

Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING
Product Identifier

Perihal Produk:

Product Description:

Cat No. :

Synonyms

Rivaroxaban
Rivaroxaban

461600000; 461600010; 461602500

5-chloro-N-([(5S)-2-oxo-3-[4-(3-oxomorpholin-4-yl)phenyl]-1,3-oxazolidin-5-yl]methyl) thiophene-2-carboxamide

366789-02-8

CAS No

Molecular Formula

C19 H18 Cl N3 O5 S

Relevant identified uses of the substance or mixture and uses advised against

Recommended Use

Laboratory chemicals.

Uses advised against

No Information available

Company

 Thermo Fisher Scientific Fisher Scientific (M) Sdn Bhd
 Hap Seng Business Park, Lot 01-03, 01-04 Aras 1 Unity Square,
 No 12, Persiaran Perusahaan, Seksyen 23, 40300 Shah Alam,
 Selangor Darul Ehsan, Malaysia.
 Main line: +60 3-5525 7888

E-mail address

Enquiry.my@thermofisher.com

Emergency Telephone Number

Tel: +03-5525 7888

 CHEMTREC Malaysia **1-800-815-308** (Malay)

 CHEMTREC Malaysia (Kuala Lumpur) **+(60)-327884561** (Malay)

SECTION 2: HAZARDS IDENTIFICATION
Classification of the substance or mixture

Acute oral toxicity	Category 4 (H302)
Chronic aquatic toxicity	Category 2 (H411)

Label Elements


Signal Word

Warning

Hazard Statements

H302 - Harmful if swallowed

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H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements

Prevention

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

Response

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

P330 - Rinse mouth

Storage

P403 - Store in a well-ventilated place

Disposal

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

Other Hazards

No information available

This product does not contain any known or suspected endocrine disruptors

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight %
Rivaroxaban	366789-02-8	<=100

SECTION 4: FIRST AID MEASURES

Description of 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.

Ingestion

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

Inhalation

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

Self-Protection of the First Aider

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

Most important symptoms and effects, both acute and delayed

None reasonably foreseeable.

Indication of any immediate medical attention and special treatment needed

Notes to Physician

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

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Extinguishing media

Suitable Extinguishing Media

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

Extinguishing media which must not be used for safety reasons

No information available.

Special hazards arising from the substance or mixture

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

Hazardous Combustion Products

Nitrogen oxides (NO_x), Carbon monoxide (CO), Carbon dioxide (CO₂), Sulfur oxides, Hydrogen chloride gas.

Advice for fire-fighters

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, Protective Equipment and Emergency Procedures

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

Environmental precautions

Do not flush into surface water or sanitary sewer system.

Methods and Material for Containment and Cleaning Up

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

Reference to Other Sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

Conditions for Safe Storage, Including any Incompatibilities

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

Specific End Uses

Use in laboratories.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

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Exposure Controls

Engineering Measures

Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment

Eye Protection

Wear safety glasses with side shields (or goggles)

Hand Protection

Protective gloves

Skin and body protection

Long sleeved clothing

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.

Respiratory Protection

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators

Recommended Filter type:

Particulates filter conforming to EN 143

To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly

When RPE is used a face piece Fit Test should be conducted

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice

Environmental exposure controls

Prevent product from entering drains Do not allow material to contaminate ground water system

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance

White to off-white

Physical State

Solid

Odor

No information available

Odor Threshold

No data available

pH

Not applicable

Melting Point/Range

228 - 229 °C / 442.4 - 444.2 °F

Softening Point

No data available

Boiling Point/Range

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

Vapor Density

Not applicable

Solid

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Specific Gravity / Density	No data available
Bulk Density	No data available
Water Solubility	No information available
Solubility in other solvents	No information available

Partition Coefficient (n-octanol/water)

Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
Viscosity	Not applicable	Solid
Explosive Properties	No information available	
Oxidizing Properties	No information available	

Molecular Formula	C ₁₉ H ₁₈ Cl N ₃ O ₅ S
Molecular Weight	435.88

SECTION 10: STABILITY AND REACTIVITY

Reactivity

None known, based on information available.

Chemical Stability

Stable under normal conditions.

Possibility of Hazardous Reactions

Hazardous Polymerization	No information available.
Hazardous Reactions	None under normal processing.

Conditions to Avoid

None known.

Incompatible Materials

Strong oxidizing agents.

Hazardous Decomposition Products

Nitrogen oxides (NO_x). Carbon monoxide (CO). Carbon dioxide (CO₂). Sulfur oxides.
Hydrogen chloride gas.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Product Information

(a) acute toxicity;

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Oral	Category 4
Dermal	No data available
Inhalation	No data available

(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; No data available

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available
Target Organs None known.

(j) aspiration hazard; Not applicable
Solid

Symptoms / effects, both acute and delayed No information available.

Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any known or suspected endocrine disruptors.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity effects Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. The product contains following substances which are hazardous for the environment.

Persistence and degradability
Degradation in sewage treatment plant No information available
Contains substances known to be hazardous to the environment or not degradable in waste water treatment plants.

Bioaccumulative potential No information available

Mobility in soil No information available.

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Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors

Other adverse effects No information available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods
Waste from Residues/Unused Products 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

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

Other Information Do not flush to sewer Waste codes should be assigned by the user based on the application for which the product was used Do not empty into drains Do not let this chemical enter the environment

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO
UN-No UN3077
Hazard Class 9
Packing Group III
Proper Shipping Name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Rivaroxaban

Road and Rail Transport
UN-No UN3077
Hazard Class 9
Packing Group III
Proper Shipping Name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Rivaroxaban

IATA
UN-No UN3077
Hazard Class 9
Packing Group III
Proper Shipping Name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Rivaroxaban

Special Precautions for User No special precautions required

SECTION 15: REGULATORY INFORMATION

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

International Inventories X = listed

Component	EINECS	TSCA	DSL	PICCS	ENCS	ISHL	IECSC	AICS	KECL
Rivaroxaban	-	-	-	-	-	X	-	-	-

National Regulations

ACR46160

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Persistent Organic Pollutant
Ozone Depletion Potential

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

SECTION 16: OTHER INFORMATION

Legend

CAS - Chemical Abstracts Service

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

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

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

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

POW - Partition coefficient Octanol:Water

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

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

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

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

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

MARPOL - International Convention for the Prevention of Pollution from Ships

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

Revision Date

22-Mar-2025

Revision Summary

SDS sections updated.

In accordance with local and national regulations: Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013

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 Safety Data Sheet