TCI AMERICA

Material Safety Data Sheet

HAZARD WARNINGS	RISK PHRASES	PROTECTIVE CLOTHING
	The health risks of this compound have not been fully determined. Exposure may cause irritation of the skin, eyes, and respiratory system.	

Section I. Chemical Product and Company Identification

Chemical Name: **Simvastatin**

Catalog Number	S0509
Synonym	Not available.
Chemical Formula	$C_{25}H_{38}O_5$
CAS Number	79902-63-9

Supplier: TCI America
9211 N. Harborgate St.
Portland OR
1-800-423-8616

In case of Emergency Call: **Chemtrec®**
(800) 424-9300 (U.S.)
(703) 527-3887 (International)

Section II. Composition and Information on Ingredients

Chemical Name	CAS Number	Percent (%)	TLV/PEL	Toxicology Data
Simvastatin	79902-63-9	Min. 97.0 (HPLC)	Not available.	Rat LD_{50} (oral) 4438 mg/kg Mouse LD_{50} (oral) 3000 mg/kg Rat LD_{50} (subcutaneous) 672 mg/kg

Section III. Hazards Identification

Acute Health Effects

No specific information is available in our data base regarding the toxic effects of this material for humans. However, exposure to any chemical should be kept to a minimum. Skin and eye contact may result in irritation. May be harmful if inhaled or ingested. Always follow safe industrial hygiene practices and wear proper protective equipment when handling this compound.

Chronic Health Effects

CARCINOGENIC EFFECTS : Not available.
MUTAGENIC EFFECTS : Not available.
TERATOGENIC EFFECTS : Not available.
DEVELOPMENTAL TOXICITY: Reproductive effects.
Man TDLo Oral 14.91 mg/kg, male 30 days prior to mating
TOXIC EFFECTS:
Paternal Effects - Testes, epididymis, sperm duct
Rat TDLo Oral 300 mg/kg, female 6-17 days of pregnancy
TOXIC EFFECTS:
Effects on Embryo or Fetus - Fetotoxicity
Rat TDLo Oral 480 mg/kg, female 6-17 days of pregnancy
TOXIC EFFECTS:
Effects on Newborn - Behavioral
Repeated or prolonged exposure to this compound is not known to aggravate existing medical conditions.

Section IV. First Aid Measures

Eye Contact

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

Skin Contact

In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Inhalation

If the victim is not breathing, perform mouth-to-mouth resuscitation. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, oxygen can be administered. Seek medical attention if respiration problems do not improve.

Ingestion

INDUCE VOMITING by sticking finger in throat. Lower the head so that the vomit will not reenter the mouth and throat. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Examine the lips and mouth to ascertain whether the tissues are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive.

Section V. Fire and Explosion Data

Flammability	May be combustible at high temperature.	Auto-Ignition	Not available.
Flash Points	Not available.	Flammable Limits	Not available.

Combustion Products

These products are toxic carbon oxides (CO, CO_2).

Fire Hazards

Not available.

Explosion Hazards

Risks of explosion of the product in presence of mechanical impact: Not available.
Risks of explosion of the product in presence of static discharge: Not available.

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Fire Fighting Media and Instructions	SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. DO NOT use water jet. Consult with local fire authorities before attempting large scale fire-fighting operations.

Section VI. Accidental Release Measures

Spill Cleanup Instructions	Use a shovel to put the material into a convenient waste disposal container. Finish cleaning the spill by rinsing any contaminated surfaces with copious amounts of water. Consult federal, state, and/or local authorities for assistance on disposal.

Section VII. Handling and Storage

Handling and Storage Information	Keep away from heat. Mechanical exhaust required. When not in use, tightly seal the container and store in a dry, cool place. Avoid excessive heat and light. Do not breathe dust. Always store away from incompatible compounds such as oxidizing agents.

Section VIII. Exposure Controls/Personal Protection

Engineering Controls	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.
Personal Protection	Splash goggles. Lab coat. Dust respirator. Boots. Gloves. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product. Be sure to use a MSHA/NIOSH approved respirator or equivalent. 
Exposure Limits	Not available.

Section IX. Physical and Chemical Properties

Physical state @ 20°C	Solid. (White powder.)	Solubility	Soluble in chloroform, methanol, ethanol, hexane, hydrochloric acid, polyethylene glycol, propylene glycol, sodium hydroxide, water.
Specific Gravity	Not available.		
Molecular Weight	418.57	Partition Coefficient	Not available.
Boiling Point	Not available.	Vapor Pressure	Not applicable.
Melting Point	134°C (273.2°F)	Vapor Density	Not available.
Refractive Index	Not available.	Volatility	Not available.
Critical Temperature	Not available.	Odor	Not available.
Viscosity	Not available.	Taste	Not available.

Section X. Stability and Reactivity Data

Stability	This material is stable if stored under proper conditions. (See Section VII for instructions)
Conditions of Instability	Avoid excessive heat and light.
Incompatibilities	Reactive with oxidizing agents.

