## Section 1 - Identification

| | | |
|---|---|---|
| **(a)** | **Product Identifier:** | Argatroban Injection |
| **(b)** | **NDC:** | 25021-414-50 |
| | **Common/Trade Name:** | Argatroban |
| | **Chemical Name:** | 1-[5 [(aminoiminomethyl) amino]-1-oxo-2-[[(1, 2, 3, 4-tetrahydro-3-methyl-8- quinolinyl) sulfonyl] amino] pentyl]-4-methyl-2-piperidinecarboxylic acid, monohydrate |
| | **Chemical Family:** | Direct thrombin inhibitor |
| **(c)** | **Product Use:** | Pharmaceutical |
| | **Product Type:** | Regulated Prescription Drug |
| | **Container Information:** | Prefilled Vial |
| **(d)** | **Distributor:** | Sagent Pharmaceuticals, 1901 N. Roselle Rd, Suite 450, Schaumburg, IL 60195, 847-908-1600 |
| **(e)** | **Emergency Telephone:** | 866-625-1618 |

## Section 2 - Hazards Identification

| | | |
|---|---|---|
| **(a)** | **Classification:** | Not classified. |
| **(b)** | **Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):** | Not applicable. |
| **(c)** | **Description of Hazards:** | No known significant effects or critical hazards. |
| **(d)** | **Unknown Acute Toxicity:** | Not applicable. |

## Section 3 – Composition / Information on Ingredients

| (a) Chemical Name | (b) Common Name / Synonym | % Composition or other measure | (c) CAS No. | (d) Impurities / Stabilizing Additives |
|---|---|---|---|---|
| Argatroban | Argatroban | 50 mg in 50 mL | 74863-84-6 | N/A |

## Section 4 - First Aid Measures

**Eye Exposure:** Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

**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:** N/A

**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.

## Section 5 –Fire-fighting Measures

**(a) Extinguishing Media** Use an extinguishing agent suitable for the surrounding fire.

**(b) Hazardous Combustion Products:** Not determined

**(c) Special Protective Equipment / Precautions:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-based and is not expected to present a fire hazard concern.

## Section 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.

**Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

## Section 7 - Handling and Storage

**General Handling:** Put on appropriate personal protective equipment (see Section 8).

**Storage Conditions:** Store in original carton at 20° to 25° C (68° to 77° F) [See USP Controlled Room Temperature]. Do not freeze. Retain in the original carton to protect from light. If the solution is cloudy, or if an insoluble precipitate is noted, the vial should be discarded.

## Section 8 - Exposure Controls / Personal Protection

### (a) Exposure Limits

| Compound | Issuer | Type | Exposure Limit |
|---|---|---|---|
| Argatroban | N/A | N/A | N/A |

### (b) Engineering Controls

Ventilation: Good general ventilation should be sufficient to control airborne levels.

### (c) Individual Protection Measures

| | |
|---|---|
| Respiratory Protection: | Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use. |
| Eye Protection: | Safety glasses |
| Skin Protection: | Work uniform or laboratory coat. |
| Other Protective Equipment: | Protective Latex or Nitrile gloves |

| | |
|---|---|
| Additional Exposure Precautions: | Wash hands following use. No eating, drinking, or smoking while handling this product. |

## Section 9 - Physical and Chemical Properties

| | | |
|---|---|---|
| **(a)** | **Appearance** | Clear, colorless to pale yellow, solution |
| **(b)** | **Odor** | Not available |
| **(c)** | **Odor Threshold** | Not available |
| **(d)** | **pH** | Not available |
| **(e)** | **Melting Point:** | Not available |
| **(f)** | **Initial Boiling Point:** | Not available |
| **(g)** | **Flash Point** | Not available |
| **(h)** | **Evaporation Rate:** | Not available |
| **(i)** | **Flammability** | Not available |
| **(j)** | **Upper Lower Flammability or Explosion Limits** | Not available |
| **(k)** | **Vapor Pressure:** | Not available |
| **(l)** | **Vapor Density:** | Not available |
| **(m)** | **Relative Density** | Not available |
| **(n)** | **Solubility(ies)** | Not available |
| **(o)** | **Partition Coefficient: n-octanol/water** | Not available |
| **(p)** | **Auto-ignition Temperature** | Not available |
| **(q)** | **Decomposition Temperature** | Not available |
| **(r)** | **Viscosity** | Not available |

## Section 10 - Stability and Reactivity

| | | |
|---|---|---|
| **(a)** | **Reactivity** | No specific test data related to reactivity available for this product or its ingredients. |
| **(b)** | **Chemical Stability** | The product is stable. |
| **(c)** | **Possibility of Hazardous Reactions** | Under normal conditions of storage and use, hazardous reactions will not occur. |
| **(d)** | **Conditions to Avoid** | No specific data. |
| **(e)** | **Incompatible Materials** | Not available |

| | | |
|---|---|---|
| **(f)** | **Hazardous Decomposition Products** | Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

