

SAFETY DATA SHEET (SDS)

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Product Name

Lacosamide Oral Solution, USP 10 mg/mL

Effective Date: May 2024

1. Identification

Product Name: Lacosamide Oral Solution, USP 10 mg/mL

Manufacturer: MSN Pharmaceuticals Inc., Piscataway, NJ 08854

2. Hazards Identification

Hazard Statement: Causes serious eye irritation. Wash thoroughly after handling.

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

Wear eye protection / face protection.

3. Composition/information on ingredients

Lacosamide, USP: 10 mg/mL

4. First Aid Measures

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: Treat Symptomatically

Piscataway, NJ (USA)

S. 23.2024



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5. Fire Fighting Measures

Extinguishing Media:

Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning /Collecting: Contain the source of the spill or leak. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly. Prevent discharge.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.



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7. Handling and Storage

Precautions for Safe Handling

Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment shouldbe avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. It is recommended that all operations be fully enclosed and no air recirculated.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:

Store as directed by product packaging. Store under locked up.

Specific end use(s):

Pharmaceutical drug product

8. Exposure Controls/Personal Protection

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal protective Equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.



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9. Physical and Chemical Properties

Physical State:

Liquid

Flavor:

Strawberry Flavor

Solubility:

Very soluble in water & alcohol

10. Stability and Reactivity

Reactivity:

Chemical Stability:

Possibility of Hazardous Reactions

Oxidizing Properties:
Conditions to Avoid:
Incompatible Materials:
Hazardous Decomposition

Products:

No data available

Stable under normal conditions of use.

No data available None known

Strong acids, strong oxidizing agents

No data available

11. Toxicological Information

Information on Toxicological Effects

General Information:

Handling of formulated drug product is not expected to

cause any toxicological effects.

Toxicity to Animals:

LD/LC50:

8 mg/kg (mouse); 3 mg/kg (rat)

12. Ecological Information

Environmental Overview:

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.

13. Disposal Considerations

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be



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utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. Transport Information

International Regulations: Not Classified by transport regulations, non-regulated

IATA / ICAO - Non-Hazardous - Not Regulated

IATA Proper shipping name: N/A

IATA UN / ID No: N/A IATA Hazard Class: N/A IATA Packing Group: N/A

IATA Label: N/A

IMDG - Non-Hazardous - Not Regulated

IMDG Proper shipping name: N/A

IMDG UN / ID No: N/A IMDG Hazard Class: N/A IMDG Flash Point N/A IMDG Label: N/A

DOT - Non-Hazardous - Not Regulated

DOT Proper shipping name: N/A

DOT UN / ID No: N/A
DOT Hazard Class: N/A
DOT Flash Point N/A
DOT Packing Group: N/A

DOT Label: N/A

15. Regulatory Information

Reporting Requirements - Not Applicable



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16. Other Information

Prepared by: MSN Pharmaceutical Inc, Piscataway, New Jersey - 08554

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Disclaimer: This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. It is not meant to be an all-inclusive document on worldwide hazard communications regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment.

End Of Safety Data Sheet