Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Arsenic Trioxide Injection

Other means of identification : 12 mg per 6 mL single dose vial, NDC 55150-366-01 (single vial), NDC 55150-366-10 (pack of 10)

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

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

AuroMedics

279 Princeton Highstown Road East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Skin Irrit. 2 H315 Eye Irrit. 2 H319 Carc. 1A H350

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US)





GHS08

GHS07

Signal word (GHS US) : Danger

Hazard statements (GHS US) : H315 - Causes skin irritation

H319 - Causes serious eye irritation

H350 - May cause cancer

Precautionary statements (GHS US) : P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P264 - Wash hands, forearms and face thoroughly after handling.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 - If on skin: Wash with plenty of water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

P405 - Store locked up.

P501 - Dispose of contents/container to hazardous or special waste collection point, in

accordance with local, regional, national and/or international regulation.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

11/05/2021 EN (English US) Page 1

Safety Data Sheet

SECTION 3: Composition/Information on ingredients

Substances

Not applicable

3.2. **Mixtures**

| Name | Product identifier | % | GHS US classification |
|-------------------|---------------------|------|--|
| Water | (CAS-No.) 7732-18-5 | 99.8 | Not classified |
| Hydrochloric acid | (CAS-No.) 7647-01-0 | <1 | Skin Corr. 1, H314 Eye Dam. 1, H318 |
| Sodium hydroxide | (CAS-No.) 1310-73-2 | < 1 | Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 |
| Arsenic trioxide | (CAS-No.) 1327-53-3 | 0.2 | Acute Tox. 2 (Oral), H300 Skin Corr. 1B, H314 Carc. 1A, H350 |

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. **Description of first aid measures**

First-aid measures after inhalation : If not breathing, give artificial respiration.

First-aid measures after skin contact Remove affected clothing and wash all exposed skin area with mild soap and water, followed

by warm water rinse.

In case of contact with eyes, rinse immediately with plenty of water. First-aid measures after eye contact

First-aid measures after ingestion Go into open air and ventilate suspected area.

Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : None anticipated during normal product use.

Symptoms/effects after skin contact Causes skin irritation. Symptoms/effects after eye contact Causes serious eye irritation. Symptoms/effects after ingestion : May be harmful if swallowed.

Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media None.

Special hazards arising from the substance or mixture

Fire hazard : None known.

Advice for firefighters 5.3.

Protection during firefighting : During all fire fighting activities, wear appropriate protective equipment, including self-contained

breathing apparatus.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

Environmental precautions

Prevent entry to sewers and public waters.

Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

Methods for cleaning up Absorb spillage with suitable absorbent material. Place in a suitable container and dispose

according to local, state and federal regulations.

11/05/2021 EN (English US) 2/7

Safety Data Sheet

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid prolonged and repeated contact. Wear appropriate personal protective equipment.

Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 20° to 25°C (68° to 77°F).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Arsenic trioxide (1327-53-3)

| Not applicable | | |
|-------------------------------|-------------------------|---------|
| Hydrochloric acid (7647-01-0) | | |
| ACGIH | ACGIH OEL Ceiling [ppm] | 2 ppm |
| OSHA | OSHA PEL (Ceiling) | 7 mg/m³ |
| OSHA | OSHA PEL C [ppm] | 5 ppm |
| IDLH | IDLH [ppm] | 50 ppm |
| NIOSH | NIOSH REL (Ceiling) | 7 mg/m³ |
| NIOSH | NIOSH REL C [ppm] | 5 ppm |

| Sodium hydroxide (1310-73- | Sodium hydroxide (1310-73-2) | |
|----------------------------|------------------------------|----------|
| ACGIH | ACGIH OEL Ceiling | 2 mg/m³ |
| OSHA | OSHA PEL (TWA) [1] | 2 mg/m³ |
| IDLH | IDLH | 10 mg/m³ |
| NIOSH | NIOSH REL (Ceiling) | 2 mg/m³ |

Water (7732-18-5)

Not applicable

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : No protection is ordinarily required under normal conditions of use.

Eye protection : Wear safety glasses or goggles. Skin and body protection : Wear suitable working clothes.

Respiratory protection : No protection is ordinarily required under normal conditions of use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear.
Color : Colorless
Odor : Odorless

Odor threshold : No data available pH : No data available Melting point : No data available Freezing point : No data available Boiling point : No data available Flash point : No data available Relative evaporation rate (butyl acetate=1) : No data available

11/05/2021 EN (English US) 3/7

Safety Data Sheet

Flammability (solid, gas) : No data available Vapor pressure : No data available Relative vapor density at 20 °C : No data available Relative density : No data available Solubility : completely soluble. Partition coefficient n-octanol/water (Log Pow) : No data available Auto-ignition temperature : No data available Decomposition temperature : No data available Viscosity, kinematic : No data available Viscosity, dynamic : No data available **Explosion limits** : No data available Explosive properties : No data available Oxidizing properties : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Air contact.

