

Ibandronate Sodium Injection 3 mg/3 mL

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Ibandronate Sodium Injection 3 mg/3 mL
Other means of identification : 1 mg/mL, 3 mL PFS NDC 55150-191-83

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
6 Wheelling Road
Dayton, NJ 08810
T 609-642-1136

1.4. Emergency telephone number

Emergency number : 888-238-7880, option 2

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

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. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Water	(CAS No) 7732-18-5	> 98	Not classified
Ibandronate (as ibandronate sodium monohydrate)	(CAS No) 138926-19-9	0.1	Not classified
Acetic acid	(CAS No) 64-19-7	< 0.1	Flam. Liq. 3, H226 Acute Tox. 4 (Dermal), H312
Sodium chloride	(CAS No) 7647-14-5	< 1	Not classified
Sodium acetate trihydrate	(CAS No) 6131-90-4	< 0.1	Not classified

Full text of H-phrases: 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 : Drench affected area with water.
First-aid measures after eye contact : Rinse immediately with tap water for 10 minutes - open eyelids forcibly.
First-aid measures after ingestion : Seek immediate medical attention.

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

Symptoms/injuries after inhalation : May cause irritation to mucous membranes.
Symptoms/injuries after skin contact : May cause skin irritation.
Symptoms/injuries after eye contact : May causes eye irritation.
Symptoms/injuries after ingestion : May be harmful if swallowed.

Ibandronate Sodium Injection 3 mg/3 mL

Safety Data Sheet

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 : Stop the flow of material, if this is without risk.
Methods for cleaning up : Confine spill and soak up with absorbent. Place in an approved container and dispose in accordance with local, state and federal regulations.

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 contact with eyes, skin or clothing. Wash after handling.

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

Acetic acid (64-19-7)		
ACGIH	ACGIH TWA (ppm)	10 ppm
ACGIH	ACGIH STEL (ppm)	15 ppm
OSHA	OSHA PEL (TWA) (mg/m ³)	25 mg/m ³
OSHA	OSHA PEL (TWA) (ppm)	10 ppm

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 : Safety glasses.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : None necessary during normal operations.

Ibandronate Sodium Injection 3 mg/3 mL

Safety Data Sheet

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	: 4.2 - 5.3
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
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Vapor pressure	: No data available
Relative density	: No data available
Relative vapor density at 20 °C	: No data available
Solubility	: Completely soluble.
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: 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

Temperatures above 25°C.

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

Acetic acid (64-19-7)	
LD50 oral rat	3310 mg/kg
LD50 dermal rabbit	1060 mg/kg

Ibandronate Sodium Injection 3 mg/3 mL

Safety Data Sheet

Acetic acid (64-19-7)	
LC50 inhalation rat (mg/l)	11.4 mg/l/4h
ATE US (oral)	3310.000 mg/kg
ATE US (dermal)	1060.000 mg/kg

Sodium chloride (7647-14-5)	
LD50 oral rat	3 g/kg
LC50 inhalation rat (mg/l)	> 42 g/m ³ (Exposure time: 1 h)
ATE US (oral)	3000000.000 mg/kg

Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg

Skin corrosion/irritation : Not classified
pH: 4.2 - 5.3

Serious eye damage/irritation : Not classified
pH: 4.2 - 5.3

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

Acetic acid (64-19-7)	
LC50 fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 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 chloride (7647-14-5)	
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

Acetic acid (64-19-7)	
Log Pow	-0.31 (at 20 °C)

Sodium chloride (7647-14-5)	
BCF fish 1	(no bioaccumulation)

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Ibandronate Sodium Injection 3 mg/3 mL

Safety Data Sheet

Effect on the global warming : No known ecological damage caused by this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste 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 regulated for transport

SECTION 15: Regulatory information

15.1. US Federal regulations

Acetic acid (64-19-7)

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

Water (7732-18-5)

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

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

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Flam. Liq. 3	Flammable liquids Category 3
H226	Flammable liquid and vapor
H312	Harmful in contact with skin

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