



Product name: Levetiracetam injection

Issue date: 10/30/18

SDS

Safety Data Sheet

SDS No. : 18868981030302

Creator: BDT Chemical Technology (Shanghai) CO.,LTD

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1. Product and Company Identification

Product name : Levetiracetam injection

Product use : For the treatment of epilepsy

Manufacturer/Supplier : Hainan Poly Pharm Co. Ltd

Address : No.2 Xingyang Road, Guilinyang Economic Development Area,
Haikou, Hainan 571127, P.R.China

Telephone : +86 898 65712762

E-mail : hnpoly@hnpoly.com

Emergency telephone : +86 898 65712762
number of the company

2. Hazards Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

GHS classification of the product : Acute toxicity – oral category 4
Eye damage/irritation category 2

Label elements

Pictogram



Signal word : Warning

Hazard statement : Harmful if swallowed
Causes serious eye irritation

Precautionary statements

Prevention : Wash exposed skin thoroughly after handling.
Do not eat, drink or smoke when using this product.
Wear protective gloves / protective clothing / eye protection / face protection.

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- Response** : IF SWALLOWED: Call a POISON CENTER/doctor/if you feel unwell. Rinse mouth.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
- Disposal** : Dispose of contents/container in accordance with local/regional/national/international regulations
- Hazards not otherwise classified** : No specific dangers known, if the regulations/notes for storage and handling are considered.

3. Composition / Information on Ingredients

According to Regulation 2012 OSHA Hazard Communication Standard: 29 CFR Part 1910.1200

Components

| Chemical Name | CAS-No. | Concentration |
|---|-------------|---------------|
| (2R)-2-(2-oxopyrrolidin-1-yl)butanamide | 102767-28-2 | 90 – 95% |
| Sodium acetate | 127-09-3 | 1 – 2% |
| Sodium chloride | 7647-14-5 | 5 - 10% |
| Acetic acid | 64-19-7 | 0.1% |

4. First-Aid Measures

Description of first aid measures

- Inhalation** : If difficulties occur after vapour has been inhaled, remove to fresh air and seek medical attention.
- Skin contact** : After contact with skin, wash immediately with plenty of water. If irritation persists, consult a physician.
- Eye contact** : If you use contact lenses, remove the lenses first. Wash affected eyes for at least 15 minutes under running water with eyelids held open. If symptoms occur, consult a physician, preferably an ophthalmologist.
- Ingestion** : Rinse mouth immediately and then drink plenty of water, seek medical attention.

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Most important symptoms and effects, both acute and delayed : Aside from the information found under Description of first aid measures (above) and Indication of immediate medical attention and special treatment needed (below), any additional important symptoms and effects are described in Section 11: Toxicology Information.

Indication of any immediate medical attention and special treatment needed

Note to physician : Treatment of exposure should be directed at the the clinical condition of the patient.

5: Fire-Fighting Measures

Suitable extinguishing media : Water fog or fine spray.Dry chemical fire extinguishers.Carbon dioxide fire extinguishers.

Unsuitable extinguishing media : No data available.

Special hazards arising from the substance or mixture

Hazardous combustion products : During a fire, smoke may contain the original material in addition to combustion products of varying composition which may be toxic and/or irritating.Combustion products may include and are not limited to: Carbon monoxide.Carbon dioxide. Nitrogen oxide.

Advice for firefighters

Special protective equipment for firefighters : Wear positive-pressure self-contained breathing apparatus (SCBA) and protective fire fighting clothing (includes fire fighting helmet, coat, trousers, boots, and gloves).If protective equipment is not available or not used, fight fire from a protected location or safe distance.

6: Accidental release measures

Personal precautions, protective equipment and emergency procedures : Avoid eye contact.Use personal protective equipment.

Environmental precautions : Contain contaminated water/firefighting water. Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.

Methods and materials for containment and cleaning up : Contain spilled material if possible.Collect in suitable and properly labeled containers.

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7: Handling and storage

Advice on safe handling : Avoid contact with the skin, eyes and clothing .Ensure adequate ventilation.

Conditions for safe storage, including any incompatibilities : Keep tightly closed in a dry and well-ventilated place.

8: Exposure Controls/Personal Protection

Control parameters

| Chemical name | Occupational Exposure Limits | | Regulation |
|---------------|------------------------------|------|------------|
| acetic acid | 10 ppm | TWA | ACGIH |
| acetic acid | 15 ppm | STEL | ACGIH |

Personal protective equipment

Respiratory protection : None required under normal conditions. Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines.