10.5. Incompatible materials

Serious eye damage/irritation

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

| Arsenic trioxide (1327-53-3) | |
|-------------------------------|--------------------------------|
| LD50 oral rat | 20 mg/kg |
| ATE US (oral) | 20 mg/kg body weight |
| Hydrochloric acid (7647-01-0) | |
| LD50 oral rat | 238 – 277 mg/kg |
| LD50 dermal rabbit | > 5010 mg/kg |
| LC50 Inhalation - Rat | 1.68 mg/l (Exposure time: 1 h) |
| ATE US (oral) | 238 mg/kg body weight |
| ATE US (vapors) | 1.68 mg/l/4h |
| ATE US (dust, mist) | 1.68 mg/l/4h |
| Sodium hydroxide (1310-73-2) | |
| LD50 oral rat | 140 – 340 mg/kg |
| LD50 dermal rabbit | 1350 mg/kg |
| ATE US (dermal) | 1350 mg/kg |
| Water (7732-18-5) | |
| LD50 oral rat | > 90 ml/kg |
| Skin corrosion/irritation | : Causes skin irritation. |

11/05/2021 EN (English US) 4/7

: Causes serious eye irritation.

Safety Data Sheet

Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : May cause cancer.

| Arsenic trioxide (1327-53-3) | |
|--|-----------------------------|
| IARC group | 1 - Carcinogenic to humans |
| National Toxicology Program (NTP) Status | 2 - Known Human Carcinogens |
| In OSHA Hazard Communication Carcinogen list | Yes |
| Hydrochloric acid (7647-01-0) | |

3 - Not classifiable

Reproductive toxicity : Not classified STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

IARC group

| Arsenic trioxide (1327-53-3) | | |
|------------------------------|--|--|
| LC50 - Fish [1] | 135 mg/l (Exposure time: 96 h - Species: Pimephales promelas) | |
| LC50 - Fish [2] | 18.8 – 21.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [flow-through]) | |
| Sodium hydroxide (1310-73-2) | | |

LC50 - Fish [1] 45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

| Arsenic trioxide (1327-53-3) | |
|---|----------------------------------|
| BCF - Fish [1] | 80 – 236 (valence not specified) |
| Partition coefficient n-octanol/water (Log Pow) | 18.1 (at 20 °C) |

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

11/05/2021 EN (English US) 5/7

Safety Data Sheet

SECTION 15: Regulatory information

15.1. US Federal regulations

| Arsenic trioxide (1327-53-3) | | |
|--|---|--|
| ` | Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 | |
| CERCLA RQ | 1 lb | |
| SARA Section 302 Threshold Planning Quantity (TPQ) | 100 – 10000 lb | |
| Hydrochloric acid (7647-01-0) | | |

| | Tryanochione acia (1011 01 0) | |
|---|--|--|
| | Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 | |
| | | |
| | Subject to reporting requirements of United States SARA Section 313 | |
| CERCLA RQ 5000 lb | | 5000 lb |
| SARA Section 302 Threshold Planning Quantity (TPQ) 500 lb (gas only) | | 500 lb (gas only) |
| SARA Section 313 - Emission Reporting 1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any | | 1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle |

| Sodium hydroxide (1310-73 | -2) | |
|---|---------|---------|
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | | ventory |
| CERCLA RO | 1000 lb | |

| Water (7732-18-5) |
|---|
| Listed on the United Otates TOOA (Tasis Outstands of Outstands Act) inves |

Listed on the United States TSCA (Toxic Substances Control Act) inventory

size)

15.2. US State regulations

Arsenic trioxide (1327-53-3)

- U.S. Massachusetts Right To Know List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List

Hydrochloric acid (7647-01-0)

- U.S. Massachusetts Right To Know List
- U.S. Minnesota Hazardous Substance List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List

Sodium hydroxide (1310-73-2)

- U.S. Massachusetts Right To Know List
- U.S. Minnesota Hazardous Substance List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

| Acute Tox. 2 (Oral) | Acute toxicity (oral) Category 2 |
|---------------------|--|
| Carc. 1A | Carcinogenicity Category 1A |
| Eye Dam. 1 | Serious eye damage/eye irritation Category 1 |
| Eye Irrit. 2 | Serious eye damage/eye irritation Category 2 |
| Met. Corr. 1 | Corrosive to metals Category 1 |
| Skin Corr. 1 | Skin corrosion/irritation Category 1 |
| Skin Corr. 1A | Skin corrosion/irritation Category 1A |
| Skin Corr. 1B | Skin corrosion/irritation Category 1B |
| Skin Irrit. 2 | Skin corrosion/irritation Category 2 |
| H290 | May be corrosive to metals |
| H300 | Fatal if swallowed |
| H314 | Causes severe skin burns and eye damage |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H350 | May cause cancer |

11/05/2021 EN (English US) 6/7

Arsenic Trioxide InjectionSafety Data Sheet

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

EN (English US) 11/05/2021 7/7