

Safety Data Sheet for Drug product



Date of issue: 22-FEB-2017

Replaces version of: 01-FEB-2016

NEORAL SGC 25MG.002 706248 (MARS)

1. Identification of the substance/preparation and of the company

Product name NEORAL SGC 25MG.002
Chemical Class Peptide
Generic Name CYCLOSPORIN A
Pharmacological Action immunosuppressant, Transplantation of organs
Usage Pharmaceutical active ingredient
Company name Novartis Pharma AG
4002 Basel
Switzerland
Tel: +41 61 324 11 11, email: sds.support@novartis.com
Emergency phone number CHEMTEL (International) +1 813 676 1670 (365/24/7)

2. Hazards identification

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

3. Composition / information on ingredients

For classification of declared components, see section 15, "Regulatory Information"

Chemical Name	Contains:	CAS Number
ETHANOL; ETHYL ALCOHOL	8 - 15 %	64-17-5
CYCLOSPORIN A	5 - 8 %	59865-13-3

Remaining components are inert ingredients.

For TLV values of declared components, see Section 8, Exposure controls / Personal

4. First aid measures

Eye Contact Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).
Skin Contact Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.
Inhalation Remove the victim from danger zone, avoid further exposure.
Ingestion If swallowed, seek medical advice immediately and show this container or label.
Notes to Physician General measures to eliminate the substance and to reduce absorption.

5. Fire fighting measures

Suitable Extinguishing Media Water spray or fog, foam, dry chemical powder, CO2, dry sand
Unsuitable Extinguishing Media No restrictions
Dangerous Combustion Products carbon oxides, nitrogen oxides
Protective equipment for firefighters Wear self-contained breathing apparatus and fire protective suite.

6. Accidental release measures

Personal precautions Avoid contact with skin, eyes and clothing.
Environmental Must not be released into sewers, drains or wells.

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precautions

Methods for cleaning Transfer large quantities into a container. Clean up the rest with absorbent material and discharge properly.

7. Handling and storage

No special handling requirements for normal use of this material.

Store in a dry and cool place and observe special instructions from supplier.

8. Exposure controls / Personal protection

Occupational Exposure Limit (OEL)

no data available

TLV values of declared components

Contains:

ETHANOL; ETHYL ALCOHOL

List type	Value	Unit	
STEL-Spain (Short Term Exposure Limit)	1910	mg/m3	
	1000	ppm	
Italy OELs - Short term exposure limit	1000	ppm	
STEL Switzerland (Short term exposure limit)	1920	mg/m3	
	1000	ppm	
Short term exposure limit France (VLE)	9500	mg/m3	
	5000	ppm	
STEL-Ireland (Short Term Exposure Limit)	1000	ppm	
STEL (ACGIH USA) Short term exposure limit	1000	ppm	Animal carcinogen.
TLV-Values Austria	1900	mg/m3	
	1000	ppm	
Belgium OELs - TWA	1907	mg/m3	
	1000	ppm	
OEL-Spain (TLV)	1910	mg/m3	
	1000	ppm	
TLV-SUVA Switzerland	960	mg/m3	If the AGW and BGW values are complied with, there should be no risk of reproductive damage.
	500	ppm	
TLV- Germany (TRGS 900, Limit Values in the Ambient Air at the Workplace)	960	mg/m3	If the AGW and BGW values are complied with, there should be no risk of reproductive damage.
	500	ppm	
TLV-Values France (VME)	1900	mg/m3	
	1000	ppm	
OEL-Ireland (TLV)	1900	mg/m3	
	1000	ppm	
TLV-ACGIH USA			Animal carcinogen.
WEL-United Kingdom (8 hour TWA)	1920	mg/m3	
	1000	ppm	
Odour threshold	280	µg/m3	
	0.136	ppm	

Contains:

CYCLOSPORIN A

List type	Value	Unit	
Internal exposure limit	117	µg/m3	HHA Database

Personal protection for open handling

9. Physical and chemical properties

Flash Point not applicable

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10. Stability and reactivity

Under the normal conditions of use, the product is stable.

