

Safety Data Sheet

according to UK REACH Regulation

Rapamycin

Revision date: 18.10.2018

Product code: LS-1056

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Rapamycin

Further trade names

Rapamycin, RAPA, Rapamune, Sirolimus

(3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R,27R,34aS)

-9,10,12,13,14,21,22,23,24,25,26,27,32,33,34,34a-hexadecahydro-9,27-dihydroxy-3-[(1R)-2-[(1S,3R,4R)

-4-hydroxy-3-methoxycyclohexyl]-1-methylethyl]

-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-23,27-epoxy-3H-pyrido[2,1-c][1,4]

-oxaazacyclohentacontine-1,5,11,28,29 (4H,6H,31H)-pentone

(1R,9S,12S,15R,16E,18R,19R,21R,23S,24E,26E,28E,30S,32S,35R)-1,18-dihydroxy-12-[(2R)-1-[(1S,3R,4R)

-4-hydroxy-3-methoxycyclohexyl]propan-2-yl]

-19,30-dimethoxy-15,17,21,23,29,35-hexamethyl-11,36-dioxa-4-azatricyclo[30.3.1.04,?]hexatriaconta-16,24,2

6,28-tetraene-2,3,10,14,20-pentone

Abbreviation: RPM

CAS No: 53123-88-9

1.2. Relevant identified uses of the substance or mixture and uses advised against**Use of the substance/mixture**

Scientific research and development

Uses advised against

Do not use for private purposes (household).

Pharmaceutical substance

Active pharmaceutical ingredient.

Pharmaceutical industry.

1.3. Details of the supplier of the safety data sheet

Company name: Iris Biotech GmbH

Street: Adalbert-Zoellner-Straße 1

Place: D-95615 Marktredwitz, Germany

Post-office box: 568

D-95605 Marktredwitz, Germany

Telephone: +49 9231 97121 0

Telefax: +49 9231 97121 99

e-mail: info@iris-biotech.de

Contact person: Compliance Department

Telephone: +49 9231 97121 0

e-mail: sds@iris-biotech.de

Internet: www.iris-biotech.de

Responsible Department: Only available during office hours.

1.4. Emergency telephone

+49 (0)89 19240 (POISON CENTER Munich: 24 h)

number:**Further Information**

Emergency telephone: 24h

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****GB CLP Regulation**

Hazard categories:

Carcinogenicity: Carc. 2

Germ cell mutagenicity: Muta. 2

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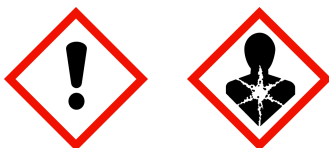
Reproductive toxicity: Repr. 2
 Skin corrosion/irritation: Skin Irrit. 2
 Serious eye damage/eye irritation: Eye Irrit. 2
 Specific target organ toxicity - single exposure: STOT SE 3
 Specific target organ toxicity - repeated exposure: STOT RE 1
 Hazard Statements:
 Causes skin irritation.
 Causes serious eye irritation.
 Suspected of causing genetic defects if swallowed.
 Suspected of causing cancer.
 Suspected of damaging fertility or the unborn child.
 May cause respiratory irritation.
 Causes damage to organs through prolonged or repeated exposure.

2.2. Label elements

GB CLP Regulation

Signal word: Danger

Pictograms:



Hazard statements

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
H361	Suspected of damaging fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.

Precautionary statements

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P302+P352	IF ON SKIN: Wash with plenty of Water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container to an approved disposal site.

Special labelling of certain mixtures

Restricted to professional users.

Additional advice on labelling

Warning - substance not yet tested completely.

