

**Safety Data Sheet (SDS)** According to the REACH Regulation (EC) No. 1907/2006

Issuing Date: 2018-04-09

Version: 1

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

**Product No** 9973  
**Product name** Cyclosporin A  
**Reach registration number** This substance/mixture contains only ingredients which have been registered, or are exempt from registration, according to Regulation (EC) No. 1907/2006.

### Contains

**Molecular Weight** 1202.6239

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Identified uses** For research use only

### 1.3. Details of the supplier of the safety data sheet

<b>Importer (Applicable in EU only)</b>	<b>Manufacturer</b>
Cell Signaling Technology Europe B.V.	Cell Signaling Technology, Inc.
Schuttersveld 2	3 Trask Lane
2316 ZA Leiden	Danvers, MA 01923
The Netherlands	United States
TEL: +31 (0)71 7200 200	TEL: +1 978 867 2300
FAX: +31 (0)71 891 0098	FAX: +1 978 867 2400

**Website** [www.cellsignal.com](http://www.cellsignal.com)

**E-mail Address** [info@cellsignal.eu](mailto:info@cellsignal.eu)

### 1.4. Emergency telephone number

**CHEMTREC** 24 hours a day, 7 days a week, 365 days a year  
 +1 703 527 3887 (INTERNATIONAL) +1 800 424 9300 (NORTH AMERICA)

**Europe** 112

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

<b>Acute oral toxicity</b>	Category 4 - (H302)
<b>Carcinogenicity</b>	Category 1A - (H350)
<b>Reproductive toxicity</b>	Category 1B - (H360)
<b>Effects on or via lactation</b>	Effects on or via lactation - (H362)

### 2.2. Label elements

**Signal word**

Danger

**Hazard statement(s)**

H302 - Harmful if swallowed

H350 - May cause cancer

H360 - May damage fertility or the unborn child

H362 - May cause harm to breast-fed children

**Precautionary statement(s)**

P201 - Obtain special instructions before use

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

P260 - Do not breathe dusts or mists

P263 - Avoid contact during pregnancy/while nursing

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

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

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

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

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

P330 - Rinse mouth

P405 - Store locked up

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

**2.3. Other hazards**

May be harmful if inhaled. May be harmful in contact with skin.

*For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16*

### SECTION 3: Composition/information on ingredients

Chemical Name	CAS No	Weight %	EC No	Classification (1272/2008)	REACH Registration Number
Cyclo(L-alanyl-D-alanyl-N-methyl-L-leucyl-N-methyl-L-leucyl-N-methyl-L-valyl-((3R,4R,6E)-6,7-didehydro-3-hydroxy-N,4-dimethyl-L-2-aminooctanoyl-L-2-aminobutanoyl-N-methylglycyl-N-methyl-L-leucyl-L-valyl-N-methylleucyl)	59865-13-3	100	-	Acute Tox. 4 (H302) Carc. 1A (H350) Repr. 1B (H360) Lact. (H362)	no data available

*For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16*

### SECTION 4: First aid measures

**4.1. Description of first aid measures****General advice**

Use first aid treatment according to the nature of the injury. When symptoms persist or in all cases of doubt seek medical advice.

**Inhalation**

IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur. If breathing is difficult, give oxygen.

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<b>Skin contact</b>	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. If skin irritation or rash occurs: Get medical advice/attention.
<b>Eye contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention immediately if irritation persists.
<b>Ingestion</b>	Do NOT induce vomiting. Drink plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.

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

Adverse effects from overexposure or overdose may include headache, nausea, central nervous system depression, burning sensation in the mouth, altered taste, hyperesthesia of the hands, burning sensation in the feet, sore gums, flushing of the face, sensation of increased abdominal girth, foot swelling, mild stomach upset, abdominal pain with mild hepatotoxicity, anxiety, diarrhea, vomiting, perspiration, sinus tachycardia, increased blood pressure and headache; vomiting and drowsiness. Principal adverse reactions to cyclosporine therapy are renal dysfunction, tremor, hirsutism, hypertension, hyperlipidemia, gum hyperplasia and nephrotoxicity.

