Lacosamide Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Date of Issue: 11/08/2022 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Lacosamide Injection, USP

Synonyms: Lacosamide

1.2. Intended Use of the Product

Lacosamide Injection is Indicated for the treatment of partial-onset seizures in patients 17 years of age and older.

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
http://www.fresenius-kabi.com/us/

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
(800)255-3924 (North America)
+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Not classified

2.2. Label Elements

GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	water / AQUA	(CAS-No.) 7732-18-5	> 98	Not classified
Lacosamide	Propanamide, 2-(acetylamino)-3-methoxy-N-(phenylmethyl)-, (2R)- / (R)-2-(acetylamino)-N-benzyl-3-methoxypropanamide	(CAS-No.) 175481-36-4	1.0	Acute Tox. 4 (Oral), H302 Eye Irrit. 2B, H320
Sodium chloride	Salt / Sodium salt of hydrochloric acid / SODIUM CHLORIDE / Sodium chloride (NaCl) / Sea salt	(CAS-No.) 7647-14-5	< 1.0	Not classified
Hydrochloric acid	HYDROCHLORIC ACID / Hydrochloric acid, anhydrous / Muriatic acid / Hydrogen chloride / hydrochloric acid	(CAS-No.) 7647-01-0	< 0.1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401

Full text of H-statements: see section 16.

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.
Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.
Skin Contact: Remove contaminated clothing. Wash with plenty of soap and water. Obtain medical attention if irritation develops or persists.
Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.
Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.
Inhalation: Prolonged exposure may cause irritation.
Skin Contact: Prolonged exposure may cause skin irritation.
Eye Contact: May cause slight irritation to eyes.
Ingestion: Ingestion may cause adverse effects.
Adverse effects may include Dizziness, Diplopia, Headache disorder, Nausea, Vomiting, Blurred vision, Ataxia, Vertigo, Injection site sequelae, Diarrhea, Fatigue, Gait abnormality, General weakness, Drowsiness, Tremor, Nystagmus, Pruritus of skin, Memory impairment, Oral hypoesthesia, Fast/slow/irregular/pounding heartbeat, Chest pain, Shortness of breath, Fainting.
Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Not flammable. Solutions do not burn. Use extinguishing media appropriate for surrounding fire.
Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Product is not flammable.
Explosion Hazard: Product is not explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.
Firefighting Instructions: Use water spray or fog for cooling exposed containers.
Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous Combustion Products: None expected under normal conditions of use. Thermal decomposition can lead to the release of irritating gases and vapors.
Other Information: No additional information available.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).
Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material, then place in suitable container. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Material may be biologically contaminated with pathogenic organisms. Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropiately to minimize risk of accidents.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations. Lacosamide is a DEA Schedule V controlled substance.

Storage Conditions: Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature] . Do not freeze.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Lacosamide Injection is Indicated for the treatment of partial-onset seizures in patients 17 years of age and older.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA OSHA	OSHA PEL (Ceiling)	7 mg/m³
USA OSHA	OSHA PEL C [ppm]	5 ppm
USA NIOSH	NIOSH REL (Ceiling)	7 mg/m³
USA NIOSH	NIOSH REL C [ppm]	5 ppm
USA IDLH	IDLH [ppm]	50 ppm
Alberta	OEL C	3 mg/m³
Alberta	OEL Ceiling [ppm]	2 ppm
British Columbia	OEL Ceiling [ppm]	2 ppm
Manitoba	OEL Ceiling [ppm]	2 ppm
New Brunswick	OEL C	7.5 mg/m³
New Brunswick	OEL Ceiling [ppm]	5 ppm
Newfoundland & Labrador	OEL Ceiling [ppm]	2 ppm
Nova Scotia	OEL Ceiling [ppm]	2 ppm
Nunavut	OEL Ceiling [ppm]	2 ppm
Northwest Territories	OEL Ceiling [ppm]	2 ppm
Ontario	OEL Ceiling [ppm]	2 ppm
Prince Edward Island	OEL Ceiling [ppm]	2 ppm
Québec	Plafond (OEL Ceiling) [ppm]	2 ppm
Saskatchewan	OEL Ceiling [ppm]	2 ppm

Yukon	OEL C	7 mg/m³
Yukon	OEL Ceiling [ppm]	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles or glasses.

Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles or safety glasses with side shields.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	:	Liquid
Appearance	:	Clear, colorless sterile solution
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	3.8 – 5.0
Evaporation Rate	:	No data available
Melting Point	:	~ 0 °C (32 °F)
Freezing Point	:	~ 0 °C (32 °F)
Boiling Point	:	~ 100 °C (212 °F)
Flash Point	:	No data available
Auto-ignition Temperature	:	No data available
Decomposition Temperature	:	No data available
Flammability	:	Not applicable
Lower Flammable Limit	:	No data available
Upper Flammable Limit	:	No data available
Vapor Pressure	:	No data available
Relative Vapor Density at 20°C	:	No data available
Relative Density	:	~ 1 (Water = 1)
Specific Gravity	:	No data available
Solubility	:	Fully miscible in water.
Partition Coefficient: N-Octanol/Water	:	No data available
Viscosity	:	No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

Thermal decomposition can lead to the release of irritating gases and vapors. These include oxides of carbon, nitrogen, chlorine, sodium.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified

Eye Damage/Irritation: Not classified.

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified non-genotoxic. Ames Test: Negative. In vivo mouse micronucleus test: Negative.

Carcinogenicity: Not classified. No evidence for Lacosamide-induce carcinogenicity has been found.

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified. Non-Teratogenic; No adverse effects on female or male retility, nor effects on reproduction have been observed.

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Symptoms/Injuries Upon Accidental Exposure Through Injection: Adverse effects may include Dizziness, Diplopia, Headache disorder, Nausea, Vomiting, Blurred vision, Ataxia, Vertigo, Injection site sequelae, Diarrhea, Fatigue, Gait abnormality, General weakness, Drowsiness, Tremor, Nystagmus, Pruritus of skin, Memory impairment, Oral hypoesthesia, Fast/slow/irregular/pounding heartbeat, Chest pain, Shortness of breath, Fainting.

Chronic Symptoms: None expected under normal conditions of use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Lacosamide (175481-36-4)	
LD50 Oral Rat	583 mg/kg
LC50 Inhalation Rat	> 2.6 mg/l (Maximum attainable concentration - no mortality occurred)

Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 mg/l (Exposure time: 1 h)

Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg

Hydrochloric acid (7647-01-0)	
IARC Group	3

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (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 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)

Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)

12.2. Persistence and Degradability

Lacosamide Injection, USP	
Persistence and Degradability	Expected to be biodegradable.

12.3. Bioaccumulative Potential

Lacosamide Injection, USP	
Bioaccumulative Potential	Not expected to bioaccumulate.

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

12.4. Mobility in Soil

Lacosamide Injection, USP	
Ecology - Soil	Leaches into groundwater.

12.5. Other Adverse Effects

Other Adverse Effects: None known.

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Treatment Methods: Can be landfilled, when in compliance with local regulations. Incineration is the preferred method for disposal of waste product.

Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Additional Information: Biologically contaminated materials should be incinerated.

Ecology - Waste Materials: Avoid unnecessary release into the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

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 - Status: Active

Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

Water (7732-18-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

15.2. US State Regulations

Hydrochloric acid (7647-01-0)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

15.3. Canadian Regulations

Sodium chloride (7647-14-5)
Listed on the Canadian DSL (Domestic Substances List)

Hydrochloric acid (7647-01-0)
Listed on the Canadian DSL (Domestic Substances List)

Water (7732-18-5)
Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 11/08/2022

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

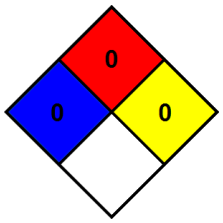
GHS Full Text Phrases:

H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H320	Causes eye irritation
H335	May cause respiratory irritation
H401	Toxic to aquatic life

NFPA Health Hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA Fire Hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health : 0 Minimal Hazard - No significant risk to health

Flammability : 0 Minimal Hazard

Physical : 0 Minimal Hazard

Personal protection : B

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.

NA GHS SDS 2015 (Can, US)