CELLCEPT Oral Suspension 200 mg/ml

Version	Revision Date:	Date of last issue: -
1.0	06/15/2025	Date of first issue: 06/15/2025

SECTION 1. IDENTIFICATION

Product name	:	CELLCEPT Oral Suspension 200 mg/ml
Product code	:	RO106-1443Z06
Common name(s), synonym(s) of the substance	:	CELLCEPT Oral Suspension (200 mg/ml)

Manufacturer or supplier's details

Company name of supplier	:	Genentech, Inc.
Address	:	1 DNA Way South San Francisco, CA 94080 USA
Telephone	:	001-(650) 225-1000
E-mail address	:	info.sds@roche.com
Emergency telephone In case of emergencies:	:	US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use	:	Formulated pharmaceutical active substance

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral)	:	Category 4
Germ cell mutagenicity	:	Category 2
Carcinogenicity	:	Category 1A
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure	:	Category 1

GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.
H341 Suspected of causing genetic defects.
H350 May cause cancer.
H360D May damage the unborn child.

H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P264 Wash 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 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
D-Glucitol	50-70-4	39.9
Water	7732-18-5	37.18
Mycophenolate mofetil	128794-94-5	20
Sodium citrate dihydrate	6132-04-3	1
Silica	7631-86-9	1
Benzoic acid, 4-hydroxy-, methyl ester	99-76-3	0.3
Lecithins	8002-43-5	0.2
non hazardous compounds	Not Assigned	0.2
Xanthan gum	11138-66-2	0.1
L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester	22839-47-0	0.1
1,2,3-Propanetricarboxylic acid, 2-hydroxy-	77-92-9	0.02

SECTION 4. FIRST AID MEASURES

General advice	:	Move out of dangerous area. Show this material safety data sheet to the doctor in attendance. Do not leave the victim unattended.
If inhaled	:	If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	Wash off with soap and water.
In case of eye contact	:	Flush eyes with water as a precaution. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	:	Induce vomiting immediately and call a physician. Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Take victim immediately to hospital.
Most important symptoms and effects, both acute and delayed	:	Harmful if swallowed. Suspected of causing genetic defects. May cause cancer. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection and use the recommended protective clothing
Notes to physician	:	Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	Do not allow run-off from fire fighting to enter drains or water courses.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NOx) Sodium oxides May release combustible and toxic gases

Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Refer to protective measures listed in sections 7 and 8.
Environmental precautions	:	Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. If the product contaminates rivers and lakes or drains inform respective authorities.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	Normal measures for preventive fire protection.
Advice on safe handling	:	Do not breathe vapors/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Dispose of rinse water in accordance with local and national regulations.
Conditions for safe storage	:	Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.
Storage temperature	:	Do not freeze. Protect from heat and light
Further information on storage stability	:	No decomposition if stored and applied as directed.

Packaging material : Suitable material: glass bottles, Plastic container of HDPE, Stainless steel, glass

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Mycophenolate mofetil The value is given in analogy to the following substances: Mycophenolic acid	128794-94-5	IOEL	0.01 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Silica	7631-86-9	PEL (respirable)	0.05 mg/m3	OSHA CARC
		TWA (Respirable dust)	0.05 mg/m3 (Silica)	NIOSH REL

Substance name	Environmental Compartment	Value
Mycophenolate mofetil	Surface waters	0.132 µg/l
	Remarks:Based on chronic data	

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

In case of contact through splashing:

Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0.11 mm

In case of full contact:

Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water

		Tightly fitting safety goggles
Skin and body protection	:	Impervious clothing Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hygiene measures	:	When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Color	:	off-white, white
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Self-ignition	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available

Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Particle characteristics		
Particle Size Distribution	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No decomposition if stored and applied as directed.
Conditions to avoid	:	No data available
		No data available
Incompatible materials	:	No data available
		Not applicable
Hazardous decomposition products	:	No data available
		No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 1,765 mg/kg Method: Calculation method

Components:

Mycophenolate mofetil:

