

# SAFETY DATA SHEET

### Classified as hazardous in accordance with the criteria of EPA New Zealand

### **Section 1 - Identification**

**Product Identifier** 

Product Name Cyclosporin A

CAS No 59865-13-3

Molecular Formula C62 H111 N11 O12

Molecular Weight 1202.61

Recommended Use Laboratory chemicals.
Uses advised against No Information available

Product Code J63191

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# **Section 2 - Hazard(s) Identification**

Classification under Work Safe New Zealand

Classified as hazardous in accordance with the criteria of EPA New Zealand

**GHS Classification** 

Physical hazards

Based on available data, the classification criteria are not met

**Health hazards** 

Acute Oral Toxicity
Carcinogenicity
Category 4
Category 1B
Reproductive Toxicity
Category 1B

**Environmental hazards** 

Based on available data, the classification criteria are not met

Label Elements

ALFAAJ63191 Version 3 15-Mar-2023 Page 1/9



Signal Word Danger

### **Hazard Statements**

H302 - Harmful if swallowed

H350 - May cause cancer

H360 - May damage fertility or the unborn child

### **Precautionary Statements**

### Prevention

P201 - Obtain special instructions before use

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

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

### Response

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

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

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 which do not result in classification

No information available

# Section 3 - Composition and Information on Ingredients

Component	CAS No	Weight %
Cyclosporin A	59865-13-3	<=100

# **Section 4 - First Aid Measures**

#### Description of first aid measures

**General Advice** Show this safety data sheet to the doctor in attendance. Immediate medical attention is

required.

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**Inhalation** Remove to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth

method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Immediate medical attention is required.

**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. Immediate medical

attention is required.

ALFAAJ63191 Version 3 15-Mar-2023 Page 2 / 9

**Ingestion** Do NOT induce vomiting. Call a physician or poison control center immediately.

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.

First Aid Facilities Eyewash, safety shower and washroom.

Most important symptoms and

effects

None reasonably foreseeable.

Notes to Physician Treat symptomatically.

### **Section 5 - Fire Fighting Measures**

### **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.

### Specific Hazards Arising from the Chemical

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

### **Hazardous Combustion Products**

None under normal use conditions.

### Special protective equipment and precautions for fire fighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Thermal decomposition can lead to release of irritating gases and vapors.

### **Section 6 - Accidental Release Measures**

### Personal Precautions, Protective Equipment and Emergency Procedures

### **Emergency procedures**

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

### **Environmental Precautions**

Should not be released into the environment.

### Methods for Containment and Clean Up

Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

### Precautions to prevent secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations

#### **Reference to Other Sections**

Refer to protective measures listed in Sections 8 and 13.

### **Section 7 - Handling and Storage**

### **Precautions for Safe Handling**

### Advice on safe handling

Wear personal protective equipment/face protection. Do not get in eyes, on skin, or on clothing. Avoid dust formation. Use only under a chemical fume hood. Do not breathe (dust, vapor, mist, gas). Do not ingest. If swallowed then seek immediate medical assistance.

ALFAAJ63191 Version 3 15-Mar-2023 Page 3 / 9

### **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice.

### Conditions for Safe Storage, Including any Incompatibilities

#### **Storage Conditions**

Keep container tightly closed in a dry and well-ventilated place. To maintain product quality; Store in freezer.

### **Incompatible Materials**

None known.

AS/NZS 2243.10:2004, Safety in laboratories - Storage of chemicals

# **Section 8 - Exposure Controls and Personal Protection**

### **Control parameters**

### **Exposure limits**

The product does not contain any hazardous materials with occupational exposure limits established.

