-No	Weight %	CLP/GHS classification
Arsenic Trioxide	EEC No. 215-481-4	Not available	1327-53-3	1 mg/ml	Acute Tox. 2; H300 Skin Corr. 1B; H314 Carc. 1A; H350 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
Sodium hydroxide	EEC No. 215-185-5	01-2119457892-27-XXXX	1310-73-2	< 1	Met. Corr. 1; H290 Skin Corr. 1A; H314
Hydrochloric Acid	EEC No. 231-595-7	01-2119484862-27-XXXX	7647-01-0	< 1	Met. Corr. 1; H290 Skin Corr. 1B; H314 STOT SE 3; H335

Full text of phrases reported in section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Skin Contact	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes.
Ingestion	Clean mouth with water, only if the person is conscious. Get medical attention.
Inhalation	If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Remove from exposure, lie down.

4.2. Most important symptoms and effects, both acute and delayed

See product insert.

4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Foam. Dry powder.

Unsuitable extinguishing media

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

5.3. Advice for firefighters

Special protective equipment for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors.

6.1.1. For non-emergency personnel

Protective equipment See section 8

Emergency procedures Evacuate the danger area and alert emergency team

6.1.2. For emergency responders

See section 8

6.2. Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so.

6.3. Methods and materials for containment and cleaning up

6.3.1. Methods for Containment

No information available.

6.3.2. For cleaning up

Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see Section 13).

6.3.3. Other information

No information available

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for Safe Handling

Handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Keep tightly closed in a dry and cool place. Keep away from direct sunlight. Avoid excessive heat. Protect from light. Keep in properly labeled containers. Keep at temperatures between 15 °C and 30 °C

7.3. Specific end use(s)

Exposure Scenario

No information available.

Other Guidelines

No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

No occupational exposure limit values have been defined by authorities in production Country.

Biological occupational exposure limits

No information available.

Derived No Effect Level (DNEL)

No information available.

Predicted No Effect Concentration (PNEC)

No information available.

8.2. Exposure controls

Engineering Measures

Appropriate Engineering Controls.

Personal protective equipment

Eye/face protection

Use eye protection appropriate for the task.

Skin protection:

- Body protection

Use protective clothing appropriate for the task.

- Hand protection

Use appropriate protective gloves.

Respiratory Protection

Use appropriate respiratory protection.

Environmental exposure controls

No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Color	Clear colorless
Physical State	aqueous solution
Odor	No information available
Odour Threshold	No information available
pH	7.0-9.0
Melting Point/Range	No information available
Boiling Point/Range	~100 °C
Flash Point	No information available
Evaporation Rate	Similar to water
Flammability (solid, gas)	No information available
Flammability Limits in Air	
Upper	No information available
Lower	No information available
Vapor Pressure	Similar to water
Vapor Density	Similar to water
Relative Density	No information available
Solubility	No information available
Water Solubility	Soluble in water
Autoignition Temperature	No information available
Decomposition Temperature	No information available
Viscosity	No information available
Explosive Properties	No information available
Oxidizing Properties	No information available
9.2. Other information	
Specific Gravity	~1
Freezing point	~0 °C

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical Stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

Do not expose to extreme temperatures.

10.5. Incompatible materials.

Strong acids. Strong bases. compounds incompatible with water.

10.6. Hazardous decomposition products

May emit toxic fumes under fire conditions.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

acute toxicity

LD50 Oral rat	10 mg/kg (Arsenic trioxide)
skin corrosion/irritation serious	No information available. No
eye damage/irritation respiratory	information available. No
or skin sensitization	information available.

germ cell mutagenicity

No information available.

carcinogenicity

Evidence of carcinogenicity in animal studies. (Arsenic trioxide).

reproductive toxicity

Predicted reproductive and developmental toxicant based on mechanism of action. Effects in offspring were only observed at or above dosage levels which resulted in maternal toxicity.

STOT - single exposure

No information available.

STOT - repeated exposures

No information available.

aspiration hazard

No information available.

Other Information

No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity effects

No information available.

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

Endocrine Disruptor Information

Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from Residues/Unused Products

Dispose of in accordance with local regulations.

Contaminated Packaging

Empty containers should be taken for local recycling, recovery or waste disposal.

SECTION 14: Transport information

14.1.

UN-No

Not hazardous for transport

14.2.

Proper Shipping Name

Not hazardous for transport

14.3. 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

14.4.

Packing Group

Not hazardous for transport

14.5. Environmental hazards

Marine Pollutant

No information available

14.6. Special precautions for user

Emergency No.

No information available

ADR/RID-Labels

No information available

SECTION 15: Regulatory information

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

- Regulation 1907/2006/EC (REACH) and successive modifications
- Regulation 1272/2008 (CLP) and successive modifications
- D.Lgs. 81/2008 and successive modifications and Dir. 2009/161/EU
- REGULATION (EU) 2015/830

15.2. Chemical Safety Assessment

No information available

SECTION 16: Other information

CLP/GHS - Regulation

Hazard Statements

Full text of H-Statements referred to under sections 2 and 3

H290 - May be corrosive to metals

H300 - Fatal if swallowed

H314 - Causes severe skin burns and eye damage

H335 - May cause respiratory irritation

H350 - May cause cancer

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

Training appropriate for workers is required to ensure protection of human health and environment.

Application/Drug Class Anti cancer.

Source of data

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES

A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS

H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK

N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

N.T.P. - NATIONAL TOXICOLOGY PROGRAM

I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

ECHA (European chemicals agency) databases

FDA (Food & Drug administration) database

EMA (European Medicines agency) documents

ChemAdvisor

Chemspider database

Issuing Date 27-Oct-2018

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End of Safety Data Sheet