

**MATERIAL SAFETY DATA SHEET**

**Lansoprazole Delayed Release Capsules USP 15 mg**

**SECTION 1**

**IDENTIFICATION**

Manufacturer's Name **Inventia Healthcare Limited.**  
(formerly known as Inventia Healthcare Pvt. Ltd.)  
Address F1-F1/1, Additional Ambernath, M.I.D.C.,  
Ambernath (East) – 421 506, dist. Thane. Maharashtra, INDIA .  
Phone No.: 91 – ( 0 ) 251 – 661 4000  
Fax No.: 91 – ( 0 ) 251 – 661 4100  
Product Name Lansoprazole Delayed Release Capsules USP 15 mg  
Date of Issue Aug. 2018  
Date of Review Jul. 2020

**SECTION 2**

**HAZARD(S) IDENTIFICATION**

**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.

**SECTION 3**

**COMPOSITION/ INFORMATION ON INGREDIENTS**

Lansoprazole USP  
Excipients q.s  
CAS No. 103577-45-3  
Chemical Name 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl] methyl] sulfinyl] benzimidazole  
Molecular Formula  $C_{16}H_{14}F_3N_3O_2S$   
Molecular Weight 369.36  
Therapeutic Category Anti-ulcerative  
Concentration in formulation 15 mg per Capsule  
Excipients Non Hazardous

**SECTION 4**

**FIRST-AID MEASURES**

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

**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.

**MATERIAL SAFETY DATA SHEET**

**Lansoprazole Delayed Release Capsules USP 15 mg**

**SECTION 6**

**ACCIDENTAL RELEASE MEASURES**

Measures for cleaning / collection	Sweep up the place; put the capsules & pellets into suitable container for disposal. Don't reuse.
Person – related safety precautions	Use aprons, nose masks & hand gloves during handling.
Measures for environmental protection	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 CONTROLS & PERSONAL PROTECTION**

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
Decomposition Temperature	Not available
Flash Point	178-182°C
Melting Point:	289.9 °C

**MATERIAL SAFETY DATA SHEET**

**Lansoprazole Delayed Release Capsules USP 15 mg**

**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<sup>-1</sup>

**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.

**MATERIAL SAFETY DATA SHEET**

**Lansoprazole Delayed Release Capsules USP 30 mg**

**SECTION 1**

**IDENTIFICATION**

Manufacturer's Name **Inventia Healthcare Limited.**  
(formerly known as Inventia Healthcare Pvt. Ltd.)  
Address F1-F1/1, Additional Ambernath, M.I.D.C.,  
Ambernath (East) – 421 506, dist. Thane. Maharashtra, INDIA .  
Phone No.: 91 – ( 0 ) 251 – 661 4000  
Fax No.: 91 – ( 0 ) 251 – 661 4100

Product Name Lansoprazole Delayed Release Capsules USP 30 mg  
Date of Issue Aug. 2018  
Date of Review Jul. 2020

**SECTION 2**

**HAZARD(S) IDENTIFICATION**

**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.

**SECTION 3**

**COMPOSITION/ INFORMATION ON INGREDIANTS**

Lansoprazole USP  
Excipients q.s  
CAS No. 103577-45-3  
Chemical Name 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl] methyl] sulfinyl] benzimidazole  
Molecular Formula  $C_{16}H_{14}F_3N_3O_2S$   
Molecular Weight 369.36  
Therapeutic Category Anti-ulcerative  
Concentration in formulation 30 mg per Capsule  
Excipients Non Hazardous

**SECTION 4**

**FIRST-AID MEASURES**

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

**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.

**MATERIAL SAFETY DATA SHEET**

**Lansoprazole Delayed Release Capsules USP 30 mg**

**SECTION 6**

**ACCIDENTAL RELEASE MEASURES**

Measures for cleaning / collection

Sweep up the place; put the capsules & pellets into suitable container for disposal. Don't reuse.

Person – related safety precautions

Use aprons, nose masks & hand gloves during handling.

Measures for environmental protection

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 CONTROLS & PERSONAL PROTECTION**

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 capsule with “Lifestar”<sup>®</sup> imprinted in white ink on black colored cap and “807” imprinted in black ink on opaque white colored body.

Odour

None

pH

N.A

Vapour pressure

N.A

Water Solubility

N.A

Decomposition

Not available

Temperature

Flash Point

178-182°C

Melting Point:

289.9 °C

**MATERIAL SAFETY DATA SHEET**

**Lansoprazole Delayed Release Capsules USP 30 mg**

**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<sup>-1</sup>

**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.

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**REGULATORY INFORMATION**

**Risk Phrases**

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**Safety Phrases**

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

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