SAFETY DATA SHEET

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA
Revision Date: 05.05.2015

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Product name : LEVETIRACETAM
Product Number : RTECS No: UX9656166
Brand : Manufactured by Neuland Laboratories Limited
CAS-No : 102767-28-2

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Anticonvulsants, Antiepileptic

1.3 Details of the supplier of the safety data sheet

Company: Neuland Laboratories Limited, Sanali Info Park, Ground Floor, 8-2-120/113, Road No.2, Banjara Hills, Hyderabad- 500034, Telangana, INDIA, Tel: +914030211600, Fax: +91-40-30211602.

1.4 Emergency telephone number

Emergency Tel: **+918458392724, +918458274211.**

2.HAZARDS IDENTIFICATION

2.1 Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

Health Hazard:

H302 : Harmful if swallowed
H315 : Causes skin irritation
H332 : Harmful if inhaled
H319 : Causes serious eye irritation.

Precautionary statements:

Prevention precautionary statement:
P262 : Do not get in eyes, on skin, or on clothing
P280+P284 : Wear protective gloves/protective clothing/eye protection/face protection, Wear respiratory protection.

Responce precautionary statement:

P305+P351+P313 : IF IN EYES: Rinse continuously with water for several minutes.Get medical advice/attention
P302+P361+P352 : IF ON SKIN: Remove/Take off immediately all contaminated clothing. Wash with plenty of soap and water.
P333+P313 : If skin irritation or a rash occurs: Get medical advice/attention
P304+P341+P313 : IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.Get medical advice/attention
P301+P330+P313 : IF SWALLOWED: Rinse mouth.Get medical advice/attentioniting.

2.2.2. Labelling according to Directive 67/548/EEC or 1999/45/EC
Hazard symbols :

Xn – Harmful

R-phrases : R40 - Limited evidence of a carcinogenic effect
S-phrases : (S1/2) - (Keep locked up and out of reach of children)
(S27) - (Take off immediately all contaminated clothing)
S3/7 - Keep container tightly closed in a cool place
S7 - Keep container tightly closed
S20/21 - When using do not eat, drink or smoke
S24/25 - Avoid contact with skin and eyes.
S64 - If swallowed, rinse mouth with water (only if the person is conscious)
Extra phrases : Safety data sheet available for professional user on request
To avoid risks to man and the environment, comply with the instructions for use

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances
Synonyms: No data available
Chemical Name: (S)-α-ethyl-2-oxo-1-pyrrolidineacetamide
Formula : $C_8H_{14}N_2O_2$
Molecular Weight:170.21
Component Concentration:Pure material
CAS No: 102767-28-2

4. FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures general :
Allow the victim to rest in a well ventilated area. Seek immediate Medical attention. check the

vital fuctions-Unconscious:maintain adequate airway andrespiration. Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

First-aid measures after inhalation :

Allow the victim to rest in a well ventilated area. Seek immediate Medical attention. Immediately wash skin with soap and copious Amounts of waterfor at least 15 minutes. If Irritation persists seek medical attention . Remove the victim into fresh air-Respiratory problems:consult a doctor/medical service. Remove to fresh air and keep patient at rest. Seek medical attention immediately. Rewmove contaminated clothing. Flush arera with large amount of water. USE SOAP. seek medical attention.

First-aid measures after skin contact :

Immediately wash skin with soap and copious Amounts of waterfor at least 15 minutes. If Irritation persists seek medical attention . Rewmove contaminated clothing. Flush arera with large amount of water. USE SOAP. seek medical attention. Wash immediately with lots of water-Sope may be used-Do not apply(chemical)neutralizing agents-Take victim to a doctor if irritation persists.

First-aid measures after eye contact :

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Immediately flush eyes with running water for at least 15 minutesSeek medical attention. Rinse immediately with lots of water-Do not apply neutralizing agents-Take victim to an ophthalmoglogist if irritation persists.

