

SAFETY DATA SHEET

LACOSAMIDE INJECTION 200 mg/20 mL (10 mg/mL)

SECTION 1: IDENTIFICATION	
Material	Lacosamide Injection 200 mg/20 mL (10 mg/mL) Single-Dose Vials
Manufactured for	Somerset Therapeutics, LLC. Somerset, NJ 08873
Customer Care	1-800-417-9175
SECTION 2: HAZARD(S) IDENTIFICATION	
Hazard statements	Toxic if swallowed. Wash thoroughly after handling. Do not eat, drink or smoke when using this product.
SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS	
Ingredients	CAS
Lacosamide	175481-36-4
Sodium Chloride	7647-14-5
Hydrochloric acid	7647-01-0
SECTION 4: FIRST-AID MEASURES	
Inhalation	In case of unconsciousness place patient stably in side position for transportation
Skin Contact	Immediately wash with water and soap and rinse thoroughly.
Eye Contact	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
General information	Immediately remove any clothing soiled by the product. In case of irregular breathing or respiratory arrest provide artificial respiration.
SECTION 5: FIRE-FIGHTING MEASURES	
Extinguishing Media (Suitable)	Use firefighting measures that suit the environment. A solid water stream may be inefficient.
Special Firefighting Procedures	No further relevant information available.
Protective equipment	No special measures required.
SECTION 6: ACCIDENTAL RELEASE MEASURES	
Clean-up Methods	Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to local regulations.
Personal Precautions:	Wear protective equipment. Keep unprotected persons away.
Environmental Precautions:	Do not allow to enter sewers /surface or ground floor.
SECTION 7: HANDLING AND STORAGE	
Handling:	No special precautions are necessary if used correctly.
Storage:	As per package insert label.
Information about protection against explosions and fires	No special measures required.
SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION	
Personal Protective Equipment: General protective and hygienic measures	Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work Avoid contact with the eyes and skin.
Breathing equipment	Not required
Protection of hands	The glove material has to be impermeable and resistant to the product /the substance/the preparation .Due to missing tests no recommendation to the glove material can be given for the product/the preparation /the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION	
Material of gloves	The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
Penetration time of glove material	The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES	
Physical Form	Injection
Colour	Clear, colorless
Description	Lacosamide injection is a clear, colorless, sterile solution containing 10 mg lacosamide per mL for intravenous infusion. One 20-mL vial contains 200 mg of lacosamide drug substance. Pack of 10 Single Dose Vials NDC 70069-471-10
SECTION 10: STABILITY AND REACTIVITY	
Thermal decomposition/conditions to be avoided	No decomposition if used according to specifications
Conditions to avoid	No further relevant information available.
Incompatible materials	Strong acids, strong oxidizing agents
Hazardous decomposition products	No dangerous decomposition products known.
SECTION 11: TOXICOLOGICAL INFORMATION	
Additional toxicological information: Carcinogenic categories IARC (International Agency for research on cancer)	Substance is not listed.
NTP(National Toxicology program)	Substance is not listed.
OSHA-Ca(Occupational safety & Health Administration)	Substance is not listed.
LD/LC50 values that are relevant for classification:	8 mg/kg (mouse) 3 mg/kg (rat)
SECTION 12: ECOLOGICAL INFORMATION	
General notes:	Water hazard class 1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
SECTION 13: DISPOSAL CONSIDERATIONS	
Waste treatment methods Recommendation:	Must not be disposed of together with household garbage. Do not allow Product to reach sewage system.
Uncleaned packaging's: Recommendation:	Disposal must be made according to official regulations.
SECTION 14: TRANSPORT INFORMATION	
UN-Number DOT,IMDG,IATA	UN2811
UN proper shipping name DOT, IMDG, IATA	Toxic solids, Organic, n.o.s (Lacosamide) Toxic SOLID, Organic. N.O.S. (Lacosamide) Toxic solid, organic, n.o.s (Lacosamide)
Transport hazard class(es) DOT	Not regulated
Packing group DOT,IMDG,IATA	III

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SECTION 15: REGULATORY INFORMATION

No further relevant information available

SECTION 16: OTHER INFORMATION

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Further information

Revision date: NA

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Somerset Therapeutics Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Somerset Therapeutics Limited reserves the right to revise this SDS.

END OF SAFETY DATA SHEET