Acute oral toxicity	:	LD50 Oral (Rat, female): 353 mg/kg

Sodium citrate dihydrate:

Acute oral toxicity	:	LD50 Oral (Mouse): 5,400 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 Dermal (Rat, male and female): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity Remarks: No mortality observed at this dose. The value is given in analogy to the following substances: citric acid

Silica:

Acute oral toxicity	:	LD50 (Rat, male and female): > 5,000 mg/kg GLP: yes
Acute inhalation toxicity	:	LC50 (Rat, male and female): > 5.01 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 436 GLP: yes Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity	:	LD50 Dermal (Rabbit): > 5,000 mg/kg Method: No information available. GLP: No information available.

L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester:

Acute oral toxicity	:	LD50 (Mouse): > 10,000 mg/kg LD50 (Rat): > 10,000 mg/kg

Skin corrosion/irritation

Not classified due to lack of data.

Components:

Mycophenolate mofetil:

Species	:	laboratory animal
Result	:	No skin irritation

Sodium citrate dihydrate:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
Test substance	:	anhydrous substance

Silica:

Species	:	Rabbit
Exposure time	:	4 h
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
GLP	:	No information available.

L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester:

Remarks	:	This information is not available.

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:

Mycophenolate mofetil:

Species	:	laboratory animal
Result	:	No eye irritation

Sodium citrate dihydrate:

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405
Test substance	:	anhydrous substance

Silica:

Species	:	Rabbit
Result	:	No eye irritation
Exposure time	:	24 h
GLP	:	no

L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester:

Remarks	:	This information is not available.

Respiratory or skin sensitization

Skin sensitization

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Components:

Mycophenolate mofetil:

Result	:	Did not cause sensitization on laboratory animals.

Sodium citrate dihydrate:

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406
Test substance	:	anhydrous substance

Silica:

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406
Result	:	Did not cause sensitization on laboratory animals.
GLP	:	yes

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:

Mycophenolate mofetil:

Genotoxicity in vitro	:	Test Type: Ames test

Result: negative
The value is given in analogy to the following substances: Mycophenolic acid

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 473
Result: negative
The value is given in analogy to the following substances: Mycophenolic acid

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: positive
The value is given in analogy to the following substances: Mycophenolic acid

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Method: OECD Test Guideline 474
Result: positive
The value is given in analogy to the following substances: Mycophenolic acid

Germ cell mutagenicity - Assessment : In vitro tests showed mutagenic effects

Sodium citrate dihydrate:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative

Test Type: Micronucleus test
Test system: Human lymphocytes
Method: OECD Test Guideline 487
Result: positive

Genotoxicity in vivo : Test Type: dominant lethal test
Species: Rat
Application Route: Oral
Method: Regulation (EC) No. 440/2008, Annex, B.22
Result: negative

Test Type: Chromosome aberration test in vitro
Species: Rat
Cell type: Bone marrow
Application Route: Oral
Method: OECD Test Guideline 475
Result: negative

Silica:

Genotoxicity in vitro	:	Test Type: Microbial mutagenesis assay (Ames test) Test system: Salmonella typhimurium Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471 Result: negative GLP: yes Test Type: Microbial mutagenesis assay (Ames test) Test system: Escherichia coli Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471 Result: negative GLP: yes Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 490 Result: negative GLP: yes
Genotoxicity in vivo	:	Species: Rat (male) Cell type: Bone marrow Application Route: Oral Method: OECD Test Guideline 475 Result: negative GLP: no

Carcinogenicity

May cause cancer.

Components:

Mycophenolate mofetil:

Species	:	laboratory animal
Result	:	negative

Silica:

Species	:	Rat, male and female
Application Route	:	Oral
Exposure time	:	2 Years
Method	:	No information available.
Result	:	negative
GLP	:	No information available.

L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester:

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC	Group 2B: Possibly carcinogenic to humans	
	L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester	22839-47-0
OSHA	OSHA specifically regulated carcinogen	
	Silica (crystalline silica)	7631-86-9
NTP	Known to be human carcinogen	
	Silica (Silica, Crystalline (Respirable Size))	7631-86-9

Reproductive toxicity

May damage the unborn child.