Hand protection : None required under normal conditions.

Eye protection : In case of risk of spray, Use safety glasses (with side shields).

Skin and body protection : None required under normal conditions.

9: Physical and chemical properties

Form : liquid

Colour : clear

Odour : none

pH : 5.0-6.0

Melting point : no data available

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Boiling point : no data available

Flash point : no data available

Thermal decomposition : no data available
temperature

Relative density : 1.0212

Water solubility : no data available

Viscosity, dynamic : no data available

10: Stability and Reactivity

Reactivity : No hazardous reactions if stored and handled as prescribed/indicated.

Chemical stability : Stable under recommended storage conditions.

Possibility of hazardous : This material is considered stable.
reactions

Conditions to avoid : Avoid extreme temperatures.

Incompatible materials : Avoid contact with: Strong alkali, strong acid, strong oxidizers.

Hazardous : Carbon monoxide. Carbon dioxide. Nitrogen oxide.
decomposition products

11: Toxicological information

Information on toxicological effects

Acute toxicity

Acute Toxicity: oral

Sodium chloride
LD50/rat: 3 550 mg/kg bw

Sodium acetate
LD50: 2.72 other: g/kg bw

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Acute Toxicity: inhalation

Sodium chloride
LC50/1 h/rat:> 42 mg/L air

Sodium acetate
LC50/4 h:> 5.81 mg/L air

Acute Toxicity: dermal

Sodium chloride
LD50/rabbit:> 10 000 mg/kg bw

Sodium acetate
LD50:> 28 269.15 mg/kg bw

Skin irritation/corrosion

Sodium chloride
rabbit
not irritating

Sodium acetate
not irritating

Serious eye damage/irritation

Sodium chloride
rabbit
not irritating

Sodium acetate
not irritating

Respiratory or skin sensitisation

Sodium chloride
mouse
not sensitising

Sodium acetate
not sensitising

Germ cell mutagenicity

Evidence analysis showed that the substance did not induce gene mutations.

Carcinogenicity

Evidence analysis showed that the substance was not a carcinogen.

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Reproductive toxicity

Animal tests showed no developmental toxicity.

STOT-single exposure

No information available

STOT-repeated exposure

No information available

Aspiration hazard

No information available

12: Ecological information

Aquatic Toxicity

Short-term toxicity to fish

Sodium chloride
LC50/96 h/Lepomis macrochirus:5 840 mg/L

Sodium acetate
LC50/96 h/Danio rerio (previous name: Brachydanio rerio):> 100 mg/L

Long-term toxicity to fish

Sodium chloride
NOEC/33 d/Pimephales promelas:252 mg/L

Short-term toxicity to aquatic invertebrates

Sodium chloride
LC50/48 h/Daphnia magna:874 mg/L

Sodium acetate
EC50/48 h/Daphnia magna:> 1 000 mg/L

Long-term toxicity to aquatic invertebrates

Sodium chloride
NOEC/21 d/Daphnia pulex:314 mg/L

Toxicity to microorganisms

Sodium chloride
NOEC/activated sludge:5 000 - 8 000 mg/L

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Sodium acetate
EC10/16 h/Pseudomonas putida:3.5 g/L

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

13: Disposal considerations

Product : Observe national and local legal requirements.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.

14: Transport Information

Land transport

DOT

UN number : not applicable

UN proper shipping name : not applicable

Transport hazard class(es) : not applicable

Packing group : not applicable

Sea transport

IMDG

UN number : not applicable

UN proper shipping name : not applicable

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Transport hazard : not applicable

class(es) :

Packing group : not applicable

Air transport

IATA/ICAO

UN number : not applicable

UN proper shipping : not applicable

name :

Transport hazard : not applicable

class(es) :

Packing group : not applicable

15: Regulatory information

Federal Regulations

Registration status:

Chemical TSCA, US released / listed

EPCRA 311/312 (Hazard categories): Acute

CA Prop. 65:

There are no listed chemicals in this product.

NFPA Hazard codes:

Health : 1 Fire: 1 Reactivity: 0 Special:

HMIS III rating

Health: 1 Flammability: 1 Physical hazard: 0

16: Other information

SDS Prepared by:

BDT Chemical Technology (Shanghai) CO.,LTD

SDS Prepared on: 10/30/18

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The information herein is provided in good faith and believed to be accurate as of the effective date shown above. However, no warranty, express or implied, is given. Regulatory requirements are subject to change and may differ between various locations. It is the buyer's/user's responsibility to ensure that his activities comply with all federal, state, provincial or local laws. The information presented here pertains only to the product as shipped. Since conditions for use of the product are not under the control of the manufacturer, it is the buyer's/user's duty to determine the conditions necessary for the safe use of this product. Due to the proliferation of sources for information such as manufacturer-specific SDSs, we are not and cannot be responsible for SDSs obtained from any source other than ourselves. If you have obtained an SDS from another source or if you are not sure that the SDS you have is current, please contact us for the most current version.

