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

Product Name  Loramet
Common Name  Not available
Chemical Name  Not applicable
Synonyms  Lormetazepam
Product Use  Pharmaceutical product
Classification  Anxiolytics, Sedatives, and Hypnotics
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

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 drowsiness, mental confusion, lethargy, dizziness, lightheadedness, weakness, unsteadiness, slurred speech, abdominal or stomach cramps or pain, blurred vision, changes in libido, constipation, diarrhea, dryness of mouth or increased thirst, euphoria, headache, increased bronchial secretions or excessive salivation, muscle spasm, nausea, vomiting, problems with urination, tremor, and unusual tiredness or weakness. 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)  Central nervous system.

Not listed by OSHA, NTP or IARC.
Potential Environmental Effects
There is no known ecological information for this product.

### 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.

**Aggravated Medical Conditions**
Strong sedative effect.

### 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
Lormetazepam

Exposure Guideline
0.005 mg/m³ (Schering OEG)

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>Not available</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 (n-octanol/water)</td>
<td>Not available</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>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Practically insoluble in water</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition Temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Lower</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

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

Lormetazepam

<table>
<thead>
<tr>
<th>Effect</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 Oral</td>
<td>&gt;5000 mg/kg rats</td>
</tr>
<tr>
<td>Acute Dermal Irritation</td>
<td>Not a skin irritant.</td>
</tr>
<tr>
<td>Primary Eye Irritation</td>
<td>Mild eye irritation.</td>
</tr>
<tr>
<td>Sensitization</td>
<td>Not applicable</td>
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</tbody>
</table>

Multiple Dose Toxicity

Lormetazepam

<table>
<thead>
<tr>
<th>Effect</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Toxicologic Effect</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Maximum Tolerated Dose (MTD), Oral

Lormetazepam

<table>
<thead>
<tr>
<th>Effect</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogenicity</td>
<td>No studies to assess the carcinogenic potential have been performed.</td>
</tr>
<tr>
<td>Genetic Toxicity</td>
<td>No studies to assess the mutagenic potential have been performed.</td>
</tr>
<tr>
<td>Reproductive Toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>Reproduction studies in rats and rabbits revealed no evidence of teratogenic effect after the administration of maternally toxic doses.</td>
</tr>
</tbody>
</table>

Target Organ(s) of Toxicity: No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information: Not available

Ecotoxicity: Not available

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
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   Changes to composition.

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