Section XI. Toxicological Information

RTECS Number	EK7798000
Routes of Exposure	Eye Contact. Ingestion. Inhalation.
Toxicity Data	Rat LD_{50} (oral) 4438 mg/kg Mouse LD_{50} (oral) 3000 mg/kg Rat LD_{50} (subcutaneous) 672 mg/kg
Chronic Toxic Effects	**CARCINOGENIC EFFECTS** : Not available. **MUTAGENIC EFFECTS** : Not available. **TERATOGENIC EFFECTS** : Not available. **DEVELOPMENTAL TOXICITY**: Reproductive effects. Man TDLo Oral 14.91 mg/kg, male 30 days prior to mating TOXIC EFFECTS: Paternal Effects - Testes, epididymis, sperm duct Rat TDLo Oral 300 mg/kg, female 6-17 days of pregnancy TOXIC EFFECTS: Effects on Embryo or Fetus - Fetotoxicity Rat TDLo Oral 480 mg/kg, female 6-17 days of pregnancy TOXIC EFFECTS: Effects on Newborn - Behavioral Repeated or prolonged exposure to this compound is not known to aggravate existing medical conditions.
Acute Toxic Effects	No specific information is available in our data base regarding the toxic effects of this material for humans. However, exposure to any chemical should be kept to a minimum. Skin and eye contact may result in irritation. May be harmful if inhaled or ingested. Always follow safe industrial hygiene practices and wear proper protective equipment when handling this compound.

Continued on Next Page Emergency phone number (800) 424-9300

Section XII. Ecological Information

Ecotoxicity	Not available.
Environmental Fate	Simvastatin's production and use as antiperlipidemic may result in its release to the environment through various waste streams. If released to air, an estimated vapor pressure of 6.4X10-13 mm Hg at 25 deg C indicates simvastatin will exist solely in the particulate phase in the ambient atmosphere. Particulate-phase simvastatin will be removed from the atmosphere by wet and dry deposition. If released to soil, simvastatin is expected to have no mobility based upon an estimated Koc of 8,400. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 2.8X10-10 atm-cu m/mole. Biodegradation data were not available. If released into water, simvastatin is expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant. An estimated BCF of 800 suggests the potential for bioconcentration in aquatic organisms is high. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions. Occupational exposure to simvastatin may occur through inhalation and dermal contact with this compound at workplaces where simvastatin is produced or used. The general population may be exposed to simvastatin via ingestion of pharmaceutical products containing simvastatin.

Section XIII. Disposal Considerations

Waste Disposal	Recycle to process, if possible. Consult your local regional authorities. You may be able to dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber system. Observe all federal, state and local regulations when disposing of the substance.

Section XIV. Transport Information

DOT Classification	Not a DOT controlled material (United States).
PIN Number	Not applicable.
Proper Shipping Name	Not applicable.
Packing Group (PG)	Not applicable.
DOT Pictograms	

Section XV. Other Regulatory Information and Pictograms

TSCA Chemical Inventory (EPA)	This product is **NOT** on the EPA Toxic Substances Control Act (TSCA) inventory. The following notices are required by 40 CFR 720.36 (C) for those products not on the inventory list: (i) These products are supplied solely for use in research and development by or under the supervision of a technically qualified individual as defined in 40 CFR 720.0 et sec. (ii) The health risks of these products have not been fully determined. Any information that is or becomes available will be supplied on an MSDS sheet.
WHMIS Classification (Canada)	Not controlled under WHMIS (Canada).
EINECS Number (EEC)	404-520-2
EEC Risk Statements	Not available.
Japanese Regulatory Data	Not available.

Section XVI. Other Information

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Notice to Reader

TCI laboratory chemicals are for research purposes only and are NOT intended for use as drugs, food additives, households, or pesticides. The information herein is believed to be correct, but does not claim to be all inclusive and should be used only as a guide. Neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All chemical reagents must be handled with the recognition that their chemical, physiological, toxicological, and hazardous properties have not been fully investigated or determined. All chemical reagents should be handled only by individuals who are familiar with their potential hazards and who have been fully trained in proper safety, laboratory, and chemical handling procedures. Although certain hazards are described herein, we can not guarantee that these are the only hazards which exist. Our MSDS sheets are based only on data available at the time of shipping and are subject to change without notice as new information is obtained. Avoid long storage periods since the product is subject to degradation with age and may become more dangerous or hazardous. It is the responsibility of the user to request updated MSDS sheets for products that are stored for extended periods. Disposal of unused product must be undertaken by qualified personnel who are knowledgeable in all applicable regulations and follow all pertinent safety precautions including the use of appropriate protective equipment (e.g. protective goggles, protective clothing, breathing equipment, facial mask, fume hood). For proper handling and disposal, always comply with federal, state, and local regulations.