

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Cyclosporin A

Revision date: 28.06.2019

Product code: LS-1021

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

Cyclosporin A

Further trade names

(3S,6S,9S,12R,15S,18S,21S,24S,30S,33S)-30-ethyl-33-[(1R,2S,E)-1-hydroxy-2-methylhex-4-en-1-yl]-6,18,24-triisobutyl-3,9,21-triisopropyl-1,4,7,10,12,15,19,25,28-nonamethyl-1,4,7,10,13,16,19,22,25,28,31-undecaazacyclotritriacontan-2,5,8,11,14,17,20,23,26,29,32-undecaone

(3S,6S,9S,12R,15S,18S,21S,24S,30S,33S)-30-Ethyl-33-[(1R,2R,4E)-1-hydroxy-2-methylhex-4-en-1-yl]-6,9,18,24-tetraisobutyl-3,21-diisopropyl-1,4,7,10,12,15,19,25,28-nonamethyl-1,4,7,10,13,16,19,22,25,28,31-undecaazacyclotritriacontane-2,5,8,11,14,17,20,23,26,29,32-undecone

Cyclo[[[(E)-(2S,3R,4R)-3-hydroxy-4-methyl-2-(methylamino)-6-Octenoyl]-L-2-aminobutyryl-Nmethylglycyl-N-methyl-L-leucyl-L-valyl-N-methyl-L-leucyl-L-alanyl-D-alanyl-N-methyl-L-leucyl-Nmethyl-L-leucyl-N-methyl-L-valyl]

Cyclosporine
Antibiotic S 7481F1
Ciclosporin A
Ramihyphin A
CsA
Sandimmune

CAS No: 59865-13-3

EC No: 611-907-1

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

Laboratory chemical. Manufacture of the substance.

Uses advised against

Do not use for private purposes (household).

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
e-mail: info@iris-biotech.de
Contact person: Compliance Department
e-mail: sds@iris-biotech.de
Internet: www.iris-biotech.de
Responsible Department: Only available during office hours.

Telefax: +49 9231 97121 99

Telephone: +49 9231 97121 0

1.4. Emergency telephone number:

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

Further Information

Emergency telephone: 24 h

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

Regulation (EC) No. 1272/2008

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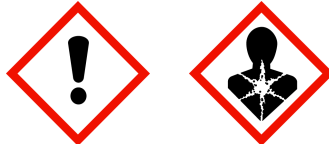
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Hazard categories:
Carcinogenicity: Carc. 1B
Reproductive toxicity: Repr. 1B
Reproductive toxicity: Lact.
Acute toxicity: Acute Tox. 4
Specific target organ toxicity - single exposure: STOT SE 3
Hazard Statements:
May cause respiratory irritation.
Harmful if swallowed.
May cause cancer.
May damage fertility or the unborn child.
May cause harm to breast-fed children.

2.2. Label elements**Regulation (EC) No. 1272/2008****Signal word:** Danger**Pictograms:****Hazard statements**

H302	Harmful if swallowed.
H335	May cause respiratory irritation.
H350	May cause cancer.
H360	May damage fertility or the unborn child.
H362	May cause harm to breast-fed children.

Precautionary statements

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P263	Avoid contact during pregnancy and while nursing.
P264	Wash hands thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330	Rinse mouth.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312	Call a POISON CENTER/doctor if you feel unwell.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
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

No information available.

SECTION 3: Composition/information on ingredients**3.1. Substances**

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Chemical characterization

(3S,6S,9S,12R,15S,18S,21S,24S,30S,33S)-30-ethyl-33-((1R,2S,E)-1-hydroxy-2-methylhex-4-en-1-yl)-6,18,24-triisobutyl-3,9,21-triisopropyl-1,4,7,10,12,15,19,25,28-nonamethyl-1,4,7,10,13,16,19,22,25,28,31-undecazacyclotriatriacontan-2,5,8,11,14,17,20,23,26,29,32-undecaone

Sum formula: C₆₂H₁₁₁N₁₁O₁₂

Molecular weight: 1202,6 g/mol

Hazardous components

CAS No	Chemical name	Quantity
	EC No	
	Index No	
	REACH No	
	GHS Classification	
59865-13-3	Cyclosporin A	<= 100 %
	611-907-1	
	Carc. 1B, Repr. 1B, Lact., Acute Tox. 4, STOT SE 3; H350 H360 H362 H302 H335	

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	
59865-13-3	611-907-1	Cyclosporin A	<= 100 %
		oral: LD50 = 1480 mg/kg	

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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

Wash with plenty of water. Immediately remove any contaminated clothing, shoes or stockings. 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

No information available.

