SAFETY DATA SHEET

Issue Date: 04/20/2023 **Revision Date: N/A** **Revision Number: 01**

1. IDENTIFICATION

Product identifier: Lacosamide Oral Solution, USP CV
NDC Numbers: 0121-1012-05, NDC 0121-1012-95, NDC 0121-2024-10, NDC 0121-2024-95, 0121-3036-15, NDC 0121-3036-95, NDC 0121-4048-74, and NDC 0121-4048-95

Supplier Name and Address: Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605
Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug – treatment of seizures
Restrictions on use: Prescription use only.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Reproductive Toxicity Category 2

Label Elements:
Warning!

Hazard statement(s)

Suspected of damaging the unborn child.

Precautionary statement(s)

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective clothing and gloves.
IF exposed or concerned: Get medical attention.
Store locked up.
Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Lacosamide	175481-36-4	1.0%
Acesulfame potassium	55589-62-3	Proprietary
Sodium chloride	7647-14-5	Proprietary
Citric Acid	77-92-9	Proprietary
Polyethylene Glycol	25322-68-3	Proprietary
Sorbitol Solution	50-70-4	Proprietary

Cherry Flavor	Mixture	Proprietary
Sodium carboxymethylcellulose	9004-32-4	Proprietary
Glycerin	56-81-5	Proprietary
Methyl Paraben	99-76-3	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs, get medical attention.
Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists**.**
Ingestion: In the case of unintentional ingestion or overdosage, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Swallowing may cause double vision, headache, dizziness, nausea and sleepiness. Inhalation of mists may cause respiratory irritation and effects similar to ingestion.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for unintended ingestion or overdosage.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not classified as flammable or combustible but will burn in a fire after the water has evaporated.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and **c**ollect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Lacosamide	None Established
Acesulfame potassium	None Established
Sodium chloride	None Established
Citric Acid	None Established
Polyethylene Glycol	10 mg/m3 TWA AIHA WEEL
Sorbitol Solution	None Established
Cherry Flavor	None Established
Sodium carboxymethylcellulose	None Established
Glycerin	5 mg/m3 (respirable) 15 mg/m3 (total particulate) TWA OSHA PEL
Methyl Paraben	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.
Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Clear liquid
Odor: None

Odor threshold: Not applicable	**pH:** Not determined
Melting point/freezing point: Not determined	**Boiling Point:** Not determined
Flash point: Not applicable	**Evaporation rate:** Not determined
Flammability (solid, gas): Not applicable	**VOC:** Not determined
Flammable limits: LEL: Not determined	**UEL:** Not determined
Vapor pressure: Not determined	**Vapor density:** Not determined
Relative density: Not determined	**Solubility(ies):** Soluble

Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Viscosity:** Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: Avoid oxidizing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and effects similar to ingestion.
Ingestion: . Swallowing may cause double vision, headache, dizziness, nausea and sleepiness.
Skin contact: May cause mild irritation.
Eye contact: May cause mild irritation with redness and tearing.
Chronic Effects: None known.
Sensitization: Components are not known to be sensitizers.
Germ Cell Mutagenicity: Components are not classified as germ cell mutagens. Lacosamide was negative in an *in vitro* Ames test and an *in vivo* mouse micronucleus assay. Lacosamide induced a positive response in the *in vitro* mouse lymphoma assay.
Reproductive Toxicity: Components are not classified as reproductive toxins. No adverse effects on male or female fertility or reproduction were observed in rats administered lacosamide. Oral administration of lacosamide to pregnant rats (20, 75, or 200 mg/kg/day) and rabbits (6.25, 12.5, or 25 mg/kg/day) during the period of organogenesis did not produce any effects on the incidences of fetal structural abnormalities. However, the maximum doses evaluated were limited by maternal toxicity in both species and embryofetal death in rats. In two studies in which lacosamide (25, 70, or 200 mg/kg/day and 50, 100, or 200 mg/kg/day) was orally administered to rats throughout pregnancy and lactation, increased perinatal mortality and decreased body weights in the offspring were observed at the highest dose tested. The no-effect dose for pre- and postnatal developmental toxicity in rats was 70 mg/kg/day. Oral administration of lacosamide (30, 90, or 180 mg/kg/day) to rats during the neonatal and juvenile periods of development resulted in decreased brain weights and long-term neurobehavioral changes (altered open field performance, deficits in learning and memory). The early postnatal period in rats is generally thought to correspond to late pregnancy in humans in terms of brain development. The no-effect dose for developmental neurotoxicity in rats was associated with a plasma lacosamide AUC less than that in humans at the MRHD.
Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA. There was no evidence of drug related carcinogenicity in mice or rats administered lacosamide. Mice and rats received lacosamide once daily by oral administration for 104 weeks at doses producing plasma exposures (AUC) up to approximately 1 and 3 times, respectively, the plasma AUC in humans at the maximum recommended human dose (MRHD) of 400 mg/day.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg
Lacosamide: Oral LD50 >300 - 2000 mg/kg
Citric Acid: LD50 oral mouse 5400 mg/kg; LD50 dermal rat >2000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.
Ecotoxicity values: No data available.
Persistence and degradability: No data available.
Bioaccumulative potential: No data available.
Mobility in soil: No data is available.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA**.**

California Proposition 65: This product is not known to contain regulated chemicals.

CANADA:
Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

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SDS Revision History: N/A

Disclaimer : The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.