

Safety Data Sheet

Issuing date: 11AUG2015

Revision date: 23Aug2022

Revision number: 04

1. Identification of the substance/preparation and the company/undertaking

GHS product identifier

Product name: Levetiracetam Oral Solution USP

Other means of identification

Product code(s): 0121-0799-16, 0121-4799-05, 0121-4799-10, 0121-0799-05, 0121-0799-15, 0121-4799-50, 0121-1598-10 and 0121-1598-20

UN-Number: NA

Synonyms: Compare to Keppra®

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used as adjunctive therapy in the treatment of partial onset seizures in adults and children 1 month of age and older with epilepsy.

Uses advised against: Do not use except as prescribed.

Supplier address/information

Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number:

CHEMTREC 800.424.9300

2. Hazards Identification

Classification This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Chemical family: Mixture

Statement of Hazard: Material is a liquid dosage form intended for human consumption. Solution is not considered hazardous taken as directed.

Additional Hazard Information:

Short term: The most common side effects include sleepiness, weakness, dizziness, and infection. In children additional side effects may include accidental injury, irritability and hostility.

Long term: No data available

Known Clinical Effects: Like other antiepileptic drugs, Levetiracetam may cause suicidal thoughts or actions in a very small number of people using it.

EU Indication of danger: Not classified.

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Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

Precautionary statements

General advice: Seek medical attention in case of accidental exposure or overdose.

Eyes: Avoid contact with eyes.

Skin Contact: Avoid skin contact.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

3. Composition/Information on ingredients

Chemical Name	CAS-No	mg/mL	Trade Secret
Levetiracetam	102767-28-2	100 mg/mL	
Citric Acid	77-92-9		X
Glycerin	56-81-5		X
Maltitol Solution	585-88-6		X
Methylparaben	99-76-3		X
Potassium Acesulfame	55589-62-3		X
Propylparaben	94-13-3		X
Sodium Citrate	6132-04-3		X
Grape Flavor	Mixture		X

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4. First aid measures

Description of necessary first-aid measures

Eye contact: Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

Skin contact: Wash contaminated area thoroughly. If irritation persists, contact medical personnel.

Inhalation: Remove to fresh air and contact medical personnel.

Overdosage or accidental ingestion: Contact medical personnel if overdosage or accidental ingestion is suspected.

Most important symptoms/effects, acute and delayed

Overdosage may cause somnolence, agitation, aggression, depressed level of consciousness, respiratory depression and coma.

Indication of immediate medical attention and special treatment needed, if necessary

Not available

Notes to Physician:

NA

5. Fire-fighting measures

Suitable extinguishing media: Use carbon dioxide, dry chemical or water spray.

Specific hazards arising from the chemical None

Explosion data: Not applicable

Protective equipment and precautions for firefighters 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 materials for containment and cleaning up

- **Methods for containment:** Isolate area around spill as specified by site procedures.
- **Methods for cleaning up:** Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

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7. Handling and storage

Precautions for safe handling

Handling: No special handling required for hazard control under conditions of normal product use.

Conditions for safe storage, including any incompatibilities

Storage: No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products: None applicable

8. Exposure controls/personal protection

Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Levetiracetam	Not Available	Not Available	Not Available
Citric Acid	10 mg/m ³ TWA	15 mg/m ³ TWA	Not Available
Glycerin	10 mg/m ³ TWA	10 mg/m ³ TWA	Not Available
Maltitol Solution	Not Available	Not Available	Not Available
Methylparaben	Not Available	Not Available	Not Available
Potassium Acesulfame	Not Available	Not Available	Not Available
Propylparaben	Not Available	Not Available	Not Available
Sodium Citrate	Not Available	Not Available	Not Available
Grape Flavor	Not Available	Not Available	Not Available

Appropriate engineering controls

Engineering measures: Engineering controls should be used to limit exposure.

Individual protection measures, such as personal protective equipment

Eye/face protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection: Not required under normal use of the product. If the applicable PEL (Permissible Exposure Limit) is exceeded use an appropriate respirator.

Hygiene measures: Wash hands thoroughly after use.

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9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: Solution
 Odor: Grape
 Appearance: Clear colorless to slightly yellowish liquid
 Odor threshold: Not available

Property	Values	Remarks/Method
pH	5.2- 6.0	Current USP
Melting point/range	Not Applicable	
Boiling point/boiling range	Not Applicable	
Flash point	Not Applicable	
Evaporation rate	Not Applicable	
Flammability (solid, gas)	Not Applicable	
Flammability limits in air	Not Applicable	
-upper flammability limit	Not Applicable	
-lower flammability limit	Not Applicable	
Vapor pressure	Not Applicable	
Vapor density	Not Applicable	
Specific gravity	1.0 – 1.3	Current USP
Water solubility	Not Applicable	
Solubility in other solvents	Not Applicable	
Partition coefficient: n-octanol/water	Not Applicable	
Autoignition temperature	Not Applicable	
Decomposition temperature	Not Applicable	
Viscosity	Not Applicable	
Flammable properties	Not Applicable	
Explosive properties	Not Applicable	
Oxidizing properties	Not Applicable	