### **Biological limit values**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

#### Appropriate engineering 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

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

**Eye Protection** Wear safety glasses with side shields (or goggles) (Australian/New Zealand Standard

AS/NZS 1337 - Eye protectors for Industrial applications)

Hand Protection Protective gloves

Glove material	Breakthrough time	Glove thickness	AUS/NZ Standard	Glove comments
Nitrile rubber, Neoprene,	See manufacturers	-	AS/NZS 2161	(minimum requirement)
Natural rubber, PVC.	recommendations			

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

Repiratory Protection Use an AS/NZS 1716 approved respirator if exposure limits are exceeded or if irritation or

other symptoms are experienced. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained in line with AS/NZS 1715 on the use

and maintenance of repiratory protective devices

**Recommended Filter type:** Particulates filter conforming to EN 143 (or AUS/NZ equivalent)

Recommended half mask:- Particle filtering: EN149:2001 (or AUS/NZ equivalent)

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

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

ALFAAJ63191 Version 3 15-Mar-2023 Page 4/9

Environmental exposure controls No information available.

# **Section 9 - Physical and Chemical Properties**

### Information on basic physical and chemical properties

Physical State Solid

**Appearance** 

Odor No information available
Odor Threshold No data available
pH Not applicable

Melting Point/Range 146 - 151 °C / 294.8 - 303.8 °F

Softening Point No data available
Boiling Point/Range No information available

Flammability (liquid) Not applicable Solid

Flammability (solid,gas)

Explosion Limits

No information available

No data available

Flash Point No information available Method - No information available

Autoignition TemperatureNo data availableDecomposition TemperatureNo data available

Viscosity Not applicable Solid

Water Solubility Insoluble in water
Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Componentlog PowCyclosporin A2.92

Vapor PressureNo data availableDensity / Specific GravityNo data availableBulk DensityNo data available

Vapor Density Not applicable Solid

Particle characteristics No data available

Other information

Molecular Formula C62 H111 N11 O12

Molecular Weight 1202.61

Evaporation Rate Not applicable - Solid

# **Section 10 - Stability and Reactivity**

Reactivity None known, based on information available

**Stability** Stable under normal conditions.

Sensitivity to Mechanical Impact No information available

Sensitivity to Static Discharge No information available

Hazardous Polymerization Hazardous polymerization does not occur.

**Hazardous Reactions** None under normal processing.

Conditions to Avoid Incompatible products, Excess heat.

Incompatible Materials None known.

Hazardous Decomposition Products None under normal use conditions.

ALFAAJ63191 Version 3 15-Mar-2023 Page 5 / 9

# **Section 11 - Toxicological Information**

### **Acute Effects**

Information on likely routes of exposure

### **Product Information**

**Inhalation** Not an expected route of exposure.

EyesAvoid contact with eyes.SkinAvoid contact with skin.IngestionMay be harmful if swallowed.

### Numerical measures of toxicity

(a) acute toxicity;

Oral Category 4
Dermal No data available
Inhalation No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation	
Cyclosporin A	1480 mg/kg			

(b) skin corrosion/irritation; No data available

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

(d) respiratory or skin sensitization;

**Respiratory**Skin
No data available
No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; Category 1B

The table below indicates whether each agency has listed any ingredient as a carcinogen

Component	New Zealand	Australia	New South Wales	Western Australia	IARC	EU	UK	Germany
Cyclosporin A					Group 1			

(g) reproductive toxicity; Category 1B Reproductive Effects Category 1B

(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.

ALFAAJ63191 Version 3 15-Mar-2023 Page 6 / 9

# **Section 12 - Ecological Information**

**Ecotoxicity** 

Aquatic ecotoxicity Contains no substances known to be hazardous to the environment or that are not

degradable in waste water treatment plants.

Terrestrial ecotoxicity There is no data for this product

Persistence and Degradability

**Persistence** Persistence is unlikely.

Bioaccumulative Potential Bioaccumulation is unlikely

Component	log Pow	Bioconcentration factor (BCF)
Cyclosporin A	2.92	No data available

Mobility Spillage unlikely to penetrate soil. Is not likely mobile in the environment due its low water

solubility.

Other adverse effects

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 treatment methods

Waste from Residues/Unused

**Products** 

Other Information

Do not allow into drains or watercourses or dispose of where ground or surface waters may be affected. Wastes, including emptied containers, are controlled wastes and should be disposed of in accordance with all federal, E.P.A., state and local regulations. Assure conformity with all applicable regulations.

