

Pravastatin, Sodium Salt

sc-203218



The Power to Question

Material Safety Data Sheet

Hazard Alert Code Key: **EXTREME** **HIGH** **MODERATE** **LOW**

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Pravastatin, Sodium Salt

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

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EMERGENCY:

ChemWatch
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SYNONYMS

C23-H35-O7.Na, "1-naphthaleneheptanoic acid, 1, 2, 6, 7, 8, 8a-hexahydro-2-methyl-", "8-(2-methyl-1-oxobutoxy)-beta, delta, 6-trihydroxy-, monosodium salt(1S-", "(1alpha(beta-S*, delta-S*), 2alpha, 6alpha, 8beta(R*), 8alpha)", Cholstat, CS-514, "Epastatin sodium", Lipostat, Mevalotin, Pravachol, SQ-31000, "lipid regulating agent/ cholesterol biosynthesis inhibitor/ hypolipidaemic", "HMG CoA reductase inhibitor", "decalin derivative"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability:	1	
Toxicity:	2	
Body Contact:	2	
Reactivity:	1	
Chronic:	2	

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- HMG-CoA inhibitor poisoning may cause headache, an itchy rash, and stomach upset. Muscles may be inflamed, especially in liver disease.

EYE

- Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.

SKIN

- The material may cause moderate inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterized by redness, swelling and blistering.
- Skin contact is not thought to have harmful health effects, however the material may still produce health damage following entry through wounds, lesions or abrasions.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

- The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models). Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

- There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.
- Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.
- HMG-CoA inhibitors may cause pain, tenderness, weakness and disease of the muscles. They may cause birth defects and affect fetal development, so they should not be used while pregnant or breast feeding.
- When administered in subacute and/ or chronic toxicity studies, adverse effects were seen in the liver and/or kidneys of rabbits, mice and monkeys; these generally occurred at much higher doses than those intended for human therapeutic use. Cerebral haemorrhage was seen in dogs; dogs are especially susceptible to the effects of this substance. The no-effect-level for this lesion was 12.5 mg/kg/day. Results of additional studies indicate that dogs exhibit higher blood levels for more prolonged periods, following exposure to pravastatin sodium when compared to the other species which have been subject to studies. Pravastatin was shown to induce peroxisome proliferation in the liver of mice and rats and may have the potential to induce liver tumours in these species.
- In chronic studies lasting 20-22 months, in mice, daily oral doses of 10, 30 or 100 mg/kg produced a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared with controls. The incidence was not dose-related and male mice were not affected.
- In an oral carcinogenicity bioassay in CD rats, a daily dose of 100 mg/kg/day produced slight but statistically significant increases in the incidence of hepatic carcinomas in male rats (NOEL = 30 mg/kg/day).
- In a separate study with Fischer rats, pravastatin did not produce tumours when given at doses of up to 40 mg/kg/day for two years. A dose-dependent increase in incidence and severity of fatty liver was also seen in this study. A dose of 10 mg/kg/day could be considered to be a low-adverse-effect-level for this end-point.
- The material was not foetotoxic or teratogenic when tested in rabbits nor did it produce adverse reproductive effects.
- Results in animal studies suggest minimal antigenic potential.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
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Section 4 - FIRST AID MEASURES

SWALLOWED

· If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

EYE

■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED

· If dust is inhaled, remove from contaminated area. · Encourage patient to blow nose to ensure clear passage of breathing. · If irritation or discomfort persists seek medical attention.

NOTES TO PHYSICIAN

■ Treat symptomatically.

The first clinical effect is a reduction in serum cholesterol. Changes in liver function tests may occur with long-term exposure. Myopathy should be considered in persons with complaints of diffuse myalgia, muscle tenderness or weakness, and/or marked elevation of CPK. Potential drug interactions can occur in persons taking cyclosporin, anticoagulants, antifungal agents, fibric acid derivatives, or large doses of niacin or nicotinic acid.

A reversible increase in liver function tests can be seen in patients receiving therapeutic doses.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

EXTINGUISHING MEDIA

· Water spray or fog.
· Foam.

FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.
· Wear breathing apparatus plus protective gloves.

When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 100 metres in all directions.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

· Combustible solid which burns but propagates flame with difficulty.

· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), other pyrolysis products typical of burning organic material.

FIRE INCOMPATIBILITY

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:

Chemical goggles.

