

SAFETY DATA SHEET

Creation Date 14-May-2019 Revision Date 24-Dec-2021 Revision Number 2

1. Identification

Product Name Pravastatin sodium salt hydrate

Cat No.: AC464880000; AC464880010; AC464882500

CAS No 2244386-63-6

Synonyms No information available

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Fisher Scientific Company
One Reagent Lane
Fair Lawn, NJ 07410
Acros Organics
One Reagent Lane
Fair Lawn, NJ 07410
Fair Lawn, NJ 07410

Tel: (201) 796-7100

Emergency Telephone Number For information US call: 001-800-ACROS-01 / Europe call: +32 14 57 52 11

Emergency Number **US:**001-201-796-7100 / **Europe:** +32 14 57 52 99 **CHEMTREC** Tel. No.**US:**001-800-424-9300 / **Europe:**001-703-527-3887

2. Hazard(s) identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive Toxicity Category 2

Effects on or via lactation

Label Elements

Signal Word

Warning

Hazard Statements

Suspected of damaging fertility or the unborn child May cause harm to breast-fed children



Precautionary Statements

Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Use personal protective equipment as required

Do not breathe dust/fume/gas/mist/vapors/spray

Avoid contact during pregnancy/while nursing

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Response

IF exposed or concerned: Get medical attention/advice

Storage

Store locked up

Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

None identified

WARNING. Reproductive Harm - https://www.p65warnings.ca.gov/.

3. Composition/Information on Ingredients

Component	CAS No	Weight %
Pravastatin sodium salt hydrate	2244386-63-6	>95
Pravastatin sodium salt	81131-70-6	-

4. First-aid measures

General Advice If symptoms persist, call a physician.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

Most important symptoms and

effects

None reasonably foreseeable.

Notes to Physician Treat symptomatically

5. Fire-fighting measures

Unsuitable Extinguishing Media No information available

Pravastatin sodium salt hydrate

Flash Point No information available Method - No information available

Autoignition Temperature

Explosion Limits

Not applicable

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

None known.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

HealthFlammabilityInstabilityPhysical hazards010N/A

Accidental release measures

Personal Precautions Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust

formation.

Environmental Precautions Should not be released into the environment.

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed

Up containers for disposal.

7. Handling and storage

Wear personal protective equipment/face protection. Ensure adequate ventilation, Avoid

ingestion and inhalation. Avoid dust formation. Do not get in eyes, on skin, or on clothing.

Storage. Keep container tightly closed in a dry and well-ventilated place. To maintain product quality:

Keep refrigerated.

8. Exposure controls / personal protection

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure

limitsestablished by the region specific regulatory bodies.

Engineering Measures None under normal use conditions.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protectionWear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection No protective equipment is needed under normal use conditions.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical State Solid Powder
Appearance White to yellow

Odor No information available
Odor Threshold No information available
pH No information available

Melting Point/Range 171 - 173 °C / 339.8 - 343.4 °F

Boiling Point/Range
No information available
No information available
No information available

Evaporation Rate Not applicable

Flammability (solid,gas)

No information available

Flammability or explosive limits

Upper No data available
Lower No data available
Vapor Pressure No information available
Vapor Density Not applicable

Vapor DensityNot applicableSpecific GravityNo information availableSolubilitySoluble in waterPartition coefficient; n-octanol/waterNo data available

Autoignition Temperature Not applicable

Decomposition TemperatureNo information available

Viscosity Not applicable

Molecular Formula C23 H35 O7 Na . x H2 O

Molecular Weight 446.51

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Stable under normal conditions.

Conditions to Avoid Incompatible products.

Incompatible Materials Strong oxidizing agents

Hazardous Decomposition Products None under normal use conditions

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Pravastatin sodium salt	LD50 > 12 g/kg (Rat)	Not listed	Not listed

Toxicologically Synergistic No information available

Products

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation No information available

Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Pravastatin sodium salt hydrate

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Pravastatin sodium salt hydrate	2244386-63-6	Not listed				
Pravastatin sodium salt	81131-70-6	Not listed				

Mutagenic Effects No information available

Reproductive Effects No information available.

No information available. **Developmental Effects**

Teratogenicity No information available.

None known STOT - single exposure STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects,both acute and No information available

delayed

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability Soluble in water Persistence is unlikely based on information available.

Bioaccumulation/ Accumulation No information available.

Will likely be mobile in the environment due to its water solubility. **Mobility**

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and

national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

Not regulated DOT Not regulated TDG IATA Not regulated IMDG/IMO Not regulated

15. Regulatory information

United States of America Inventory

Component	CAS No	CAS No TSCA TSCA Inventory notification - Active-Inactive		TSCA - EPA Regulatory Flags	
Pravastatin sodium salt hydrate	2244386-63-6	=	-	-	
Pravastatin sodium salt	81131-70-6	-	-	-	

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA 12(b) - Notices of Export Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Pravastatin sodium salt hydrate	2244386-63-6	-	-	-	-	-		-	-	-
Pravastatin sodium salt	81131-70-6	-	-	-	-	-	Χ	-	-	-

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

U.S. Federal Regulations

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and

Health Administration

Not applicable

CERCLA Not applicable

California Proposition 65 This product contains the following Proposition 65 chemicals.

Component	Component CAS No		Prop 65 NSRL	Category
Pravastatin sodium salt 81131-70-6		Developmental	-	Developmental

U.S. State Right-to-Know

Regulations

Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH

Safety, health and environmental regulations/legislation specific for the substance or mixture

	Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Ī	Pravastatin sodium salt hydrate	2244386-63-6	Not applicable	Not applicable	Not applicable	Not applicable
Γ	Pravastatin sodium salt	81131-70-6	Not applicable	Not applicable	Not applicable	Not applicable

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
Pravastatin sodium salt hydrate	2244386-63-6	Not applicable	Not applicable	Not applicable	Not applicable
Pravastatin sodium salt	81131-70-6	Not applicable	Not applicable	Not applicable	Not applicable

16. Other information

Prepared By Regulatory Affairs

Thermo Fisher Scientific

Email: EMSDS.RA@thermofisher.com

 Creation Date
 14-May-2019

 Revision Date
 24-Dec-2021

 Print Date
 24-Dec-2021

Revision Summary

This document has been updated to comply with the US OSHA HazCom 2012 Standard

replacing the current legislation under 29 CFR 1910.1200 to align with the Globally

Harmonized System of Classification and Labeling of Chemicals (GHS).

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of SDS