

MATERIAL SAFETY DATA SHEET

Lansoprazole Delayed Release Capsules USP 15 mg

SECTION 1

Distributor's Name

Address

Phone No.

Manufacturer's Name

Address

Phone No.

Fax No.

Product Name

Date of Issue

Date of Review

SECTION 2

CAS No.

Chemical Name

Molecular Formula

Molecular Weight

Therapeutic Category

Concentration in
formulation

Excipients

SECTION 3

SECTION 4

IDENTIFICATION

Lifestar Pharma LLC

1200 MacArthur Boulevard

Mahwah, New Jersey 07430

1-888-995-4337

Inventia Healthcare Pvt. Ltd.

F1-F1/1, Additional Ambernath, M.I.D.C.,

Ambernath (East) – 421 506, dist. Thane. Maharashtra, INDIA .

91 – (0) 251 – 661 4000

91 – (0) 251 – 661 4100

Lansoprazole Delayed Release Capsules USP 15 mg

April 2018

March 2020

COMPOSITION

Lansoprazole USP

Excipients q.s

103577-45-3

2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl] methyl] sulfinyl]
benzimidazole

C₁₆H₁₄F₃N₃O₂S

369.36

Anti-ulcerative

15 mg per Capsule

Non Hazardous

HAZARD / EXPOSURE & SYMPTOMS

Capsule - If consumed in large quantity can cause nausea, vomiting, headache, dizziness, constipation, sweating & nervousness. Lethargy, cardiac arrhythmia

Capsules are non combustible, non corrosive. During fire, irritating or toxic gases may be generated by thermal decomposition.

FIRST AID MEASURES

1. Eye protection : Avoid eye contact
2. Skin protection : -
3. Respiratory protection : -

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SECTION 5

FIRE FIGHTING MEASURES

All extinguishing agents allowed. In case of fire, use water spray, dry chemical, carbon dioxide or appropriate foam.
 Wear self contained breathing apparatus & full protective gear during fire fighting, since irritating & toxic gas may be generated by thermal decomposition or combustion of material.

SECTION 6

ACCIDENTAL RELEASE MEASURES

Measures for cleaning / collection
 Person – related safety precautions
 Measures for environmental protection

Sweep up the place; put the capsules & pellets into suitable container for disposal. Don't reuse.
 Use aprons, nose masks & hand gloves during handling.

N.A

SECTION 7

STORAGE & HANDLING

Storage

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

Handling

Avoid contact with eyes. Avoid ingestion. Keep containers tightly closed. Use Stainless steel scoop for handling of product. Use aprons, nose masks & hand gloves while handling. Wash hands after handling. Product is moisture & temperature sensitive, so adequate precaution in handling should be taken.

SECTION 8

EXPOSURE CONTROL & PERSONAL CONTROL

Use gloves, goggles, shoes, Air hood, Respirator to be worn while handling dry powder.


SECTION 9

PHYSICAL & CHEMICAL PROPERTIES

Physical State

Capsules

Appearance

White to off white spherical to oval pellets filled in hard gelatin capsule with “  ”imprinted in grey ink on green colored cap and “806” imprinted in black ink on opaque white colored body.

Odour

None

pH

N.A

Vapour pressure

N.A

Water Solubility

N.A

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Decomposition Temperature Not available

Flash Point 178-182°C

Melting Point: 289.9 °C

SECTION 10

STABILITY & REACTIVITY

Chemical Stability

Stable under room temperature & humidity for period of two years from date of manufacture when properly stored. Purity decreases if stored at elevated temperature & humidity.

Conditions

To avoid excess heat, moisture, oxidant, acids & incompatible materials.

Hazardous decomposition / product

No data available

SECTION 11

TOXICOLOGICAL INFORMATION

ORL-RAT LD50 > 5000 mg kg⁻¹

Eye Contact

Mechanical action may cause irritation or eye injury.

Skin Contact

Intact capsules are generally non irritant.

SECTION 12

ECOLOGICAL INFORMATION

No data available

SECTION 13

DISPOSAL CONSIDERATION

Dispose off capsules & pellets in a manner consistent with federal, state & local regulation.

SECTION 14

TRANSPORT INFORMATION

Product non-hazardous & material not classified.

SECTION 15

REGULATORY INFORMATION

Risk Phrases

Harmful when swallowed in large doses.

Safety Phrases

Avoid contact with eye. In case of accident, seek medical advice immediately.

SECTION 16

OTHER INFORMATION

The enclosed information is given in good faith & to the best of our knowledge for the purpose of the control of substances.

No guarantee or warranty as to quality or properties is expressed or guaranteed.



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