11. Toxicological information

Acute Toxicity	Data of CYCLOSPORIN A LD50: 1480 mg/kg Route: oral Species: rat
Irritation, Corrosion	no data available
Sensitisation	no data available
Mutagenicity	Data of CYCLOSPORIN A Negative with and without metabolic activation (AMES-Test (reverse mutation assay)) in vitroCell: Strains of salmonella typhimurium. Data of CYCLOSPORIN A Negative with and without metabolic activation (Chromosome Aberration Study) in vitroCell: Chinese hamster ovary (CHO) cells Data of CYCLOSPORIN A Negative (Micronucleus Test) in vivo, Species: mouse
Chronic Effects	Data of CYCLOSPORIN A Pathological findings (Repeated Dose Toxicity) NOAEL: 14 mg/kg/d Route: oral Species: rat, Organ: Multiple organs Dosage: <= 90 mg/kg/d, Duration: 13 weeks Data of CYCLOSPORIN A Histopathological changes (Repeated Dose Toxicity) NOAEL: 15 mg/kg/d Route: oral Species: dog, Organ: Skin Dosage: <= 45 mg/kg/d, Duration: 52 weeks Data of CYCLOSPORIN A Immunosuppressive (Repeated Dose Toxicity) NOAEL: 60 mg/kg/d Route: oral Species: monkey, Organ: Immune system Dosage: <= 300 mg/kg/d, Duration: 13 weeks Data of CYCLOSPORIN A No evidence for carcinogenicity (Carcinogenesis) NOAEL: 0.52 mg/kg/d Route: oral Species: rat Dosage: <= 8 mg/kg/d, Duration: 104 weeks Data of CYCLOSPORIN A No evidence for carcinogenicity (Carcinogenesis) NOAEL: 4 mg/kg/d Species: mouse Dosage: <= 16 mg/kg/d, Duration: 78 weeks
Reproduction Toxicity	Data of CYCLOSPORIN A Effect at high dose (Fertility and general reproductive performance study) NOAEL: 5 mg/kg/d Route: oral Species: rat, Sex: both sexes Data of CYCLOSPORIN A

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Maternal toxicity (Embryo-Fetal Development)
NOAEL: 17 mg/kg/d
Route: oral
Species: rat

Data of CYCLOSPORIN A
Embryotoxicity at maternally toxic dose (Embryo-Fetal Development)
NOAEL: 30 mg/kg/d
Route: oral
Species: rabbit

Data of CYCLOSPORIN A
Maternal toxicity (Embryo-Fetal Development)
NOEL: 6 mg/kg
Route: intravenous
Species: rat

Data of CYCLOSPORIN A
Embryotoxicity at maternally non toxic dose (Embryo-Fetal Development)
NOEL: 3 mg/kg
Route: intravenous
Species: rat

Data of CYCLOSPORIN A
Effect at high dose (Peri- and Postnatal Development)
NOAEL: 15 mg/kg/d
Route: oral
Species: rat

12. Ecological information

Biological Elimination Data of CYCLOSPORIN A
Degradation: 84 % (aerobic: Temperature: 20 - 24 °C CO₂)
rapid and complete biodegradation
Initial conc.: approx. 11 mg/l, Duration: 28 days
Method: OECD 301B * 1981

Fish acute toxicity Data of CYCLOSPORIN A
LC0: 100 mg/l
LC50: > 100 mg/l
LC100: > 100 mg/l
Species: rainbow trout (*salmo gairdneri*, *oncorhynchus mykiss*)
Exp. time: 96 hours
Method: OECD 203 * 1984 * acute toxicity

Aquatic invertebrate acute toxicity Data of CYCLOSPORIN A
EC0: 7.35 mg/l
EC50: 20.2 mg/l
EC100: > 77.85 mg/l
Species: *daphnia magna* (water flea)
Exp. time: 48 hours
Method: OECD 202 * 1984 * Acute Immobilisation Test

Algae Toxicity Data of CYCLOSPORIN A
IC50: > 100 mg/l
Species: *Desmodesmus subspicatus*/*Scenedesmus subspicatus* (Green algae)
Exp. time: 72 hours
Method: OECD 201 * 1984 * Growth inhibition

Bacterial Respiration Inhibition Data of CYCLOSPORIN A
IC20: > 100 mg/l
IC50: > 100 mg/l
Species: activated sludge
Exp. time: 3 hours
Method: OECD 209 * 1984

Ecotoxicity Summary Data of CYCLOSPORIN A

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Avoid release to the environment.

13. Disposal considerations

Disposal Requirements Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control. Local regulations should be adhered to.

14. Transport information

Regulation	Class	UN No.	PG	Label	LQ
RID/ADR:	Not restricted	0			N.A.
IMDG-Code:	Not restricted	0			
ICAO/IATA-DGR:	Not restricted	0			

ICAO/IATA-DGR: no dangerous good

Proper shipping name: -

15. Regulatory information

Classifications of components:

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
ETHANOL; ETHYL ALCOHOL	8 - 15 %	64-17-5		D	H225
CYCLOSPORIN A	5 - 8 %	59865-13-3		W	H302, H351, H373, H402, H412

Remaining components are inert ingredients.

16. Other information

Changes since the previous version in Section
3. Composition / information on ingredients
15. Regulatory information
16. Other information

Abbreviations used

H225: Highly flammable liquid and vapour.

H302: Harmful if swallowed.

H351: Suspected of causing cancer.

H373: May cause damage to organs through prolonged or repeated exposure.

H402: Harmful to aquatic life.(in EU not leading to classification as hazardous)

H412: Harmful to aquatic life with long lasting effects.

Recipient
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Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.