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

**Notes to physician** Treat symptomatically.

## **SECTION 5: Firefighting measures**

### **5.1. Extinguishing media**

**Suitable Extinguishing Media** Water spray. Carbon dioxide (CO<sub>2</sub>). Dry chemical. Foam.  
**Unsuitable Extinguishing Media** No information available.

### **5.2. Special hazards arising from the substance or mixture**

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

### **5.3. Advice for firefighters**

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment.

## **SECTION 6: Accidental release measures**

### **6.1. Personal precautions, protective equipment and emergency procedures**

**For non-emergency personnel** Ensure adequate ventilation. Avoid dust formation. Avoid contact with skin, eyes and clothing. Use personal protective equipment. For personal protection see section 8. Wash thoroughly after handling.  
**For emergency responders** Use personal protection recommended in Section 8.

### **6.2. Environmental precautions**

Prevent further leakage or spillage if safe to do so. Do not allow material to contaminate ground water system. Local authorities should be advised if significant spillages cannot be contained.

### **6.3. Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.  
**Methods for cleaning up** For dust cleanup use protective equipment. Avoid dust formation. Do not dry sweep dust. Wet dust with water before sweeping or use a vacuum to collect dust.

### **6.4. Reference to other sections**

See Sections 8 & 13 for additional information.

## **SECTION 7: Handling and storage**

### **7.1. Precautions for safe handling**

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Handle in accordance with good industrial hygiene and safety practice. Wear personal protective equipment. Remove and wash contaminated clothing before re-use. Avoid contact with skin, eyes and clothing. Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed. In case of insufficient ventilation, wear suitable respiratory equipment. Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

Recommended storage temperature -20 °C.

### 7.3. Specific end use(s)

Use as a laboratory reagent.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

### 8.2. Exposure controls

#### Appropriate engineering controls

Showers, eyewash stations, and ventilation systems.

#### Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with side-shields
Skin protection	
Hand protection	Impervious gloves.
Other	Wear suitable protective clothing.
Respiratory protection	In case of inadequate ventilation wear respiratory protection.

#### Environmental Exposure Controls

No information available.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder
Color	White to off-white
Odor	No information available
Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH		No information available
Melting point/freezing point	148-151 °C	No information available
Initial boiling point and boiling range		No information available
Flash point		No information available.
Evaporation rate		No information available
Flammability (solid, gas)		No information available
Upper flammability limit		No information available
Lower flammability limit		No information available
Vapor pressure		No information available
Vapor density		No information available
Relative density		No information available
Solubility	Practically insoluble	No information available
Partition coefficient: n-octanol/water		No information available
Autoignition temperature		No information available

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<b>Decomposition temperature</b>	No information available.
<b>Viscosity</b>	No information available
<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available

### 9.2. Other information

<b>Softening point</b>	No information available
<b>Molecular Weight</b>	1202.6239
<b>Solubility in other solvents</b>	No information available
<b>VOC content</b>	No information available
<b>Density</b>	No information available.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No information available.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

<b>Hazardous polymerization</b>	Hazardous polymerization does not occur.
<b>Hazardous reactions</b>	None under normal processing.

### 10.4. Conditions to avoid

None known based on information supplied.

### 10.5. Incompatible materials

No information available.

### 10.6. Hazardous decomposition products

Thermal decomposition can lead to release of irritating and toxic gases and vapors: Nitrogen oxides (NO<sub>x</sub>).

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

This material should only be handled by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals. It should be borne in mind that the toxicological and physiological properties of this compound is not well defined.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Cyclo(L-alanyl-D-alanyl-N-methyl-L-leucyl-N-methyl-L-leucyl-N-methyl-L-leucyl-N-methyl-L-valyl-((3R,4R,6E)-6,7-didehydro-3-hydroxy-N,4-dimethyl-L-2-aminooctanoyl-L-2-aminobutanoyl-N-methylglycyl-N-methyl-L-leucyl-L-valyl-N-methylleucyl)	= 1480 mg/kg (Rat)	-	-

### Information on likely routes of exposure

<b>Inhalation</b>	May be harmful if inhaled. May cause irritation of respiratory tract.
<b>Eye contact</b>	Contact with eyes may cause irritation.
<b>Skin contact</b>	Prolonged contact may cause redness and irritation. May be harmful in contact with skin.
<b>Ingestion</b>	Harmful if swallowed.