First-aid measures after ingestion :

If swallowed, wash out mouth with water, provided Person is conscious. Seek medical advice. 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. Rinse mouth with water-Immediately after ingestion:give lots of water to drink.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries :

On continuous/repeated exposure/contact:-Red skin -Dry skin-itching-Cracking of the skin. Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediatly.

Symptoms/injuries after inhalation :

Expousuren to high concentrations: Coughing-Dry/sore throat. Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms/injuries after skin contact :

Remove contaminated clothing. Flush area with large amounts of water. Use sope. Seek medical attention. Tingling/irritation of the skin.

Symptoms/injuries after eye contact :

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediatly.

Symptoms/injuries after ingestion :

After absorption of high quantities:-CNS depression-Headache-Dilation of the blood vessels-Low arterial pressure. Never give anything by mouth to an unconscious person. Wash out mouth with water.Do not induce vomting unless directed by medical personnel. Seek medical attention immediately.

Symptoms/injuries upon intravenous administration:
For information on potential signs and symptoms of exposure.See section2-Hazards identification and/or section11-Toxicological information.

4.3 Indication of immediate medical attention and special treatment needed
No data available

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media.
Suitable extinguishing media.
SMALL FIRE: Water spray, Carbon dioxide or Dry chemical powder Fire Extinguisher.
LARGE FIRE: Incase large fires Water spray(fog), Carbon dioxide, Dry chemical powder or appropriate foam for surrounding fire.
5.2 Special hazards arising from the substance or mixture
When heated to decomposition material emits toxic fumes of Nox.
5.3 Explosion hazard.
This material is assumed to be combustuble . As it all dry powders it is advisable to Ground Mechanical Equipment in contact with dry material to dissipate the potential build up of static electricity.
5.4 Precautions for fire-fighters
Self-contained breathing equipment. Protective clothing.
5.5 Further information
Wear a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment like Approved respirator,Chemically resistant gloves,Safety goggles. Protective clothing, Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.
6.2 Environmental precautions
For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
6.3 Methods and materials for containment and cleaning up
Collect and place it in a suitable, properly labeled container for recovery or disposal. Avoid contact and breathing dust.

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

7.2 Conditions for safe storage, including any incompatibilities

P401 : Store at 25°C (77°F); excursions permitted to 15 to 30°C (59-86°F)

7.3 Specific end uses

Use original container.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Exposure controls : Ventilation should be matched to conditions.Use adequate general or local exhaustive ventilation to keep airborne concentrations below the permissible exposure limits. Use process enclosure, local exhaust ventilation, or other engineering controls to control airborne levels.

8.2 Exposure Limits: Not Available.

8.3 Exposure Controls-Appropriate engineering controls -Use adequate general or local exhaustive ventilation to keep airborne concentrations below the permissible exposure limits. Use process enclosure, local exhaust ventilation, or other engineering controls to control airborne levels.

Personal protective equipment

Eye/face protection

When isolation is not possible ,chemical splash goggles or equivalent eye and face protection must be used with other applicable protective equipment

Skin protection

Protect exposed skin.

Body Protection

Wear appropriate protective clothing to prevent skin exposure.

Respiratory protection

Wear a NIOSH approved respirator,if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance Form	:	Solid
b) Colour:	:	White to off white crystalline powder.
c) Odour	:	Faint Odour
d) Odour Threshold	:	No data available
e) pH	:	No data available
f) Melting point	:	117º C
g) Boiling point	:	Not applicable
h) Flash point	:	Not applicable
i) Evaporation rate	:	Not applicable
j) Flammability	:	No data available
k) UEL/LEL	:	No data available

l) Vapour pressure : Not applicable
m) Vapour density : Not applicable
n) Density : 1.168 g/cm3 (20 C)
o) Solubility : Soluble in water
p) Partition coefficient: -0.52 (n-octane/water)
q) Auto ignition temp : 432º C
r) Decomposition temp: No data available
s) Viscosity : Not applicable
t) Explosive properties: No data available
u) Oxidizing properties: No data available

9.2 Other safety information

This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.2 Chemical stability

No data available

10.3 Possibility of hazardous reactions

Will not occur

10.4 Conditions to avoid

Avoid exposure to light and heat.