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION

Company Name: Application:

Application Number for NDA/ANDA/BLA (drug): PMA/S10(k)/med device:

DUNS:

Proprietary Name (if Applicable) and Established Name:

Selling Unit NDC: Individual Unit NDC: UPC:

UDI: CVX Code: MVX Code:

Description:

Active Ingredient(s):

URL for Additional Product Information:

Address: State: Address 2:

City: Zip:

Key Contact: Email:

Phone Number: Fax:

Product Therapeutic Classification:

SPECIAL HANDLING AND STORAGE REQUIREMENTS

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range:
 Other Temperature Range Requirement (write in):

Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?

b. Contact for temperature excursion questions:
 Name:
 Number:
 Group E-mail:

c. Special regulations for product in any states?
 Special returns requirements for this product?

d. Store product (unit of sale) upright?
 Protect product (unit of sale) from light?

e. Shelf life:
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 a legend device?
 reverse numbered?
 ca-certified?
 Is the Product...
 Is the Product...

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose NDC, indicate NDC here:

Country of Origin:

Is this product covered under the Trade Agreements Act (TAA)?

PRODUCT DESCRIPTION INFORMATION

Size:

Strength:

Dosage Form:

Product Shape:

Product Color:

Product Imprint:

ORDER INFORMATION

Unit of Sale: Bottle, Box/ Carton, Ampule, Glass, Tube, x Vial Liquid Sgl, Vial Liquid Mult, Vial Powder Sgl, Vial Powder Mult, Other: Write In

What is the NDC selling unit?

 (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

If Yes, how many of which package type?
 Each, Inner/ Carton/ Pack, Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: Authorized Generic *If Authorized Generic, other action fields are not applicable

II. Generic Equivalent to What Brand?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

Rx billing unit to pharmacy:
 Each, Gram, Milliter

(Write-in, e.g. 1 Vial)

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? GLN:

Is product exempt from DSCSA?

If yes, select exemption:
 Other exemption - Write in:

Is product repackaged? If Yes, was original product purchased direct from mfr?

Is product sold by manufacturer's exclusive distributor? If yes, attach documentation from FDA.

Has FDA granted waiver/exemption/exception for product?

ITEM AND PACKING INFORMATION

| Item: | Weight Lbs. | Dimensions (US mm in.) Depth | Height | Width | Volume (Cube) | # Pkcs. |
|----------------------------------|----------------------------|---------------------------------|--------|-------|---------------|---------|
| Box/ Carton/ Bundle/ Inner Pack: | 1.06 | 4.52 | 4.52 | 2.95 | | 1 |
| Case: | 25.44 | 14.17 | 11.02 | 9.44 | | 24 |
| Pallet: | | | | | | |
| UPC: | Case: <input type="text"/> | Carton: <input type="text"/> | | | | |

GTIN / PRODUCT INFORMATION

| Serialized? | Level | Saleable Unit | Quantity | GTIN-14 |
|--|----------------------------|---------------|----------|----------------------------|
| <input type="text" value="No"/> | 1 Item | Yes | 20 | X Linear 1 002851224013264 |
| If not, when? <input type="text" value="01/2019"/> | 3 Cases/Bundles/Inner Pack | No | 20 | X Linear 24 80361224013259 |
| Repackaged? | Case | | 20 | Linear |
| | Pallet | | 20 | Linear |
| | | | 20 | Linear |
| | | | 20 | Linear |
| | | | 20 | Linear |
| | | | 20 | Linear |

COST INFORMATION

Regular Cost Vendor #:

Invoice Cost (WAC) (\$) Whsl. Code #:

Federal Excise Tax Per Unit of Sale Pallet Code:

As of date:

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply)

- a. Cytotoxic? No
- b. CA Prop 65 Carcinogen or Reproductive Toxicant? No
- Is the product a CA Prop 65 carcinogen? No
- Is the product a CA Prop 65 reproductive toxicant? No
- Does the product label bear a CA Prop 65 warning? No

- c. Contact Hazard? No
- d. Does this product require special clean-up instructions? No
- (If yes, attach SDS with special instructions)
- e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA?

