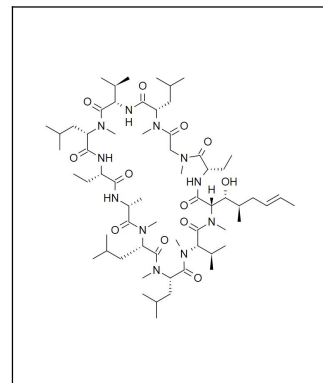


SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier Ciclosporin EP Impurity E
Catalog number C0009.17
CAS number 108027-46-9
Synonyms (3S,6S,9S,12R,15S,18S,21S,24S,30S,33S)-15,30-Diet
hyl-33-[(1R,2R,4E)-1-hydroxy-2-methylhex-4-en-1-yl]-1,
4,7,10,12,19,25,28-octamethyl-6,9,18,24-tetrakis(2-met
hylpropyl)-3,21-bis(propan-2-yl)-1,4,7,10,13,16,19,22,2
5,28,31-Undecaazacyclotritriacontan-2,5,8,11,14,17,20,
23,26,29,32-undecone



Chemical name Ciclosporin EP Impurity E
Product uses To be used only for scientific research and development. Not for use in humans or animals.
Manufacturer/Supplier information
Company name Aozeal Certified Standards(HK) Co., Limited
Address Suite 603, 6/F Hang Pont Commercial Building
31 Tonkin Street, Cheung Sha Wan, Kowloon, Hong Kong
Telephone +85253499607
Email info@aozeal.com
Website www.aozeal.com
Emergency telephone number +1 (510) 225-4077

2. HAZARDS IDENTIFICATION

Physical hazards Not classified.
Environmental hazards Not classified.
OSHA defined hazards Not classified.

Classification of the substance or mixture and label elements

GHS hazards classification (According to EU Regulation 1272/2008 and US OSHA 1910.1200)

Acute Toxicity, Oral (Category 5)

GHS hazards identification (According to EU Regulation 1272/2008 and US OSHA 1910.1200)

Signal word None
GHS hazard statements None
GHS precautionary statements Not a hazardous substance according to GHS.

Unclassified hazards/Hazards not otherwise classified No data available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	Ciclosporin EP Impurity E
Common name and synonyms	(3S,6S,9S,12R,15S,18S,21S,24S,30S,33S)-15,30-Diethyl-33-[(1R,2R,4E)-1-hydroxy-2-methylhex-4-en-1-yl]-1,4,7,10,12,19,25,28-octamethyl-6,9,18,24-tetrakis(2-methylpropyl)-3,21-bis(propan-2-yl)-1,4,7,10,13,16,19,22,25,28,31-Undecaazacyclotritriacontan-2,5,8,11,14,17,20,23,26,29,32-undecone
Molecular formula:	C ₆₃ H ₁₁₃ O ₁₂ N ₁₁
Molecular weight:	1216.66
CAS #:	108027-46-9
Mixtures :	Not a mixture.

4. FIRST AID MEASURES

General advice	If medical attention is required, show this safety data sheet to the doctor.
Inhalation	If inhaled, move person to fresh air. If not breathing, give artificial respiration and consult a physician.
Skin contact	Wash affected area with soap and water. Consult a physician if any exposure symptoms are observed.
Eye contact	Immediately rinse eyes with plenty of water for at least 15 minutes. Consult a physician
Ingestion	Never give anything by mouth to an unconscious person. Rinse mouth with water. Do NOT induce vomiting unless advised to do so by a physician or Poison Control Center. Seek medical attention.
Most important symptoms and effects, both acute and delayed	Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.
Indication of any immediate medical attention and special treatment needed	No data available.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance or mixture	Carbon oxides, Nitrogen oxides
Advice for firefighters	Wear self contained breathing apparatus for fire fighting if necessary.
Further information	No data available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Wear respiratory protection. Avoid dust formation. Avoid breathing vapours. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
Method and materials for containment and cleaning up	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

