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
P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-688-4400

Emergency Telephone Number
Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

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

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

<table>
<thead>
<tr>
<th>Eyes</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>Not available</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Not available</td>
</tr>
<tr>
<td>Ingestion</td>
<td>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 pricking 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.</td>
</tr>
</tbody>
</table>

Therapeutic Target Organ(s)
Gastrointestinal system.
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/m³

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pharmaceutical tablet</td>
</tr>
<tr>
<td>Color</td>
<td>White to yellow White</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>Not available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Partition Coefficient</td>
<td>Not available</td>
</tr>
<tr>
<td>(n-octanol/water)</td>
<td></td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td>Explosion Limits</td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td>Chemical Stability</td>
<td>Stable at room temperature.</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>No materials to be especially mentioned.</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>None under normal use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td>None under normal use.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Effect</th>
<th>Lansoprazole</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Dermal Irritation</td>
<td>Not available</td>
</tr>
<tr>
<td>Primary Eye Irritation</td>
<td>Not available</td>
</tr>
<tr>
<td>Sensitization</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Lansoprazole</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive Toxicity</td>
<td>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.</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>Did not show teratogenic effects in rats.</td>
</tr>
</tbody>
</table>

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

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End of MSDS