10.5 Incompatible materials

Strong oxidizing agents, strong bases,

10.6 Hazardous polymerization

Not available.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity -LD50 (mice) >1g/kg .

LD50 Oral (rat): >5000 mg/kg .

Serious eye damage/eye irritation - No data available

Respiratory or skin sensitization - No data available

Germ cell mutagenicity - Levetiracetam was not mutagenic in the Ames test or in mammalian cells in vitro in the Chinese hamster ovary/HGPRT locus assay. It was not clastogenic in an in vitro analysis of metaphase chromosomes
obtained from Chinese hamster ovary cells or in an in vivo mouse micronucleus assay. The hydrolysis product and major human metabolite of levetiracetam (ucb L057) was not mutagenic in the Ames test or the in vitro mouse lymphoma assay.

Carcinogenicity - Rats were dosed with Levetiracetam in the diet for 104 weeks at doses of 50, 300 and 1800 mg/kg/day. The highest dose corresponds to 6 times the maximum recommended daily

human dose (MRHD) of 3000mg on a mg/m² basis and it also provided systemic exposure (AUC)approximately 6 times that achieved in humans receiving the MRHD.
There was no evidence of carcinogenicity. A study was conducted in which mice received Levetiracetam in the diet for 80 weeks at doses of 60, 240 and 960 mg/kg/day (high dose is equivalent to 2 times the MRHD on a mg/m² or exposure basis). Although no evidence for carcinogenicity was seen, the potential for a carcinogenic response has not been fully evaluated in that species because adequate doses
have not been studied.
Reproductive toxicity - No data available
Specific target organ toxicity - single exposure
No data available
Specific target organ toxicity - repeated exposure
Inhalation - No data available
Aspiration hazard
No data available
Potential health effects
Inhalation – May be harmful if inhaled . May cause Respiratory Tract Irritation .
Ingestion - May be harmful if ingested. Ingestion may cause nausea, drowsiness, hypotension,hallucinations, as well as other central nervous system and systemic effects.
Skin - May cause Skin Irritation
Eyes - May cause Eye Irritation
Signs and Symptoms of Exposure
Over dose may cause dizziness or fainting sodium depletion, and increased levels of potassium in the blood.
Additional Information
The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause nausea, dizziness, visual hallucinations, palpitations and nightmares.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
Do not allow product to enter drinking water supplies, waste water or soil.

12.2 Persistence and degradability
No data available
12.3 Bioaccumulation potential
NTP: NO **IARC**: NO **OSHA:** NO **OTHER:**NO
12.4 Mobility in soil
No data available
12.5 Results of PBT and vPvB assessment
No data available
12.6 Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Product

P501: Dispose of contents/container in accordance with local/regional/national/international regulations.

14. TRANSPORT INFORMATION

14.1 UN-Number: No data available
14.2 UN proper shipping name: No data available
14.3 Transport hazard class: No data available
14.4 Packaging group: No data available
14.5 Environmental hazards: No data available
14.6 Special precautions for users: No data available

15. REGULATORY INFORMATION

EU Signal Word : Xn – Harmful
EU Indication of danger :

Risk Phrases: R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
Safety Phrases: S36/37 Wear suitable protective clothing and gloves

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available.
15.2 Chemical Safety Assessment
No data available

16. OTHER INFORMATION

History

Date of issue	-- 05.05.2015
Date of previous issue	-- 28.08.2013
Prepared by	-- NEULAND LABORATORIES LIMITED

Further information
This MSDS is compiled from available information in the public domain and for internal use only.

NOTICE::
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