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

Disposal agencies or waste contractors must comply with the New Zealand Hazardous Substances (Disposal) Regulations. 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** 

Not regulated

IATA Not regulated

IMDG/IMO Not regulated

ALFAAJ63191 Version 3 15-Mar-2023 Page 7/9

**Environmental hazards** No hazards identified

Transport in bulk according to Annex II of MARPOL 73/78 and the

**IBC Code** 

Not applicable, packaged goods

**Special Precautions** 

No special precautions required. Please refer to the applicable dangerous goods

regulations for additional information.

Additional information None known

# **Section 15 - Regulatory Information**

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

### **National Regulations**

There are no applicable tolerable exposure limits or environmental exposure limits according to the EPA Controls for Hazardous Substances

### Certified handlers, tracking and controlled substance license requirements

Certified handlers are required for some substances. This includes substances requiring a controlled substance license, and most explosives, vertebrates toxic agents, and certain fumigants. Acutely toxic substances which are a Category 1 or 2, such as pesticides also require Certified handlers. Please check the Health and Safety at Work Act 2015 for further information. Tracking is required for some highly hazardous substances. These substances need to be under the control of an appropriately trained person or appropriately secured. Please check the Health and Safety at Work Act 2015 for further information.

### Prohibition or notification/licensing requirements

Shown below are details of specific prohibition/notifications or licencing requirements when they apply.

### International Regulations

**Ozone Depletion Potential** This product does not contain any known or suspected substance

**Persistent Organic Pollutant** This product does not contain any known or suspected substance

**Rotterdam Convention (PIC)** Not applicable

**Authorisation/Restrictions** according to EU REACH

Not applicable

### International Inventories

New Zealand (NZIoC), Australia (AICS), Europe (EINECS/ELINCS/NLP), Korea (KECL), China (IECSC), Taiwan (TCSI), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	NZIoC	AICS	EINECS	ELINCS	NLP	KECL	IECSC	TCSI
Cyclosporin A	59865-13-3	X	ı	-	-	ı	-	X	X

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	PICCS	ISHL	ENCS
Cyclosporin A	59865-13-3	-	-	X	-	-	-	-

Legend: X - Listed '-' - Not Listed **KECL** - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

**ALFAAJ63191** Version 3 15-Mar-2023 Page 8/9

### **Section 16 - Other Information**

# This safety data sheet complies with the requirements of the EPA Hazardous Substances (Hazard Classification) Notice 2020 and WorkSafe New Zealand Regulations

#### Legend

NZIoC - New Zealand Inventory of Chemicals

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

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

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

PICCS - Philippines Inventory of Chemicals and Chemical Substances

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer NZS 5433:2020 - Transport of Dangerous Goods on Land

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

 $\ensuremath{\mathsf{MARPOL}}$  - International Convention for the Prevention of Pollution from Ships

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50% WEL - Workplace Exposure Limit DNEL - Derived No Effect Level

**POW** - Partition coefficient Octanol:Water **vPvB** - very Persistent, very Bioaccumulative

**VOC** - (Volatile Organic Compound)

AICS - Australian Inventory of Chemical Substances

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

ENCS - Japanese Existing and New Chemical Substances

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

CAS - Chemical Abstracts Service

**ACGIH** - American Conference of Governmental Industrial Hygienists

PNEC - Predicted No Effect Concentration

**OECD** - Organisation for Economic Co-operation and Development **IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code

 $\ensuremath{\mathbf{ADG}}$  - Australian Code for the Transport of Dangerous Goods by Road and Rail

LC50 - Lethal Concentration 50% ATE - Acute Toxicity Estimate

RPE - Respiratory Protective Equipment NOEC - No Observed Effect Concentration

**BCF** - Bioconcentration factor

PBT - Persistent, Bioaccumulative, Toxic

### Key literature references and sources for data

HSNO classifications provided in the New Zealand Chemical Classification Information Database (CCID).

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

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

EPA Guide to classifying hazardous substances in New Zealand

EPA - Assigning a product to an existing HSNO approval guide

### **Training Advice**

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

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

Revision Date 15-Mar-2023

Revision Summary SDS sections updated

#### **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**

ALFAAJ63191 Version 3 15-Mar-2023 Page 9/9