Safety Data Sheet
European Format

Loramet

Preparation Date 08-Dec-2006 **Revision Date** 27-Mar-2007 **Revision Number** 1

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	**Exposure Guideline**
Lormetazepam	0.005 mg/m^3 (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

Appearance	Pharmaceutical Tablet	**Physical State**	Solid
Color	Not available	**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 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

Lormetazepam

LD50 Oral	>5000 mg/kg rats
Acute Dermal Irritation	Not a skin irritant.
Primary Eye Irritation	Mild eye irritation.
Sensitization	Not applicable

Multiple Dose Toxicity

Lormetazepam

No Toxicologic Effect Dose/Species/Study Length:	Not applicable

Maximum Tolerated Dose (MTD), Oral

Lormetazepam

Carcinogenicity	No studies to assess the carcinogenic potential have been performed.
Genetic Toxicity	No studies to assess the mutagenic potential have been performed.
Reproductive Toxicity	No data available
Developmental Toxicity	Reproduction studies in rats and rabbits revealed no evidence of teratogenic effect after the administration of maternally toxic doses.

Lormetazepam

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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End of MSDS