



SAFETY DATA SHEET

100-1646 - Cyclosporin A

Revision Date 14-Feb-2024

Revision Number 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Cyclosporin A

Other means of identification

Catalog Number 100-1646

Document Number 10000027257

Synonym CsA, Cyclosporine, Sandimmune

Recommended use of the chemical and restrictions on use

Recommended Use Laboratory chemical

Details of the supplier of the safety data sheet

Manufacturer/Supplier

STEMCELL Technologies Canada Inc.
Suite 500 - 1618 Station Street
Vancouver, British Columbia V6A 1B6 Canada

Emergency telephone number

Emergency Telephone 1-800-667-0322

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral	Category 4
Carcinogenicity	Category 1B
Reproductive toxicity	Category 1B

Hazards not otherwise classified (HNOC)

Not applicable

Label elements



SAFETY DATA SHEET

100-1646 - Cyclosporin A

Revision Date 14-Feb-2024

Revision Number 1

Danger

Hazard statements

Harmful if swallowed

May cause cancer

May damage fertility or the unborn child



Appearance Powder

Physical state Solid

Odor No data available

Precautionary Statements - Prevention

Obtain special instructions before use

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

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

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Precautionary statements - Response

IF exposed or concerned: Get medical advice/attention

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other Information

Not Applicable

Unknown acute toxicity

0 % of the mixture consists of ingredient(s) of unknown toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. COMPOSITION/INFORMATION ON INGREDIENTS



SAFETY DATA SHEET

Revision Date 14-Feb-2024

Revision Number 1

100-1646 - Cyclosporin A

Substance

Synonym CsA, Cyclosporine, Sandimmune.

Chemical name	CAS No.	Weight-%
(3S,6S,9S,12R,15S,18S,21S,24S,30S,33S)-30-ethyl-33-[(E,1R,2R)-1-hydroxy-2-methylhex-4-enyl]-1,4,7,10,12,15,19,25,28-nonamethyl-6,9,18,24-tetrakis(2-methylpropyl)-3,21-di(propan-2-yl)-1,4,7,10,13,16,19,22,25,28,31-undecazacyclotritriacontane-2,5,8,11,14,17,20,23,26,29,32-undecone	59865-13-3	100

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of first aid measures

General advice	IF exposed or concerned: Get medical advice/attention. Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.



SAFETY DATA SHEET

100-1646 - Cyclosporin A

Revision Date 14-Feb-2024

Revision Number 1

Unsuitable extinguishing media	CAUTION: Use of water spray when fighting fire may be inefficient.
Specific hazards arising from the chemical	No information available.
Explosion data	
Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
Other Information	Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.
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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	Pick up and transfer to properly labeled containers.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.
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Conditions for safe storage, including any incompatibilities

Storage Conditions	Store in accordance with information listed on the Product Information Sheet (PIS).
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SAFETY DATA SHEET

100-1646 - Cyclosporin A

Revision Date 14-Feb-2024

Revision Number 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state Solid
Appearance Powder
Color white
Odor No data available
Odor threshold No data available



SAFETY DATA SHEET

Revision Date 14-Feb-2024

Revision Number 1

100-1646 - Cyclosporin A

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	Product is not flammable.	None known
Flammability Limit in Air		None known
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No data available	
Oxidizing properties	No information available	
<u>Other Information</u>		
Softening point	No information available	
Molecular weight	1202.6	
Molecular formula	C ₆₂ H ₁₁₁ N ₁₁ O ₁₂	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under recommended transport or storage conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Carbon dioxide (CO ₂). Carbon monoxide. Nitrogen oxides (NO _x).

11. TOXICOLOGICAL INFORMATION



SAFETY DATA SHEET

Revision Date 14-Feb-2024

Revision Number 1

100-1646 - Cyclosporin A

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 1,480.00 mg/kg

Unknown acute toxicity 0 % of the mixture consists of ingredient(s) of unknown toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Product Information

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
(3S,6S,9S,12R,15S,18S,21S,24S,30S,33S)-30-ethyl-33-[(E,1R,2R)-1-hydroxy-2-methylhex-4-enyl]-1,4,7,10,12,15,19,25,28-nomethyl-6,9,18,24-tetrakis(2-methylpropyl)-3,21-di(propan-2-yl)-1,4,7,10,13,16,19,22,25,28,31-undecacyclopentriacontane-2,5,8,11,14,17,20,23,26,29,32-undecone 59865-13-3	= 1480 mg/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure



SAFETY DATA SHEET

Revision Date 14-Feb-2024

Revision Number 1

100-1646 - Cyclosporin A

Skin corrosion/irritation No information available.

Product Information

Serious eye damage/eye irritation No information available.

Product Information

Respiratory or skin sensitization No information available.

Product Information

Germ cell mutagenicity No information available.

Product Information

Carcinogenicity Classification based on data available for ingredients.

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

Chemical name	ACGIH	IARC	NTP	OSHA
(3S,6S,9S,12R,15S,18S,21S,24S,30S,33S)-30-ethyl-33-[(E,1R,2R)-1-hydroxy-2-methylhex-4-enyl]-1,4,7,10,12,15,19,25,28-nonamethyl-6,9,18,24-tetrakis(2-methylpropyl)-3,21-di(propan-2-yl)-1,4,7,10,13,16,19,22,25,28,31-undecacyclotritriacontane-2,5,8,11,14,17,20,23,26,29,32-undecone 59865-13-3	-	Group 1	Known	X

Reproductive toxicity Classification based on data available for ingredients.

Product Information

STOT - single exposure No information available.

Product Information

STOT - repeated exposure No information available.

Product Information

Aspiration hazard No information available.
RTECS # GZ4120000

12. ECOLOGICAL INFORMATION

Ecotoxicity The environmental impact of this product has not been fully investigated.

Product Information



SAFETY DATA SHEET

100-1646 - Cyclosporin A

Revision Date 14-Feb-2024

Revision Number 1

Persistence and degradability	No information available.
Bioaccumulation	There is no data for this product.
Other adverse effects	No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>ICAO (air)</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated
<u>RID</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	Not regulated

15. REGULATORY INFORMATION

<u>International Inventories</u>	
TSCA	Does not comply



SAFETY DATA SHEET

Revision Date 14-Feb-2024

Revision Number 1

100-1646 - Cyclosporin A

DSL/NDSL	Complies
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Complies
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply

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 Chemical Substances/European 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**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	Yes
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations**California Proposition 65**

This product contains the following Proposition 65 chemicals.



SAFETY DATA SHEET

Revision Date 14-Feb-2024

Revision Number 1

100-1646 - Cyclosporin A

Chemical name	California Proposition 65
(3S,6S,9S,12R,15S,18S,21S,24S,30S,33S)-30-ethyl-33-[(E,1R,2R)-1-hydroxy-2-methylhex-4-enyl]-1,4,7,10,12,15,19,25,28-nona-methyl-6,9,18,24-tetrakis(2-methylpropyl)-3,21-di(propan-2-yl)-1,4,7,10,13,16,19,22,25,28,31-undecazacyclotritriacontane-2,5,8,11,14,17,20,23,26,29,32-undecone - 59865-13-3	Carcinogen

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION, INCLUDING DATE OF PREPARATION OF THE LAST REVISION

Prepared By, Quality Control. STEMCELL Technologies Canada Inc.

Revision Date 14-Feb-2024

Revision Note No information available.

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. STEMCELL Technologies Inc. shall not be held liable for any damage resulting from handling or from contact with the product.

End of Safety Data Sheet