## Section 11 - Toxicological Information

| | | |
|---|---|---|
| **(a)** | **Likely Routes of Exposure** | Ingestion, Inhalation, skin, eye |
| **(b)** | **Symptoms related to the physical, chemical and toxicological characteristics** | No data available. |
| **(c)** | **Delayed and immediate effects and also chronic effects from short and long term exposure** | No data available. |

### (d) Acute Toxicity

| Component | Type | Route | Species | Dosage |
|---|---|---|---|---|
| Argatroban | N/A | N/A | N/A | N/A |

- Carcinogenicity studies with argatroban have not been performed.
- Argatroban was not genotoxic in the Ames test, the Chinese hamster ovary cell (CHO/HGPRT) forward mutation test, the Chinese hamster lung fibroblast chromosome aberration test, the rat hepatocyte, and WI-38 human fetal lung cell unscheduled DNA synthesis (UDS) tests, or the mouse micronucleus test.
- Argatroban at intravenous doses up to 27 mg/kg/day (0.3 times the recommended maximum human dose based on body surface area) had no effect on fertility and reproductive function of male and female rats.

### (e) Hazardous Chemical Listings

NTP: No IARC: No OSHA: Not listed NIOSH: Not listed

## Section 12 - Ecological Information

| | | |
|---|---|---|
| **(a)** | **Ecotoxicity** | No data available |

| | | |
|---|---|---|
| **(b)** | **Persistence and degradability** | No data available |
| **(c)** | **Bioaccumulative potential** | No data available |
| **(d)** | **Mobility in soil** | No data available |
| **(e)** | **Other Adverse Effects** | No data available |

## Section 13 - Disposal Considerations

Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

## Section 14 - Transport Information

| | | |
|---|---|---|
| **(a)** | **UN Number** | N/A |
| **(b)** | **UN Proper Shipping Name** | N/A |
| **(c)** | **Transport Hazard Class(es)** | N/A |
| **(d)** | **Packing Group** | N/A |
| **(e)** | **Environmental Hazards** | N/A |
| **(f)** | **Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)** | N/A |
| **(g)** | **Special Precautions** | N/A |

**DOT:** Not dangerous goods.
**IATA:** Not dangerous goods.
**IMDG:** Not dangerous goods.

## Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations**:
TSCA: No
CERCLA: Not on this list
SARA 302: Not on this list
SARA 313: Not on this list
CA Prop 65: Not listed

## Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Sagent Pharmaceuticals
1901 N. Roselle Rd, Suite 450
Schaumburg, IL 60195
847-908-1600

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

| | |
|---|---|
| ACGIH | American Conference of Governmental Industrial Hygienists |
| AIHA | American Industrial Hygiene Association |
| CAS Number | Chemical Abstract Service Registry Number |
| CERCLA | Comprehensive Environmental Response Compensation and Liability Act (of 1980) |
| CHAN | Chemical Hazard Alert Notice |
| CHEMTREC | Chemical Transportation Emergency Center |
| DOT | Department of Transportation |
| EPA | Environmental Protection Agency |
| HEPA | High Efficiency Particulate Air (Filter) |
| IARC | International Agency for Research on Cancer |
| ICAO/IATA | International Civil Aviation Organization/International Air Transport Association |
| IMO | International Maritime Organization |
| KOW | Octanol/Water Partition Coefficient |
| LEL | Lower Explosive Limit |
| MSDS | Material Safety Data Sheet |
| MSHA | Mine Safety and Health Administration |
| NA | Not Applicable, except in Section 14 where NA = North America |
| NE | Not Established |
| NADA | New Animal Drug Application |
| NAIF | No Applicable Information Found |
| NCI | National Cancer Institute |
| NIOSH | National Institute for Occupational Safety and Health |

| | |
|---|---|
| NOS | Not Otherwise Specified |
| NTP | National Toxicology Program |
| OSHA | Occupational Safety and Health Administration |
| OEL | Occupational Exposure Limit |
| PEL | Permissible Exposure Limit (OSHA) |
| RCRA | Resource Conservation and Recovery Act |
| RQ | Reportable Quantity |
| RTECS | Registry of Toxic Effects of Chemical Substances |
| SARA | Superfund Amendments and Reauthorization Act |
| SDS | Safety Data Sheet |
| STEL | Short Term Exposure Limit |
| TLV | Threshold Limit Value (ACGIH) |
| TPQ | Threshold Planning Quantity |
| TSCA | Toxic Substances Control Act |
| TWA | Time Weighted Average/8 Hours Unless Otherwise Noted |
| UEL | Upper Explosive Limit |
| UN | United Nations |
| USP | United States Pharmacopeia |
| WEEL | Workplace Environmental Exposure Level (AIHA) |