<b>Symptoms</b>	Adverse effects from overexposure or overdose may include headache, nausea, central nervous system depression, burning sensation in the mouth, hyperesthesia of the hands, burning sensation in the feet, sore gums. flushing of the face, sensation of increased abdominal girth, foot swelling, mild stomach upset, abdominal pain with mild hepatotoxicity, anxiety, diarrhea, vomiting, perspiration, sinus tachycardia, increased blood pressure and headache; vomiting and drowsiness. Principal adverse reactions to cyclosporine therapy are renal dysfunction, tremor, hirsutism, hypertension, hyperlipidemia, gum hyperplasia and nephrotoxicity.
<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Sensitization</b>	No information available.
<b>Mutagenic effects</b>	In a single study, Cyclosporin was reported to increase the incidence of chromosomal aberrations in the lymphocytes of kidney transplant patients. It did not induce dominant lethal mutations in mice, chromosomal aberrations in the bone marrow of Chinese hamsters or micronuclei in the bone marrow of Chinese hamsters or mice in vivo. It induced sister chromatid exchange in human peripherallymphocytes in vitro but did not induce gene mutations in Chinese hamster cells. Cyclosporin did not induce mutations in Salmonella typhimurium.
<b>Carcinogenic effects</b>	No information available.
<b>Reproductive toxicity</b>	Nephrotoxicity, a drug side-effect in adults, was identified in experimental animal offspring exposed prenatally to Cyclosporines. Cyclosporines have been reported to cross the human placenta and passes into breast milk.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Target Organ Effects</b>	Kidney, Liver, Central nervous system (CNS), Immune system.
<b>Aspiration Hazard</b>	No information available.
<b>Other information</b>	No information available.

## SECTION 12: Ecological information

### 12.1. Toxicity

No information available.

### **Unknown Aquatic Toxicity**

100% of the mixture consists of components of unknown hazards to the aquatic environment.

### 12.2. Persistence and degradability

No information available.

### 12.3. Bioaccumulative potential

<b>Bioaccumulation</b>	No information available.
<b>Bioconcentration factor (BCF)</b>	No information available.

### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

No information available.

### 12.6. Other adverse effects

No information available

## SECTION 13: Disposal considerations

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**13.1. Waste treatment methods**

<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal.
<b>Other information</b>	Waste codes should be assigned by the user based on the application for which the product was used.

**SECTION 14: Transport information**

**IMDG/IMO**

<b>14.1 UN number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	None
<b>14.6 Special precautions for user</b>	None
<b>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not regulated

**ADR/RID**

<b>14.1 UN number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	None
<b>14.6 Special precautions for user</b>	None

**IATA**

<b>14.1 UN number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	None
<b>14.6 Special precautions for user</b>	None

**SECTION 15: Regulatory information**

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

**Candidate List of Substances of Very High Concern for Authorization Information**

This product does not contain Substances of Very High Concern (SVHC).

**SEVESO Directive Information**

This product does not contain substances identified in the SEVESO Directive.

**International inventories**

<b>TSCA 8(b)</b>	-
<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	-
<b>ENCS</b>	-
<b>IECSC</b>	Complies
<b>KECL</b>	-
<b>PICCS</b>	-
<b>AICS</b>	-

**International inventories legend**

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

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

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

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

### **15.2. Chemical safety assessment**

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

## **SECTION 16: Other information**

### **Full text of H-Statements referred to under Sections 2 and 3**

H302 - Harmful if swallowed

H350 - May cause cancer if swallowed

H360 - May damage fertility or the unborn child if inhaled.

H362 - May cause harm to breast-fed children

**Classification procedure:** Expert judgment and weight of evidence determination.

**Issuing Date:** 2018-04-09

#### **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.**