2.3. Other hazards

This substance does not meet the criteria for classification as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

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Chemical characterization

(3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R,27R,34aS)
-9,10,12,13,14,21,22,23,24,25,26,27,32,33,34,34a-hexadecahydro-9,27-dihydroxy-3-[(1R)-2-[(1S,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylethyl]
-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-23,27-epoxy-3H-pyrido[2,1-c][1,4]
-oxaazacyclohentacontine-1,5,11,28,29 (4H,6H,31H)-pentone

Sum formula: C₅₁H₇₉NO₁₃

Molecular weight: 914,19 g/mol

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
53123-88-9	Rapamycin			<= 100 %
	Carc. 2, Muta. 2, Repr. 2, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, STOT RE 1; H351 H341 H361 H315 H319 H335 H372			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
53123-88-9		Rapamycin	<= 100 %
		oral: LD50 = 2500 mg/kg	

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down. In all cases of doubt, or when symptoms persist, seek medical advice.

After inhalation

Provide fresh air. Medical treatment necessary. Remove casualty to fresh air and keep warm and at rest. In case of irregular breathing or respiratory arrest provide artificial respiration. In all cases of doubt, or when symptoms persist, seek medical advice.

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary. After contact with skin, wash immediately with plenty of water and soap. In all cases of doubt, or when symptoms persist, seek medical advice.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink plenty of water. Induce vomiting when the affected person is not unconscious. Medical treatment necessary. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person or a person with cramps. In all cases of doubt, or when symptoms persist, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed

Refer to chapter 11.

4.3. Indication of any immediate medical attention and special treatment needed

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Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.
Water spray, alcohol resistant foam, Dry extinguishing powder, Carbon dioxide (CO₂).

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

Non-flammable. Thermal decomposition can lead to the escape of irritating gases and vapours. In case of fire may be liberated: Carbon dioxide (CO₂), Carbon monoxide (CO), Nitrogen oxides (NO_x).

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General measures**

Provide adequate ventilation. Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment. Provide adequate ventilation. Avoid dust formation. Avoid contact with skin, eyes and clothes. Wear personal protection equipment. In case of fire: Evacuate area.

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Do not empty into drains; dispose of this material and its container in a safe way.

6.3. Methods and material for containment and cleaning up**Other information**

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Clear contaminated areas thoroughly.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid dust formation. Do not breathe dust. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin, eyes and clothes. Provide adequate ventilation. Avoid generation of dust. Conditions to avoid: generation/formation of aerosols

Advice on protection against fire and explosion

Fight fire with normal precautions from a reasonable distance.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or

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drink.

Further information on handling

Keep container tightly closed and dry. Keep in a cool, well-ventilated place. Protect from moisture.

Recommended storage temperature: +2°C to +8°C

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only.

Provide adequate ventilation as well as local exhaust at critical locations.

Keep away from sources of ignition - No smoking. Do not use light alloy primary packaging.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Additional advice on limit values**

The receiver of our product is singularly responsible for adhering to existing laws and regulations.

8.2. Exposure controls**Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust.

Remove contaminated, saturated clothing immediately. Protect skin by using skin protective cream. After work, wash hands and face. When using do not eat, drink or smoke. Avoid contact with skin, eyes and clothes. Provide adequate ventilation. Wash hands before breaks and after work.

Individual protection measures, such as personal protective equipment**Eye/face protection**

Suitable eye protection: goggles. Wear suitable protective clothing, gloves and eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Wear suitable gloves. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Wear suitable protective clothing. Wear suitable protective clothing, gloves and eye/face protection.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Use appropriate respiratory protection.

Environmental exposure controls

Discharge into the environment must be avoided.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:

solid

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Colour: white/ whitish

Odour: odourless

Changes in the physical state

Melting point/freezing point: 168 - 185 °C

Boiling point or initial boiling point and boiling range: not determined

Sublimation point: No data available

Softening point: No data available

: No data available

Flash point: No data available

Flammability

Solid/liquid: not determined

Gas: not applicable

Explosive properties

No data available

Lower explosion limits: not determined

Upper explosion limits: not determined

Auto-ignition temperature: not determined

Self-ignition temperature

Solid: not determined

Gas: not applicable

Decomposition temperature: No data available

Oxidizing properties

No data available

pH-Value: not determined

Viscosity / dynamic: not applicable

Viscosity / kinematic: not applicable

Flow time: not applicable

Water solubility: insoluble

Solubility in other solvents

Soluble in: Toluene, Diethyl ether, Dichloromethane, Methanol. Ethanol (18,28 mg/ml). Dimethylsulfoxide (DMSO) (45,71 mg/ml)

