

Serax

Preparation Date 20-Nov-2006

Revision Date 27-Mar-2007

Revision Number 1

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

<b>Product Name</b>	Serax
<b>Common Name</b>	Not available
<b>Chemical Name</b>	Not applicable
<b>Synonyms</b>	Oxazepam, Adumbran, Alopam, Anxiolit, Anxiolit Retard, Azutranquil, Durazepam, Noctazepam, Oksazepan, Opamox, Oxahexal, Oxapam, Oxepam, Praxiten, Psiquivas, Quilibrex, Serepax, Seresta, Seresta Forte, Sobile, Sobrile, Serpax, Serenal
<b>Product Use</b>	Pharmaceutical product
<b>Classification</b>	Central Nervous System, Tranquilizer
<b>Supplier</b>	Wyeth P.O. Box 8299 Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400
<b>Emergency Telephone Number</b>	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.

<b>Appearance</b> Pharmaceutical tablet or capsule	<b>Physical State</b> Solid	<b>Odor</b> Not available
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**Potential Physical Hazards** Powders and solids are presumed to be combustible.

#### Potential Health Effects

<b>Eyes</b>	Not available
<b>Skin</b>	Not available
<b>Inhalation</b>	Not available
<b>Ingestion</b>	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.

#### 5. FIRE-FIGHTING MEASURES

**Flammable Properties**

Not flammable

**Extinguishing Media**

**Suitable Extinguishing Media**  
**Unsuitable Extinguishing Media**

Use water spray, foam, dry chemical or carbon dioxide.  
 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

<b>Engineering Controls</b>	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.
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Provide eye protection based on risk assessment.
<b>Skin Protection</b>	Wear nitrile or latex gloves. Wear protective garment.
<b>Respiratory Protection</b>	Base respirator selection on a risk assessment.
<b>General Hygiene Considerations</b>	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
<b>Other</b>	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

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

## 10. STABILITY AND REACTIVITY

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

## 11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

### Acute Toxicity

Oxazepam

LD50 Oral	>5000 mg/kg mice
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

**Multiple Dose Toxicity****Oxazepam**

No Toxicologic Effect Dose/Species/Study Length:	See Carcinogenicity
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**Maximum Tolerated Dose (MTD), Oral****Oxazepam**

Carcinogenicity	Chronic toxicity studies in dogs showed no toxic manifestation. An increase in benign thyroid follicular cell tumors, testicular interstitial cell adenomas, and prostatic adenomas was observed in long-term studies in rats. In mice, a dose-related increase in liver carcinomas was also observed.
Genetic Toxicity	No studies to assess the mutagenic potential have been performed.
Reproductive Toxicity	Breeding studies in rats through two successive litters did not produce fetal abnormality.
Developmental Toxicity	Reports suggest an increased incidence of congenital abnormalities in children whose mothers used anticonvulsants during pregnancy.

**Oxazepam**

Target Organ(s) of Toxicity	No data available
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**12. ECOLOGICAL INFORMATION**

The following effects are based on the Active Pharmaceutical Ingredient.

<u>Chemical Fate Information</u>	Not available
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<u>Ecotoxicity</u>	Not available
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**13. DISPOSAL CONSIDERATIONS**

Waste Disposal Method	Dispose of in accordance with local and national regulations.
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**14. TRANSPORT INFORMATION**

Transport Information	This material is not classified as hazardous for transport.
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**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
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**16. OTHER INFORMATION**

<b>Format</b>	This MSDS was prepared in accordance with Directive 2001/58/EC.
<b>List of References</b>	See Patient Package Insert for more information.
<b>Revision Summary</b>	Addition to synonyms. Changes to composition.

## Disclaimer:

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**End of MSDS**