

# Argatroban in Sodium Chloride Injection

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Argatroban in Sodium Chloride Injection  
Other means of identification : 50 mL single-dose vial (NDC 55150-241-01), Carton of 10 vials (NDC 55150-241-10)

#### 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

Not classified

#### 2.2. Label elements

##### GHS-US labeling

No labeling applicable

#### 2.3. Other hazards

No additional information available

#### 2.4. Unknown acute toxicity (GHS US)

Not applicable

### SECTION 3: Composition/Information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

| Name                 | Product identifier  | %     | GHS-US classification |
|----------------------|---------------------|-------|-----------------------|
| Water                | (CAS No) 7732-18-5  | <= 99 | Not classified        |
| Sodium chloride      | (CAS No) 7647-14-5  | 0.9   | Not classified        |
| D-Glucitol           | (CAS No) 50-70-4    | 0.3   | Not classified        |
| Argatroban anhydrous | (CAS No) 74863-84-6 | 0.1   | Not classified        |

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 inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

First-aid measures after skin contact : In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.

First-aid measures after eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

First-aid measures after ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

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

Symptoms/injuries after inhalation : Inhalation not likely under normal use conditions. May cause respiratory tract irritation.

Symptoms/injuries after skin contact : May cause irritation and/or allergic reactions.

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Symptoms/injuries after eye contact : May cause eye irritation.  
Symptoms/injuries after ingestion : May be harmful if swallowed.

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.  
Unsuitable extinguishing media : None.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

### 5.3. Advice for firefighters

Protection during firefighting : Firefighters should wear full protective gear.

## SECTION 6: Accidental release measures

### 6.1. 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

No additional information available

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

For containment : For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

### 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 : Wash thoroughly after handling.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F).

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Water (7732-18-5)

Not applicable

#### Sodium chloride (7647-14-5)

Not applicable

#### Argatroban anhydrous (74863-84-6)

Not applicable

#### D-Glucitol (50-70-4)

Not applicable

### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.  
Hand protection : Use chemical resistant, impervious gloves.

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|                          |  |
|--------------------------|--|
| Eye protection           | : Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use. |
| Skin and body protection | : Wear suitable working clothes.   |
| Respiratory protection   | : If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.                                  |

### 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 |
| 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                                  | : Soluble in 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

None.

#### 10.5. Incompatible materials

Oxidizing agents.

#### 10.6. Hazardous decomposition products

None known.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

|                |                  |
|----------------|------------------|
| Acute toxicity | : Not classified |
|----------------|------------------|

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| <b>Water (7732-18-5)</b>                           |  |
|--|--|
| LD50 oral rat                                      | > 90 ml/kg                                 |
| <b>Sodium chloride (7647-14-5)</b>                 |  |
| LD50 oral rat                                      | 3 g/kg                                     |
| LC50 inhalation rat (mg/l)                         | > 42 g/m <sup>3</sup> (Exposure time: 1 h) |
| ATE US (oral)                                      | 3000000 mg/kg                              |
| <b>D-Glucitol (50-70-4)</b>                        |  |
| LD50 oral rat                                      | 15900 mg/kg                                |
| Skin corrosion/irritation                          | : Not classified                           |
| Serious eye damage/irritation                      | : Not classified                           |
| Respiratory or skin sensitization                  | : Not classified                           |
| Germ cell mutagenicity                             | : Not classified                           |
| Carcinogenicity                                    | : Not classified                           |
| Reproductive toxicity                              | : Not classified                           |
| Specific target organ toxicity – single exposure   | : Not classified                           |
| Specific target organ toxicity – repeated exposure | : Not classified                           |
| Aspiration hazard                                  | : Not classified                           |

## SECTION 12: Ecological information

### 12.1. Toxicity

| <b>Sodium chloride (7647-14-5)</b> |  |
|------------------------------------|--|
| LC50 fish 1                        | 5560 - 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through]) |
| EC50 Daphnia 1                     | 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)                             |
| LC50 fish 2                        | 12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])             |
| EC50 Daphnia 2                     | 340.7 - 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])           |

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

| <b>Sodium chloride (7647-14-5)</b> |                      |
|------------------------------------|----------------------|
| BCF fish 1                         | (no bioaccumulation) |

### 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

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### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

**Water (7732-18-5)**

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

**Sodium chloride (7647-14-5)**

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

**D-Glucitol (50-70-4)**

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

#### 15.2. US State regulations

No additional information available

### SECTION 16: Other information

*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*