

Zoton

Preparation Date 05-Jan-2007

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Revision Number 1

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

Product Name Zoton
Common Name Not available
Chemical Name Not applicable
Synonyms Not available
Product Use Pharmaceutical product
Classification Gastrointestinal Drug; Anti-ulcer

Supplier Wyeth
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 Chemtrec International 1-703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	EC No.	Composition	Classification
Inactive Ingredients	Not applicable	Not applicable	Remainder	Not applicable
Lansoprazole	103577-45-3	None assigned	15 - 30 mg/tablet	R 63/64, S13/36/37/38

3. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical tablet

Physical State Solid

Odor Not available

Potential Physical Hazards

Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes

Not available

Skin

Not available

Inhalation

Not available

Ingestion

The most common effects may include headache, diarrhea, stomach pain, nausea, vomiting, changes in taste, dizziness, vertigo, confusion, blurred vision, hallucinations, constipation, wind, dry or sore mouth and throat, fatigue, burning or prickling feeling, itching, thinning of hair, sensitivity to light, muscle or joint pain, fluid retention, swelling, depression, kidney problems, inflammation of the kidney, and changes in kidney or liver function.

May cause harm to the unborn child. May cause harm to breastfed babies.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s)

Gastrointestinal system.

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects

See Section 12.

4. FIRST AID MEASURES

Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Inhalation	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable
Extinguishing Media	
Suitable Extinguishing Media	Use water spray, foam, dry chemical or carbon dioxide.
Unsuitable Extinguishing Media	Do NOT use water jet.
Fire Fighting	Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.
Hazardous Combustion Products	Carbon oxides, nitrogen oxides.
Protective Equipment and Precautions for Firefighters	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Refer to protective measures listed in Sections 7 and 8.
Environmental Precautions	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
Methods for Containment	Not available
Methods for Cleaning up	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling	For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
Storage	No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Lansoprazole	Exposure Guideline 60 mcg/m ³
Engineering Controls	Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.
Personal Protective Equipment	
Eye/face Protection	Provide eye protection based on risk assessment.
Skin Protection	Wear nitrile or latex gloves. Wear protective garment.
Respiratory Protection	Base respirator selection on a risk assessment.
General Hygiene Considerations	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
Other	Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Pharmaceutical tablet	Physical State	Solid
Color	White to yellow White	Odor	Not available
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not applicable	Water Solubility	Practically insoluble in water
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Density	Not applicable
Vapor Pressure	Not applicable		
Boiling Point	Not available	Autoignition Temperature	Not available
Flash Point	Not available	Melting Point	Not available
Flammability Limits in Air	Upper Not applicable	Lower Not applicable	
Explosion Limits	Upper Not applicable	Lower Not applicable	

10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature.
Conditions to Avoid	No data available
Materials to Avoid	No materials to be especially mentioned.
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Lansoprazole	
LD50 Oral	>5 gm/kg rats >2 gm/kg dogs
Acute Dermal Irritation	Not available
Primary Eye Irritation	Not available
Sensitization	Not available

Multiple Dose Toxicity

Lansoprazole	
No Toxicologic Effect Dose/Species/Study Length:	See Carcinogenicity

Maximum Tolerated Dose (MTD), Oral

Lansoprazole	
Carcinogenicity	Gastric tumors were reported in long-term studies in rats. An increased incidence of spontaneous retinal atrophy was also reported in long-term studies in rats. These lesions are common to albino laboratory rats but have not been reported in non-human primates, dogs or mice. Therefore, they are regarded as rat-specific effects. No such treatment related effects have been reported in humans treated continuously for long periods of time. In a 2-year study in rats Gastric tumors a small increase in testicular interstitial cell adenomas with high doses was reported. The relevance to humans is not known.
Genetic Toxicity	Non-mutagenic in Ames test; non-clastogenic in chromosomal aberrations assay. Non-mutagenic in the mouse micronucleus assay. Positive in the human lymphocyte chromosomal aberration assay.
Reproductive Toxicity	Studies in rats and rabbits were found to have no effect on fertility and reproductive performance. At maternally toxic doses, there was a small decrease in fetal survival in rabbits and pup weight in rats.
Developmental Toxicity	Did not show teratogenic effects in rats.

Lansoprazole	
Target Organ(s) of Toxicity	No data available

12. ECOLOGICAL INFORMATION

Chemical Fate Information

Lansoprazole	
Mobility	Not available
Biodegradability	Not available
Stability in Water	Not available
Bioaccumulation	Not available

Ecotoxicity

Lansoprazole	
Microorganisms	NOEC at all concentrations tested.
Algae	Not available
Daphnia	EC50/48h/daphnia, NOEC > 21.9 mg/l
Fish	LC60/96h/trout = 18.3 mg/l, NOEC = 6.2 mg/l

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety
Format This MSDS was prepared in accordance with Directive 2001/58/EC.
List of References See Patient Package Insert for more information.
Revision Summary Not applicable

Disclaimer:

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End of MSDS