Other information

VOC content (%): NA

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10. Stability and reactivity

Reactivity	Stable at normal conditions
Chemical stability	Stable at normal conditions
Possibility of hazardous reactions	Stable at normal conditions
Conditions to avoid	None known
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	None known

11. Toxicological information

Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information in the table below is for the individual components and not the product:

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Levetiracetam	>5000 mg/kg Rat	Not Available	Not Available
Citric Acid	5400 mg/kg Rat	>2000 mg/kg Rabbit	Not Available
Glycerin	12600 mg/kg Rat	10000 mg/kg Rabbit	Not Available
Maltitol Solution	Not Available	Not Available	Not Available
Methylparaben	2100 mg/kg Rat	No skin irritation 24 hr. Rabbit	Not Available
Potassium Acesulfame	7431 mg/kg Rat	Not Available	Not Available
Propylparaben	7500 mg/kg Mouse	Not Available	Not Available
Sodium Citrate	Not Available	Not Available	Not Available
Grape Flavor	Not Available	Not Available	Not Available

Symptoms related to the physical, chemical and toxicological characteristics

- Not Available

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Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: Not carcinogenetic
- Reproductive toxicity: No data available
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

Numerical measures of toxicity – product

- No data available

12. Ecological information

Ecotoxicity

Environmental properties have not been thoroughly evaluated. Releases to the environment should be avoided.

Persistence and Degradability

No data available

Bioaccumulation

No data available

Other adverse effects

No data available

The following table lists the data for the individual components and not the product:

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Micro-organisms	Daphnia Magna (water flea)
Levetiracetam	Not Available	Not Available	Not Available	Not Available
Citric Acid	Not Available	440 mg/L 48 hr Leuciscus idus melanotus	Not Available	1535 mg/L 24 hr.
Glycerin	Not Available	58.5 ppm 96 hr Trout	Not Available	Not Available
Maltitol Solution	Not Available	Not Available	Not Available	Not Available
Methylparaben	91 mg/L 72 hr. Pseudokirchneriela subcapitata	59.5 mg/L 89 hr Oryzias latipes	Not Available	41.1 mg/L 48 hr
Potassium Acesulfame	1800 mg/L 96 hr. Zebra fish	Not Available	Not Available	Not Available
Propylparaben	7.6 mg/L 72 hr. Pseudokirchneriela subcapitata	6.4 mg/L 96 hr. Danio rerio	Not Available	15.4 mg/L 72hr.
Sodium Citrate	Not Available	Not Available	Not Available	Not Available
Grape Flavor	Not Available	Not Available	Not Available	Not Available

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13. Disposal considerations

Waste disposal methods

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

Contaminated packaging

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

14. Transport information

Notes:

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

15. Regulatory information

International Inventories**TSCA:**

United States Toxic Substances Control Act 8(b) inventory not applicable to product, but the following ingredients are listed on the TSCA inventory: Citric Acid, Glycerin, Maltitol Solution, Methylparaben, and Propylparaben.

EINECS:

Citric Acid, Glycerin, Methylparaben, Propylparaben, Maltitol Solution, Potassium Acesulfame and Sodium Citrate are listed on the EINECS inventory.

U.S. Federal Regulations

Not Applicable

OSHA Label:

Not Applicable

US DEA:

Not Applicable

SARA 311/312 Hazard categories:

Not Applicable

Clean Water Act:

This product **does not** contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA:

No components are listed under CERCLA.

California Proposition 65:

This product does not contain any component which is listed as a Proposition 65 chemical.

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U.S. state Right-to-Know regulations

"X" designates that the ingredients are listed on the state Right-to-Know list

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Levetiracetam	X		X		
Citric Acid	X		X		
Glycerin	X	X	X	X	X
Maltitol Solution	X		X		
Methylparaben	X		X		
Potassium Acesulfame	X		X		
Propylparaben	X		X		
Sodium Citrate	X		X		
Grape Flavor					

U.S. EPA label information:

Not applicable

16. Other information

Prepared by:

Pharmaceutical Associates Regulatory Affairs

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1. Added new NDC number for 10 mL - 0121-1598-10 (UDC) and 0121-1528-20 (pack-out size).

Revision date:

03Sep2020

1. NDC Number incorrectly listed as 0121-0799-50 and was corrected to read 0121-4799-50.

Revision date:

06Aug2020

1. Updated Age in Section 1 under recommended use.
2. Updated document formatting
3. Added NDC Code 0121-4799-50

General 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.

End of Safety Data Sheet