

# Icatibant Injection

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Icatibant Injection  
Other means of identification : 30 mg per 3 mL (10 mg/mL) Single-Dose Prefilled Syringe packaged in cartons, NDC 55150-351-01  
30 mg per 3 mL (10 mg/mL) Single-Dose Prefilled Syringe in a pack containing 3 cartons, NDC 55150-351-03

#### 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

Eugia US LLC  
279 Princeton Hightstown 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
Icatibant	(CAS-No.) 138614-30-9	1	Not classified
Sodium chloride	(CAS-No.) 7647-14-5	0.745	Not classified
Acetic acid	(CAS-No.) 64-19-7	0.132	Flam. Liq. 3, H226 Acute Tox. 4 (Dermal), H312
Sodium hydroxide	(CAS-No.) 1310-73-2	0.064	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318

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.  
First-aid measures after eye contact : In case of dust contact with eyes, rinse immediately with plenty of water.  
First-aid measures after ingestion : Go into open air and ventilate suspected area.

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

Symptoms/effects after inhalation : May cause respiratory irritation.  
Symptoms/effects after skin contact : May cause skin irritation.

# Icatibant Injection

## Safety Data Sheet

Symptoms/effects after eye contact : May cause eye irritation.  
Symptoms/effects 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 : Do not enter fire area without proper protective equipment, including respiratory protection.

## 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

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

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

For containment : Stop the flow of material, if this is without risk.  
Methods for cleaning up : Recycle product or dispose safely.

### 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 : Do not eat, drink or smoke when using this product.

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

Storage conditions : Store between 2° to 25° C (36° to 77° F).

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Sodium chloride (7647-14-5)		
Not applicable		
Acetic acid (64-19-7)		
ACGIH	ACGIH OEL TWA [ppm]	10 ppm
ACGIH	ACGIH OEL STEL [ppm]	15 ppm
OSHA	OSHA PEL (TWA) [1]	25 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) [2]	10 ppm
IDLH	IDLH [ppm]	50 ppm
NIOSH	NIOSH REL (TWA)	25 mg/m <sup>3</sup>
NIOSH	NIOSH REL TWA [ppm]	10 ppm
NIOSH	NIOSH REL (STEL)	37 mg/m <sup>3</sup>
NIOSH	NIOSH REL STEL [ppm]	15 ppm

# Icatibant Injection

## Safety Data Sheet

Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) [1]	2 mg/m <sup>3</sup>
IDLH	IDLH	10 mg/m <sup>3</sup>
NIOSH	NIOSH REL (Ceiling)	2 mg/m <sup>3</sup>
Icatibant (138614-30-9)		
Not applicable		

### 8.2. Exposure controls

Appropriate engineering controls	: Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection	: Use neoprene or rubber gloves.
Eye protection	: Wear protective goggles.
Skin and body protection	: Wear suitable working clothes.
Respiratory protection	: Wear NIOSH approved respirator when handling.

## 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	: No data available
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: No data available
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.

# Icatibant Injection

## Safety Data Sheet

### 10.4. Conditions to avoid

Air contact.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Sodium chloride (7647-14-5)	
LD50 oral rat	3 g/kg
LD50 dermal rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation - Rat	> 42 g/m <sup>3</sup> (Exposure time: 1 h)
ATE US (oral)	3000000 mg/kg

Acetic acid (64-19-7)	
LD50 oral rat	3310 mg/kg
LD50 dermal rabbit	1060 mg/kg
LC50 Inhalation - Rat	11.4 mg/l/4h
ATE US (oral)	3310 mg/kg
ATE US (dermal)	1060 mg/kg

Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 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  
STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

Sodium chloride (7647-14-5)	
LC50 - Fish [1]	5560 – 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [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 - Crustacea [2]	340.7 – 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Acetic acid (64-19-7)	
LC50 - Fish [1]	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 - Fish [2]	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

Sodium hydroxide (1310-73-2)	
LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

# Icatibant Injection

## Safety Data Sheet

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

Sodium chloride (7647-14-5)	
BCF - Fish [1]	(no bioaccumulation)
Acetic acid (64-19-7)	
Partition coefficient n-octanol/water (Log Pow)	-0.31 (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

### International Air Transport Association (IATA)

In accordance with IATA

Not applicable

## SECTION 15: Regulatory information

### 15.1. US Federal regulations

Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Acetic acid (64-19-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	5000 lb
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb

### 15.2. US State regulations

Acetic acid (64-19-7)	
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	

# Icatibant Injection

## Safety Data Sheet

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 3	Flammable liquids Category 3
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage

*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.*