

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

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

1.1 Product identifier

Trade name : Cyclosporine Formulation

Other means of identification : Optimune (A007869)
OPTIMUNE OPHTHALMIC OINTMENT (51551)

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

Use of the Sub-
stance/Mixture : Veterinary product

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Drynam Road
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Carcinogenicity, Category 1B H350: May cause cancer.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H350 May cause cancer.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

Storage:
P405 Store locked up.

Hazardous components which must be listed on the label:

Cyclosporine

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Cyclosporine	59865-13-3	Acute Tox. 4; H302 Carc. 1B; H350 Repr. 1B; H360Df STOT RE 1; H372 (Kidney, Liver, Immune system)	>= 0.1 - < 0.3

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

- When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : May cause cancer.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
-

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version 5.2 Revision Date: 14.04.2025 SDS Number: 610640-00024 Date of last issue: 28.09.2024
Date of first issue: 08.04.2016

- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe vapours or spray mist.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

- Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Petrolatum	8009-03-8	OELV - 8 hrs (TWA) (inhalable fraction)	5 mg/m ³	IE OEL
Cyclosporine	59865-13-3	TWA	10 µg/m ³ (OEB 3)	Internal
		Wipe limit	100 µg/100 cm ²	Internal

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Petrolatum	Oral (Secondary Poisoning)	9.33 mg/kg food

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter should conform to I.S. EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : ointment

Colour : colourless, to, light yellow

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

Initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics
Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Cyclosporine:

Acute oral toxicity	: LD50 (Rat): 1,480 mg/kg
	LD50 (Mouse): 2,329 mg/kg
Acute inhalation toxicity	: Remarks: No data available
Acute dermal toxicity	: Remarks: No data available
Acute toxicity (other routes of administration)	: LD50 (Mouse): 107 mg/kg
	Application Route: Intravenous
	LD50 (Rat): 25.8 mg/kg
	Application Route: Intravenous

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

Skin corrosion/irritation

Not classified based on available information.

Components:

Cyclosporine:

Remarks : No data available
May irritate skin.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Cyclosporine:

Remarks : No data available
May irritate eyes.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Cyclosporine:

Remarks : May cause sensitisation of susceptible persons.

Germ cell mutagenicity

Not classified based on available information.

Components:

Cyclosporine:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster cells Result: negative
		Test Type: sister chromatid exchange assay Result: positive
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative
		Test Type: Chromosomal aberration

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

Species: Chinese hamster

Cell type: Bone marrow

Result: negative

Test Type: Chromosomal aberration

Species: Mouse

Result: negative

Carcinogenicity

May cause cancer.

Components:

Cyclosporine:

Species	: Mouse
Application Route	: Oral
Exposure time	: 78 weeks
LOAEL	: 4 mg/kg body weight
Result	: positive
Target Organs	: Liver, lymphatic system

Species	: Rat
Application Route	: Oral
Exposure time	: 2 Years
LOAEL	: 0.5 mg/kg body weight
Result	: positive
Target Organs	: Pancreas

Species	: Humans
Result	: May cause cancer.
Target Organs	: Immune system, Skin
Remarks	: Information taken from reference works and the literature.

Carcinogenicity - Assessment	: May cause cancer.
------------------------------	---------------------

Reproductive toxicity

Not classified based on available information.

Components:

Cyclosporine:

Effects on fertility	: Test Type: One-generation reproduction toxicity study
	Species: Rat
	Application Route: Oral
	General Toxicity F1: LOAEL: 15 mg/kg body weight
	Result: No effects on fertility, Effect on reproduction capacity

Test Type: Fertility
Species: Rat, males
Application Route: Subcutaneous
Fertility: LOAEL: 10 mg/kg body weight
Result: Reduced fertility

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 30 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced foetal weight, foetal mortality, Retardations, Teratogenic effects

Test Type: Embryo-foetal development
Species: Rabbit
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced foetal weight, foetal mortality, Retardations, Teratogenic effects

Test Type: Development
Species: Rabbit
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Target Organs: Kidney
Result: Visceral malformations

Test Type: Development
Species: Rat
Application Route: Intravenous
Developmental Toxicity: LOAEL: 12 mg/kg body weight
Target Organs: Heart
Result: Visceral malformations

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Cyclosporine:

Target Organs	: Kidney, Liver, Immune system
Assessment	: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cyclosporine:

Species	: Rat
NOAEL	: 14 mg/kg
LOAEL	: 45 mg/kg

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

Application Route	:	Oral
Exposure time	:	90 Days
Target Organs	:	Kidney, Liver, Immune system
Symptoms	:	hair loss
Species	:	Monkey
NOAEL	:	20 mg/kg
LOAEL	:	60 mg/kg
Application Route	:	Oral
Exposure time	:	90 Days
Target Organs	:	Immune system
Symptoms	:	Gastrointestinal disturbance, Liver disorders, Kidney disorders
Species	:	Dog
LOAEL	:	15 mg/kg
Application Route	:	Oral
Exposure time	:	12 Months
Target Organs	:	Immune system
Symptoms	:	Changes in the blood count, Kidney disorders, Skin disorders, hair loss

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

Assessment	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
------------	---	---

Experience with human exposure

Components:

Cyclosporine:

Inhalation	:	Remarks: May cause irritation of respiratory tract.
Skin contact	:	Remarks: May irritate skin.
Eye contact	:	Symptoms: Eye irritation, eye pain
Ingestion	:	Symptoms: Kidney disorders, Tremors, hypertension, blood effects, Gastrointestinal disturbance

SECTION 12: Ecological information

12.1 Toxicity

No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3

Number on list 75: If you intend to

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

use this product as tattoo ink, please
contact your vendor.

Substance(s) or mixture(s) are listed
here according to their appearance
in the regulation, irrespective of their
use/purpose or the conditions of the
restriction. Please refer to the condi-
tions in corresponding Regulation to
determine whether an entry is appli-
cable to the placing on the market or
not.

REACH - Candidate List of Substances of Very High
Concern for Authorisation (Article 59) : Not applicable

Regulation (EU) No 2024/590 on substances that de-
plete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollu-
tants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parlia-
ment and the Council concerning the export and import
of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation
(Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of
major-accident hazards involving dangerous substances.
Not applicable

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations,
where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national
regulations, where applicable.

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version
are highlighted in the body of this document by two vertical
lines.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

Full text of H-Statements

H302	: Harmful if swallowed.
H350	: May cause cancer.
H360Df	: May damage the unborn child. Suspected of damaging fertility.
H372	: Causes damage to organs through prolonged or repeated exposure.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Carc.	: Carcinogenicity
Repr.	: Reproductive toxicity
STOT RE	: Specific target organ toxicity - repeated exposure
IE OEL	: Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA)	: Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.2	14.04.2025	610640-00024	Date of first issue: 08.04.2016

compile the Safety Data
Sheet

eChem Portal search results and European Chemicals Agen-
cy, <http://echa.europa.eu/>

Classification of the mixture:

Carc. 1B

H350

Classification procedure:

Calculation method

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IE / EN