



# Material Safety Data Sheet

12601 Twinbrook Parkway,  
Rockville, MD 20852 USA

Phone Calls: 301-881-0666  
8 a.m. to 5 p.m. EST Mon. - Fri.

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## LOVASTATIN

Catalog Number: 1370600

Revision Date:

July 13, 2005

### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

**Common Name:** Lovastatin

**Manufacturer:** U. S. Pharmacopeia

**Responsible Party:** Reference Standards Technical Services

**Mailing Address:** 12601 Twinbrook Parkway, Rockville, MD 20852 USA

**Phone:** 301-816-8129

**Hours:** 8 a.m. to 5 p.m. EST Mon. - Fri.

**Product Use:** USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

### SECTION 2 - HAZARD INFORMATION

#### EMERGENCY OVERVIEW - Reproductive Hazard.

**Adverse Effects:** Adverse effects may include constipation, diarrhea, gas, heartburn, stomach pain, dizziness, headache, nausea, skin rash, fever, muscle aches or cramps, and unusual tiredness or weakness. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Overdose Effects:** n/f

**Acute:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

**Chronic:** Possible hypersensitization.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to the material, liver disease, organ transplant with immunosuppressant therapy, and serious conditions predisposing kidney failure secondary to rhabdomyolysis (including hypotension; severe acute infection; severe metabolic, endocrine, or electrolyte disorders; uncontrolled seizures; and major surgery or trauma).

**Cross Sensitivity:** Persons sensitive to any other HMG-CoA reductase inhibitors may be sensitive to this material also.

**Target Organs:** n/f

**For additional information on toxicity, see Section 11.**

### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

**Common Name:** Lovastatin

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Formula: C<sub>24</sub>H<sub>36</sub>O<sub>5</sub>

Synonym: Mevinolin

Chemical Name: Butanoic acid, 2-methyl-, 1,2,3,7,8,8a-hexahydro-3,7-dimethyl-8-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1-naphthalenyl ester, [1S-[1alpha(R\*), 3alpha, 7beta, 8beta(2S\*, 4S\*), 8a beta]]-

CAS: 75330-75-5

RTECS Number: EK7907000

Chemical Family: Lactone

Therapeutic Category: Antihyperlipidemic; inhibitor (HMG - CoA reductase)

Composition: Pure Material

## SECTION 4 - FIRST AID MEASURES

**Inhalation:** May cause irritation. Remove to fresh air.

**Eye:** May cause irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

**Skin:** May cause irritation. Flush with copious quantities of water.

**Ingestion:** May cause irritation. Flush out mouth with water. This material is absorbed from the gastrointestinal tract.

**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

### Note to Physicians

**Overdose Treatment:** Treatment of lovastatin overdose should be symptomatic and supportive and may include the following:

1. Administer activated charcoal as a slurry.
2. For rhabdomyolysis, administer sufficient 0.9% saline to maintain urine output of 2 to 3 mL/kg/hr. Monitor input and output, serum electrolytes, CK, and renal function. Diuretics may be necessary to maintain urine output. Urinary alkalinization is not routinely recommended. [Meditext 2005]

## SECTION 5 - FIREFIGHTING MEASURES

**Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

**Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

## SECTION 7 - HANDLING AND STORAGE

**Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

**Storage:** Store in tight container under nitrogen as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. Store in a freezer under nitrogen.

## SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

**Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.

**Respiratory Protection:** Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

**Gloves:** Chemically compatible

**Eye Protection:** Safety goggle or glasses

**Protective Clothing:** Protect exposed skin.

**Exposure Limits:** n/f

<b>SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES</b>
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**Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.**

**Appearance and Odor:** White to off-white crystalline powder.

**Odor Threshold:** n/f

**pH:** n/f

**Melting Range:** 174 - 175° C (under nitrogen)

**Boiling Point:** n/f

**Flash Point:** n/f

**Autoignition Temperature:** 725° F

**Evaporation Rate:** n/f

**Upper Flammability Limit:** n/f

**Lower Flammability Limit:** n/f

**Vapor Pressure:** n/f

**Vapor Density:** n/f

**Specific Gravity:** n/f

**Solubility in Water:** Insoluble

**Fat Solubility:** n/f

**Other Solubility:** Freely soluble in chloroform; soluble in acetone, in acetonitrile, and in methyl alcohol; sparingly soluble in alcohol; practically insoluble in petroleum spirit.

**Partition Coefficient: n-octanol/water:** n/f

**Percent Volatile:** n/f

**Reactivity in Water:** n/f

**Explosive Properties:** n/f

**Oxidizing Properties:** n/f

**Formula:** C<sub>24</sub>H<sub>36</sub>O<sub>5</sub>

**Molecular Weight:** 404.54

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## SECTION 10 - STABILITY AND REACTIVITY

**Conditions to Avoid:** Avoid exposure to air and heat.

**Incompatibilities:** Oxidizing agents.

**Decomposition Products:** When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions.

**Stable?** Yes      **Hazardous Polymerization?** No

## SECTION 11 - TOXICOLOGICAL PROPERTIES

**Oral Rat:** LD50: >5 grams/kg

**Oral Mouse:** LD50: >1 gram/kg

**Other Toxicity Data:** n/f

**Irritancy Data:** n/f

**Corrosivity:** n/f

**Sensitization Data:** n/f

**Listed as a Carcinogen by:**      **NTP:** No      **IARC:** No      **OSHA:** No

**Other Carcinogenicity Data:** Studies of lovastatin in mice found an increased incidence of hepatocellular carcinomas and adenomas and an increase in pulmonary adenomas. In rats a positive dose-response relationship for hepatocellular carcinogenicity was observed. [USP DI 2005]

**Mutagenicity Data:** No evidence of mutagenicity was noted by a microbial mutagen test using strains of *Salmonella typhimurium* with or without rat or mouse liver metabolic activation. No evidence of mutagenicity was seen in an in vitro chromosomal aberration assay in mouse bone marrow. [Meditext 2005]

**Reproductive and Developmental Effects:** Inhibited formation of cholesterol may impair fetal development. Birth defects have been reported. Studies in mice and rats at doses several times of human doses found an increased incidence of skeletal malformations.

## SECTION 12 - ECOLOGICAL INFORMATION

**Ecological Information:** *Daphnia magna*: LC50: 10 mg/L/96 hrs

## SECTION 13 - DISPOSAL CONSIDERATIONS

**Disposal:** Dispose of waste in accordance with all applicable Federal, State and local laws.

## SECTION 14 - TRANSPORT INFORMATION

**Shipping Name:** n/f

**Class:** n/f

**UN Number:** n/f

**Packing Group:** n/f

**Additional Transport Information:** n/f

## SECTION 15 - REGULATORY INFORMATION

**U.S. Regulatory Information:** California Proposition 65: Developmental toxicity

**International Regulatory Information:** n/f

## SECTION 16 - OTHER INFORMATION

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**Revision:** 13-Jul-05**Previous Revision Date:** 26-Feb-01