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

Treat symptomatically.

SECTION 5: Firefighting measures

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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). Sand.

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. Usual measures for fire prevention.

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

Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment. Provide adequate ventilation. Avoid breathing dust/fume/gas/mist/vapours/spray.

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 allow to enter into soil/subsoil.

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. Take up mechanically, placing in appropriate containers for disposal. Avoid dust formation.

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. Provide adequate ventilation.

Avoid dust formation. Avoid breathing dust/fume/gas/mist/vapours/spray.

Avoid contact with skin, eyes and clothes.

Advice on protection against fire and explosion

Usual measures for fire prevention.

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, drink, smoke, sniff. Avoid contact with skin, eyes and clothes. Provide adequate ventilation.

7.2. Conditions for safe storage, including any incompatibilities

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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 container tightly closed in a cool, well-ventilated place.
Handle and store contents under inert gas. Protect from moisture. Keep away from heat. Protect from light!
storage temperature: -20 °C

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**

To date, no national critical limit values exist.

8.2. Exposure controls**Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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

Wear 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.

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.

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
Colour:	white/ whitish
Odour:	odourless

Changes in the physical state

Melting point/freezing point:	148 - 153 °C
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Boiling point or initial boiling point and boiling range:	not determined
Sublimation point:	not determined
Softening point:	not determined
Flash point:	No data available

Flammability

Solid/liquid:	not determined
Gas:	not applicable

Explosive properties

The product is not: Explosive.

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:	not determined
pH-Value:	not determined
Water solubility:	poorly soluble (5-10 µM) g/L

Solubility in other solvents

Soluble in: Dimethylsulfoxide (DMSO): 100 mg/ml, Ethanol (EtOH): 200 mg/ml, Acetone, Chloroform

Partition coefficient n-octanol/water:	not determined
Vapour pressure:	not determined
Density:	not determined
Bulk density:	not determined
Relative vapour density:	not determined

9.2. Other information**Information with regard to physical hazard classes**

Sustaining combustion:	No data available
Oxidizing properties	
No data available	

Other safety characteristics

Solvent content:	No data available
Solid content:	not determined
Evaporation rate:	not determined

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

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10.4. Conditions to avoid

Protect from moisture.
 Keep away from heat.
 Protect from light!

10.5. Incompatible materials

Oxidizing agents, strong.
 Alkali metals.
 Aluminium.

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).

Further information

In case of fire: See chapter 5.

SECTION 11: Toxicological information
11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008
Toxicokinetics, metabolism and distribution

No data available

Acute toxicity

Harmful if swallowed.
 Other information:
 Acute toxicity (oral): 2329 mg/kg (Mouse), >1g/kg (Rabbit)
 Acute toxicity:
 Intraperitoneal (LD50): 147 mg/kg (Rat)
 intravenous (LD50): 10 mg/kg (Rabbit)
 subcutan (LD50): 286 mg/kg (Rat)

Note:

Muscle contraction. Spasticity. Diarrhea. Appendix.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
59865-13-3	Cyclosporin A				
	oral	LD50 1480 mg/kg	Rat		

Irritation and corrosivity

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

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

May cause cancer. (Cyclosporin A)
 May damage fertility or the unborn child. (Cyclosporin A)
 May cause harm to breast-fed children. (Cyclosporin A)
 Germ cell mutagenicity: Based on available data, the classification criteria are not met.
 IARC: 1 - Group 1: Carcinogenic to humans

STOT-single exposure

May cause respiratory irritation. (Cyclosporin A)

STOT-repeated exposure

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

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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

Additional information on tests

Special hazards arising from the substance or mixture. Classification according to Regulation (EC) No 1272/2008 [CLP]: health hazard properties.

Practical experience

No data available

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

Nausea, vomiting. Tremor, Diarrhea. Hypertonia.

liver - human: May cause damage to organs (or state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).

Further information

RTECS: GZ4120000

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

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
59865-13-3	Cyclosporin A	2.92

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

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.

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Contaminated packaging

Hazardous waste according to Directive 2008/98/EC (waste framework directive). 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.

Inland waterways transport (ADN)

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

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)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

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%

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LD50: Lethal dose, 50%
CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H335	May cause respiratory irritation.
H350	May cause cancer.
H360	May damage fertility or the unborn child.
H362	May cause harm to breast-fed children.

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.