Partition coefficient n-octanol/water: 3,578 +/- 0,861

Vapour pressure: No data available

Vapour pressure: No data available

Density: No data available

Bulk density: not determined

Relative vapour density: No data available

9.2. Other information

Information with regard to physical hazard classes

Sustaining combustion: No data available

Other safety characteristics

Solvent content: No data available

Solid content: not determined

Evaporation rate: No data available

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Further Information

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

Keep away from heat. Take action to prevent static discharges. Remove all sources of ignition.

10.5. Incompatible materials

Do not use light alloy primary packaging. Metal container
Exothermic reaction with: Oxidising agent, Reducing agents.
Strong acid, strong alkalis

10.6. Hazardous decomposition products

Thermal decomposition can lead to the escape of irritating gases and vapours. In case of fire may be liberated: Carbon dioxide (CO₂). Carbon monoxide (CO). Nitrogen oxides (NO_x).

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Toxicokinetics, metabolism and distribution

No data available

Acute toxicity

Based on available data, the classification criteria are not met.

Intraperitoneal: LD₅₀ (Rat): 18,22 µg/kg

intravenous: TDLo (Rat): 450 µg/kg

Acute toxicity, oral TDLo (human) 4,2 mg/kg BW (intermittent)

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
53123-88-9	Rapamycin				
	oral	LD ₅₀ 2500 mg/kg	Mouse.		

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of causing genetic defects. (Rapamycin)

Suspected of causing cancer. (Rapamycin)

Suspected of damaging fertility or the unborn child. (Rapamycin)

STOT-single exposure

May cause respiratory irritation. (Rapamycin)

STOT-repeated exposure

Causes damage to organs through prolonged or repeated exposure. (Rapamycin)

Causes damage to organs (Immune system) through prolonged or repeated exposure.

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Aspiration hazard

Based on available data, the classification criteria are not met.

Specific effects in experiment on an animal

No data available

Practical experience

No data available

11.2. Information on other hazards**Other information**

This product must be handled carefully because of its possible mutagenic effects. Anyway, currently available data are insufficient to definitively prove hereditary gene alterations.

Further information

RTECS: VE6250000

Caution! To the best of our knowledge the toxicological properties of this material have not been thoroughly investigated.

SECTION 12: Ecological information**12.1. Toxicity**

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

This substance does not meet the criteria for classification as PBT or vPvB.

12.7. Other adverse effects

Warning - substance not yet tested completely.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

Discharge into the environment must be avoided.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal.

Handle contaminated packages in the same way as the substance itself.

Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information**Land transport (ADR/RID)****14.2. UN proper shipping name:**

No dangerous good in sense of these transport regulations.

Other applicable information (land transport)

Not restricted

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Inland waterways transport (ADN)

14.2. UN proper shipping name: No dangerous good in sense of these transport regulations.

Other applicable information (inland waterways transport)

Not restricted

Marine transport (IMDG)

14.2. UN proper shipping name: No dangerous good in sense of these transport regulations.

Air transport (ICAO-TI/IATA-DGR)

14.2. UN proper shipping name: No dangerous good in sense of these transport regulations.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

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

EU regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water hazard class (D): 3 - highly hazardous to water

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%

Relevant H and EUH statements (number and full text)

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H341 Suspected of causing genetic defects if swallowed.
H341 Suspected of causing genetic defects.
H351 Suspected of causing cancer.

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H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations. Employers should use this information only as a supplement to other information gathered by them, and should make independent judgement of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Material Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user. Department issuing data specification sheet: Safety department