Gloves:

Respirator:

Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

■ Environmental hazard - contain spillage.

· Clean up waste regularly and abnormal spills immediately.

· Avoid breathing dust and contact with skin and eyes.

· Wear protective clothing, gloves, safety glasses and dust respirator.

- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

MAJOR SPILLS

- Environmental hazard - contain spillage.

Moderate hazard.

- CAUTION: Advise personnel in area.
- Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
 - Wear protective clothing when risk of exposure occurs.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
 - In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

- Glass container.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

- Observe manufacturer's storing and handling recommendations.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- pravastatin sodium: CAS:81131-70-6 CAS:115873-26-2 CAS:85956-24-7 CAS:81131-73-9 CAS:87098-76-8

PERSONAL PROTECTION



RESPIRATOR

Particulate

EYE

- When handling very small quantities of the material eye protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

- Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- Contaminated gloves should be replaced.
- Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers.
- Head covering.

OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

- Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.
- HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Mixes with water.

State	Divided solid	Molecular Weight	446.5
Melting Range (°F)	342- 343	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	Not available
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	>1
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

White to yellowish-white crystalline powder; mixes with water (>300 mg/ml), methanol.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

pravastatin sodium

TOXICITY AND IRRITATION

PRAVASTATIN SODIUM:

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (rat) LD50: >12000 mg/kg	Nil Reported
Subcutaneous (rat) LD50: 3172 mg/kg	
Intravenous (rat) LD50: 440 mg/kg	
Oral (mouse) LD50: 8939 mg/kg	
Subcutaneous (mouse) LD50: 2975 mg/kg	
Intravenous (mouse) LD50: 2011 mg/kg	

■ The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. Jaundice, impaired liver function tests, dermatitis after systemic exposure, somnolence, muscle weakness, ataxia, respiratory changes, lachrymation, diarrhoea, changes in spleen blood, ptosis recorded.

CARCINOGEN

PRAVASTATIN SODIUM	US Environmental Defense Scorecard Suspected Carcinogens	Reference(s)	P65-CAND
VPVB_(VERY~	US - Maine Chemicals of High Concern List	Carcinogen	

Section 12 - ECOLOGICAL INFORMATION

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/ safety data sheets.

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations. † Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION



DOT:

Symbols: G Hazard class or Division: 9
 Identification Numbers: UN3077 PG: III
 Label Codes: 9 Special provisions: 8, 146, 335, B54, IB8, IP3, N20, T1,

TP33

Packaging: Exceptions: 155 Packaging: Non- bulk: 213

Packaging: Exceptions: 155 Quantity limitations: No limit

Passenger aircraft/rail:

Quantity Limitations: Cargo No limit Vessel stowage: Location: A
aircraft only:

Vessel stowage: Other: None

Hazardous materials descriptions and proper shipping names:

Environmentally hazardous substance, solid, n.o.s

Air Transport IATA:

ICAO/IATA Class: 9 ICAO/IATA Subrisk: None

UN/ID Number: 3077 Packing Group: III

Special provisions: A97

Cargo Only

Packing Instructions: 400 kg Maximum Qty/Pack: 400 kg

Passenger and Cargo Passenger and Cargo

Packing Instructions: 956 Maximum Qty/Pack: 956

Passenger and Cargo Limited Quantity Passenger and Cargo Limited Quantity

Packing Instructions: 30 kg G Maximum Qty/Pack: Y956

Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S. *(CONTAINS PRAVASTATIN SODIUM)

Maritime Transport IMDG:

IMDG Class: 9 IMDG Subrisk: None

UN Number: 3077 Packing Group: III

EMS Number: F-A , S-F Special provisions: 179 274 335 909

Limited Quantities: 5 kg Marine Pollutant: Yes

Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(contains pravastatin sodium)

Section 15 - REGULATORY INFORMATION

pravastatin sodium (CAS: 81131-70-6,115873-26-2,85956-24-7,81131-73-9,87098-76-8) is found on the following regulatory lists;

"US - California Proposition 65 - Priority List for the Development of MADLs for Chemicals Causing Reproductive Toxicity", "US - Maine Chemicals of High Concern List"

Section 16 - OTHER INFORMATION

Ingredients with multiple CAS Nos

Ingredient Name CAS pravastatin sodium 81131-70-6, 115873-26-2, 85956-24-7, 81131-73-9, 87098-76-8

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■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:

www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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