- (if yes, answer a-e below and provide SDS)
- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

Is the product restricted for air shipment? If so, indicate restriction.

- Passenger
- Cargo
- Passenger & Cargo

Is this a reportable quantity? No

RQ Threshold

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit? No

- (if yes, identify method below)
- Limited Quantity
- Consumer Commodity, ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit, DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101).
- SP#

ADD'L STORAGE INFORMATION

- Is the Product:
- Controlled Substance? No
- Controlled by State(s)? No
- ARCOS Reportable? No
- Schedule No. (inc. N for non-narcotic)
- Controlled Substance Code
- Listed Chemical (List I or II) No
- If yes, indicate which
- Is it a scheduled listed chemical product?

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes
- Restricted to retail pharmacy only No
- Restricted to hospital, clinics, and physician offices only No
- Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard
- Aerosol Class, Identify NFPA Storage Level

Is the product a NIOSH hazardous drug?

If yes, indicate which

Hazardous Waste Identification

EPA Hazardous Waste Code

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name Phone:

Supplier Manages REMS registry exclusively

Wholesale distributor support

Provider Name

Site Enrollment Number assigned by Supplier

DEA #:

PCPDP #:

NPI #:

Comments

Registry:

Registry Program Contact Name: Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 815-624-7685

Is product returnable for credit: Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or image of Product Barcode:

FOR DESIGNATED DROP SHIP PRODUCT ONLY - If not a designated drop ship, do not complete.

| Order Method for Designated Drop Ship Product | |
|---|---------------------------|
| Purchase orders may be accepted by: | |
| a. EDI | _____ |
| b. Autofax | _____ Fax Number: _____ |
| c. Fax | _____ Fax Number: _____ |
| d. Phone only | _____ Phone No.: _____ |
| e. Supplier Web Site only | _____ Site Address: _____ |
| Minimum Order Quantity: | _____ |
| Supplier's Customer Service Number: | _____ |
| Contracted 3PL company / contact #: | _____ |
| Name: | _____ |
| Phone: | _____ |

| Standard Order Receipt and Processing | |
|---|------------------------|
| Purchase order daily receipt cut off time by supplier | |
| Cut off time: | _____ |
| Shipping lead time of PO: | _____ Hours _____ Days |
| Ships same day for next day receipt: | _____ |
| Ships for second day receipt: | _____ |
| Ships regular ground for 3-10 days receipt: | _____ |

| Expedited Freight Charges or Other Designated Drop Ship Fees: | |
|---|-------|
| Expedited freight fees billed with each order: | _____ |
| Drop Ship service fee billed with each order: | _____ |
| Drop Ship miscellaneous fees billed: | _____ |
| Comments: | _____ |

| Overnight and Priority Overnight PO Processing | |
|--|---|
| Overnight receipt available: | |
| PO Receipt cut off time: | _____ |
| Days of week overnight is available: | <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday |
| Priority Overnight receipt available: | |
| PO Receipt Cut off time: | _____ |

| Class of Trade Restriction: | |
|---|-------|
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices | _____ |
| Restricted to retail pharmacy only: | _____ |
| Restricted to hospital, clinics, and physician offices only: | _____ |
| Restricted from US territories? (explain in comments) | _____ |
| Comments: | _____ |

| | |
|---------------------------------------|--|
| Saturday Overnight receipt available: | |
| PO Receipt Cut off time: | _____ |
| Order receipt method: | Phone: _____ Phone #: _____ Fax: _____ Fax #: _____ EDI: _____ |
| Overnight Fees apply: | _____ |
| Other fees apply: | _____ |

| Other Data Information Required to Process PO: | |
|--|-------|
| Patient Procedure Date: | _____ |
| Physician Name: | _____ |
| Physician/Clinic Phone # | _____ |
| Physician State License # | _____ |
| Physician/Clinic DEA #: | _____ |
| Physician/Clinic Specialty: | _____ |

| Return Instructions | |
|---|-------|
| Contact # if product is received damaged: | _____ |
| Is product returnable for credit: | _____ |
| URL/Link to returns policy: | _____ |
| Special regulations or returns requirements for this product in certain states? | _____ |
| If so, which states? Other requirements? Comments? | _____ |

| Miscellaneous Notes: | |
|----------------------|--|
| _____ | |

| ADDITIONAL INFORMATION | |
|---|-------|
| Is product order for scheduled patient procedure? | _____ |
| Is product order for restocking purposes? | _____ |