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Creation Date 25-Apr-2016
Revision Date 12-Apr-2024
Version 6

ACR46149

Rosuvastatin, sodium salt, 98%

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

产品说明: 瑞舒伐他汀钠

Product Description: Rosuvastatin, sodium salt, 98%

Cat No.: 461490000; 461490010

CAS No 147098-18-8

Molecular Formula C22 H27 F N3 Na O6 S

Supplier UK entity/business name

Fisher Scientific UK Bishop Meadow Road,

Loughborough, Leicestershire LE11 5RG, United Kingdom

EU entity/business name Thermo Fisher Scientific

Janssen Pharmaceuticalaan 3a, 2440 Geel, Belgium

Emergency Telephone Number For information US call: 001-800-227-6701 / 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

E-mail address begel.sdsdesk@thermofisher.com

Recommended Use Laboratory chemicals. Uses advised against No Information available

SECTION 2. HAZARD IDENTIFICATION

Physical State Appearance Odor

Solid White to off-white No information available

Emergency Overview

Suspected of damaging fertility or the unborn child.

Classification of the substance or mixture

Reproductive Toxicity Category 2

Label Elements



Signal Word Warning

Hazard Statements

H361 - Suspected of damaging fertility or the unborn child

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Precautionary Statements

Prevention

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response

P308 + P313 - IF exposed or concerned: Get medical advice/attention

Storage

P403 - Store in a well-ventilated place

Disposal

P501 - Dispose of contents/ container to an approved waste disposal plant

Physical and Chemical Hazards

None identified.

Health Hazards

Suspected of damaging fertility or the unborn child.

Environmental hazards

Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants.

Other Hazards

This product does not contain any known or suspected endocrine disruptors.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight %		
Rosuvastatin, sodium salt	147098-18-8	>95		

SECTION 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.

Self-Protection of the First Aider

No special precautions required.

Notes to Physician

Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

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Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons

No information available.

Specific Hazards Arising from the Chemical

Thermal decomposition can lead to release of irritating gases and vapors.

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.

SECTION 6. 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 Up

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

Refer to protective measures listed in Sections 8 and 13.

SECTION 7. HANDLING AND STORAGE

Handling

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.

Specific Use(s)

Use in laboratories

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents. MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

Exposure Controls

Engineering Measures

None under normal use conditions. .

Personal protective equipment

Eye Protection Wear safety glasses with side shields (or goggles) (European standard - EN 166)

Hand Protection Protective gloves

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Glove material Nitrile rubber Neoprene Natural rubber	Breakthrough time See manufacturers recommendations	Glove thickness	EU standard EN 374	Glove comments (minimum requirement)
PVC				

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Skin and body protection Long sleeved clothing

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

Large scale/emergency use Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits

are exceeded or if irritation or other symptoms are experienced

Recommended Filter type: Particle filter

Small scale/Laboratory use Maintain adequate ventilation

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

Environmental exposure controls No information available.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance White to off-white

Physical State Solid

Odor No information available
Odor Threshold No data available

pH No information available

Melting Point/Range 106 - 118 °C / 222.8 - 244.4 °F

Softening Point

Boiling Point/Range

No information available

No information available

Flash Point No information available Method - No information available

Evaporation Rate Not applicable Solid

Flammability (solid,gas) No information available

Explosion Limits No data available

Vapor Pressure
No data available
Not applicable

Vapor DensityNot applicableSolidSpecific Gravity / DensityNo data available

Bulk Density
Water Solubility
Solubility in other solvents
No data available
No information available
No information available

Partition Coefficient (n-octanol/water)

Autoignition Temperature

Decomposition Temperature

Viscosity

No data available
No data available
Not applicable

Viscosity Not applicable Solid

Explosive Properties No information available Oxidizing Properties No information available

Molecular Formula C22 H27 F N3 Na O6 S

Molecular Weight 503.53

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SECTION 10. STABILITY AND REACTIVITY

Stability No information available.

Hazardous Reactions None under normal processing.

Hazardous Polymerization No information available.

Conditions to Avoid Incompatible products.

Materials to avoid Strong oxidizing agents.

Hazardous Decomposition Products Carbon monoxide (CO). Hydrogen fluoride. Sulfur oxides. Nitrogen oxides (NOx). Carbon

dioxide (CO₂).

SECTION 11. TOXICOLOGICAL INFORMATION

Product Information

(a) acute toxicity;

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

Respiratory No data available Skin No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; Category 2

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

Target Organs No information available.

(j) aspiration hazard; Not applicable

Solid

Symptoms / effects, both acute and No information available

delayed

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity effects Contains no substances known to be hazardous to the environment or that are not

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degradable in waste water treatment plants.

Persistence and Degradability

No information available

Bioaccumulative Potential Bioaccumulation is unlikely

Mobility in soil No information available

Endocrine Disruptor Information Persistent Organic Pollutant Ozone Depletion Potential This product does not contain any known or suspected endocrine disruptors

This product does not contain any known or suspected substance This product does not contain any known or suspected substance

SECTION 13. DISPOSAL CONSIDERATIONS

Waste from Residues/Unused

Products

Other Information

Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

Dispose of this container to hazardous or special waste collection point.

Contaminated Packaging

Waste codes should be assigned by the user based on the application for which the product

was used. Do not empty into drains.

SECTION 14. TRANSPORT INFORMATION

Road and Rail Transport Not Regulated

IMDG/IMO Not regulated

IATA Not regulated

Special Precautions for User No special precautions required

SECTION 15. REGULATORY INFORMATION

International Inventories

X = listed, China (IECSC), Europe (EINECS/ELINCS/NLP), U.S.A. (TSCA), Canada (DSL/NDSL), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), Korea (KECL).

Component	The Inventory of Hazardous Chemicals (2015 Edition)		TCSI	IECSC	EINECS	TSCA	DSL	PICCS	ENCS	ISHL	AICS	KECL	
Rosuvastatin, sodium	-	-	X	-	-	-	-	-	-	Х	-	-	ĺ
salt													ĺ

National Regulations

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SECTION 16. OTHER INFORMATION

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Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Legend

CAS - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory DSL/NDSL - Canadian Domestic Substances List/Non-Domestic

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances IECSC - Chinese Inventory of Existing Chemical Substances **KECL** - Korean Existing and Evaluated Chemical Substances

ENCS - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration

PBT - Persistent, Bioaccumulative, Toxic

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

PNEC - Predicted No Effect Concentration

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50% POW - Partition coefficient Octanol:Water vPvB - very Persistent, very Bioaccumulative

ICAO/IATA - International Civil Aviation Organization/International Air **Transport Association**

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

MARPOL - International Convention for the Prevention of Pollution from

ATE - Acute Toxicity Estimate VOC - (Volatile Organic Compound)

Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Disclaimer

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End of Safety Data Sheet