SAFETY DATA SHEET

1. Identification

Product identifier **Lovastatin Epimer Mixture**

Other means of identification

Catalog number 1236833

Chemical name Epilovastatin and lovastatin 1:1 mixture

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Serious eye damage/eye irritation Category 2B
Reproductive toxicity Category 1B

OSHA hazard(s) Not classified.

Label elements

Signal word Danger

Hazard statement Causes eye irritation. May damage fertility or the unborn child.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

Response If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Mixture

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Epilovastatin		79952-44-6	50
Lovastatin		75330-75-5	50

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion Rinse mouth thoroughly. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed Irritation of eyes and mucous membranes.

Indication of immediate medical attention and special treatment needed Treatment of statin overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as an aqueous slurry. For rhabdomyolysis, administer 0.9% saline to maintain urine output of 2 - 3 milliliters/kg/hour. Monitor fluid balance, serum electrolytes, CPK, liver enzymes, and renal function. Administer diuretics if needed to maintain urine output. Urinary alkalinization is not recommended. Hemodialysis is not expected to enhance clearance. [Poisindex 2009]

General information Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire-fighting equipment/instructions Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe 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. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for safe storage, including any incompatibilities Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Components	Type	Value
Lovastatin (CAS 75330-75-5)	TWA	0.05 mg/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to off-white powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Not available.
Partition coefficient (n-octanol/water)	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	None known.

Hazardous decomposition products Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion Based on available data, the classification criteria are not met.

Inhalation Due to lack of data the classification is not possible.

Skin contact Due to lack of data the classification is not possible.

Eye contact Causes eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics Statins: Muscle pain, weakness, or stiffness. Numbness or tingling in arms or legs. Insomnia. Fever, Tiredness. Upper respiratory infection. Headache. Dizziness. Nausea. Diarrhea. Constipation. Stomach pain. Indigestion. Gas. Skin rash. Sexual dysfunction.

Delayed and immediate effects of exposure Rhabdomyolysis.

Cross sensitivity Persons sensitive to other HMG-CoA reductase inhibitors (e.g., fluvastatin, atorvastatin, pravastatin) may be sensitive to this material also.

Medical conditions aggravated by exposure Statins: Active liver disease or history of. Unexplained persistent elevations of transaminase values. Active alcoholism. Myopathy. Electrolyte, endocrine, or metabolic disorders. Severe infection. Seizure disorders. Organ transplant with immunosuppressant therapy. Amyotrophic lateral sclerosis (ALS). Kidney impairment.

Acute toxicity Based on available data, the classification criteria are not met.

Components	Species	Test Results
Lovastatin (CAS 75330-75-5)		
Acute		
Oral		
LD50	Mouse	> 20000 mg/kg
	Rat	> 5000 mg/kg
	Rodent	1300 mg/kg

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Causes eye irritation.

Local effects

Lovastatin

Eye irritancy test
Result: Slightly irritating.
Species: Rabbit
Skin irritancy test
Result: Nonirritating.
Species: Rabbit

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Due to lack of data the classification is not possible.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Mutagenicity

Lovastatin

Ames test in Salmonella typhimurium
Result: Negative.
Forward mutation assay in V-79 mammalian cells
Result: Negative.
In vitro alkaline elution assay in rat or mouse hepatocytes
Result: Negative.
In vitro chromosomal aberration assay in Chinese hamster ovary cells
Result: Negative.
In vivo chromosomal aberration assay in mouse bone marrow, with and without activation.
Result: Negative.

Carcinogenicity Based on available data, the classification criteria are not met.
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Lovastatin

20 - 500 mg/kg/day 21-month Carcinogenicity study, administered orally
Result: Increased incidence of hepatocellular adenomas and carcinomas at high dose (3-4 times expected human exposure) but no tumor increases at 20 or 100 mg/kg/day.
Species: Mouse

Lovastatin	5 - 180 mg/kg/day 24-month Carcinogenicity study Result: Positive dose-response for hepatocellular carcinogenicity in males. Species: Rat

Reproductive toxicity May damage fertility or the unborn child.
Therapeutic use of statins during pregnancy may decrease cholesterol and cholesterol-derived substances essential for fetal development. Results of animal studies indicate that many statins are associated with adverse fetal outcomes at maternally toxic doses.
An analysis of more than 200 women who used lovastatin therapeutically during their first trimester of pregnancy showed the incidence of congenital anomalies in their offspring to be comparable to that in the general population.

Reproductivity

Lovastatin	200 mg/kg/day Reproductivity and development study, administered during gestation Result: Fetotoxicity; skeletal anomalies (may be secondary to maternal toxicity at doses >/= 100 mg/kg/day). Species: Rat 5 - 15 mg/kg/day Reproductivity and development study Result: Not teratogenic. Species: Rabbit 80 mg/kg/day Reproductivity and development study, administered during gestation Result: Increase in skeletal malformations. Species: Mouse 80 mg/kg/day Reproductivity and development study, administered during gestation Result: Increase in skeletal malformations. Species: Rat Reproductivity Result: No drug-related effects on fertility. Species: Rat

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

Components		Species	Test Results
Lovastatin (CAS 75330-75-5)			
Acute			
Crustacea	LC50	Daphnia magna	10 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Not available.

Hazardous waste code Not available.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.

15. Regulatory information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No

Other federal regulations

Safe Drinking Water Act (SDWA)	Not regulated.
Food and Drug Administration (FDA)	Not regulated.
US state regulations	WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date	04-07-2014
Version #	01
Further information	Not available.

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