7. HANDLING AND STORAGE

Precautions for safe handling	Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
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	Provide appropriate exhaust ventilation at places where dust is formed.
Conditions for safe storage	Store in tightly closed container in a dry and well-ventilated place. This material should be handled and stored per label and COA instructions to ensure product integrity.
Specific end uses	For laboratory research and development only. Not for use in humans or animals.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glove box). No open handling.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection	
Hand protection	Wear nit-rile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Consider double gloves.
Other	Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task.
Respiratory protection	Chose respiratory protection appropriate to the task and the level of existing engineering controls. Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerwear and head cover for spill cleanup.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment. Pharmacological effects may be seen with occupational exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White Solid.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.

Melting point/freezing point	No data available
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility	CH ₃ CN+H ₂ O.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
Other information	Not available.

10. STABILITY AND REACTIVITY

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Not available.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	NO _x . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute toxicity	Oral LD50: Not available. Inhalation LC50: Not available. Dermal LD50: Not available.
Skin corrosion/Irritation	Not available.
Serious eye damage/Irritation	Not available.
Respiratory or Skin sensitization	Not available.
Carcinogenicity	Not available.
IARC monographs. Overall evaluation of carcinogenicity	Not listed.
OSHA specifically regulated	Not regulated.

Substances

(29 CFR 1910.1001-1050)

US. national toxicology program Not listed.

(NTP) report on carcinogens

Reproductive toxicity/Teratogenicity Not available.

Single target organ toxicity - Single exposure Not available.

Single target organ toxicity - Repeated exposure Not available.

Aspiration hazard Not available.

Potential health effects and routes of exposure

Inhalation May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion May be harmful if swallowed.

Skin May be harmful if absorbed through skin. May cause skin irritation.

Eyes May cause eye irritation.

Signs and symptoms of exposure The most important known symptoms and effects are described in the labeling
 To the best of our knowledge, the chemical, physical, and toxicological properties of this material have not been thoroughly investigated.

Additional information **RTECS:** Not available.

12. ECOLOGICAL INFORMATION

Eco-toxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degrade ability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No data available.

13. DISPOSAL CONSIDERATIONS

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste treatment methods Product may be burned in an incinerator equipped with afterburner and scrubber. Excess and expired materials are to be offered to a licensed hazardous material disposal company. Ensure that all Federal and Local regulations regarding the disposal and destruction of this material are followed.

Contaminated packaging Dispose of as above.
Other considerations Product is not to be disposed of in sanitary sewers, storm sewers, or landfills.

14. TRANSPORT INFORMATION

UN number ADR/RID: - IMDG: - IATA: -
UN proper shipping name ADR/RID: Not dangerous goods
 IMDG: Not dangerous goods
 IATA: Not dangerous goods
Transport hazard class(es) ADR/RID: - IMDG: - IATA: -
Packaging group ADR/RID: - IMDG: - IATA: -
Environmental hazards ADR/RID: no IMDG Marine pollutant: no IATA: no
Special precautions for user No data available.

15. REGULATORY INFORMATION

This safety data sheet complies with the requirements of OSHA 1910.1200 (US), WHMIS (Canada) and EU Regulation Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

United States

TSCA Status: This product is not listed on the US EPA TSCA.

Canada

DSL/NDSL Status: This product is not listed on the Canadian DSL/NDSL.

European Union

ECHA Status: This product or a component is registered with the EU ECHA.

Chemical safety assessment No data available.

16. OTHER INFORMATION

Original publication date 04/14/2025

Latest revision date (If Revised)

SDS expiry date 04/13/2028

List of abbreviations

LD50 Median lethal dose of a substance required to kill 50% of a test population.

LC50 Medial lethal concentration of a substance required to kill 50% of a test population.

IARC International Agency for Research on Cancer

NTP National Toxicology Program

RTECS Registry of Toxic Effects of Chemical Substances

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