Components:

Mycophenolate mofetil:

Effects on fetal development : Species: laboratory animal
Result: Teratogenic effects.

Reproductive toxicity - Assessment : May damage the unborn child., Presumed human reproductive toxicant

Silica:

Effects on fertility : Species: Rat, male and female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
General Toxicity Parent: NOAEL: >= 1,000 mg/kg body weight
General Toxicity F1: NOAEL: >= 1,000 mg/kg body weight
Method: OECD Test Guideline 416
GLP: yes

Effects on fetal development : Species: Mouse, female
Application Route: Oral
Dose: 13.4, 62.3, 289, 1340 mg/kg bw/day
Duration of Single Treatment: 6 - 15 d
General Toxicity Maternal: LOAEL: >= 1,340 mg/kg bw/day
Embryo-fetal toxicity.: NOAEL: >= 1,340 µg/kg body weight
Method: No information available.
GLP: No information available.

STOT-single exposure

Not classified due to lack of data.

Components:

L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester:

Assessment	:	The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

Mycophenolate mofetil:

Assessment	:	Causes damage to organs through prolonged or repeated exposure.

L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester:

Assessment	:	The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

Silica:

Species	:	Rat, male and female
NOEL	:	4000 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Method	:	OECD Test Guideline 408
GLP	:	yes

Aspiration toxicity

Not classified due to lack of data.

Components:

L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester:

No data available

Further information

Product:

Remarks	:	No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Mycophenolate mofetil:

Toxicity to fish	:	NOEC (Poecilia reticulata (guppy)): 1.7 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 GLP: no
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 GLP: no Remarks: nominal concentration NOEC (Daphnia magna (Water flea)): 27.7 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 GLP: no Remarks: average measured concentration
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): 0.6 mg/l Exposure time: 72 h Analytical monitoring: yes Method: OECD Test Guideline 201 GLP: no Remarks: average measured concentration EyC50 (Desmodesmus subspicatus (green algae)): 0.2 mg/l Exposure time: 72 h Analytical monitoring: yes Method: OECD Test Guideline 201 GLP: no Remarks: average measured concentration NOEC (Desmodesmus subspicatus (green algae)): 0.1 mg/l Exposure time: 72 h Analytical monitoring: yes Method: OECD Test Guideline 201 GLP: no Remarks: nominal concentration Lowest Observed Effect Concentration (Desmodesmus subspicatus (green algae)): 1.6 mg/l Exposure time: 14 d Analytical monitoring: yes Method: OECD Test Guideline 201 GLP: no Remarks: nominal concentration ErC50 (Anabaena flos-aquae (cyanobacterium)): 0.423 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

GLP: yes
Remarks: average measured concentration
The value is given in analogy to the following substances:
Mycophenolic acid

ErC10 (Anabaena flos-aquae (cyanobacterium)): 0.155 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: average measured concentration
The value is given in analogy to the following substances:
Mycophenolic acid

Toxicity to fish (Chronic toxicity) : EC10 (Danio rerio (zebra fish)): 0.0058 mg/l
Exposure time: 34 d
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
Method: OECD Test Guideline 210
The value is given in analogy to the following substances:
Mycophenolic acid

NOEC (Danio rerio (zebra fish)): 0.00132 mg/l
Exposure time: 34 d
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
Method: OECD Test Guideline 210
The value is given in analogy to the following substances:
Mycophenolic acid

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): 0.929 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
The value is given in analogy to the following substances:
Mycophenolic acid

Toxicity to microorganisms : (activated sludge): 100 mg/l
Exposure time: 14 d
Analytical monitoring: yes
Method: OECD Test Guideline 301F
GLP: no
Remarks: no adverse influence on substrate biodegradation
nominal concentration

Sodium citrate dihydrate:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 18,000 - 32,000 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 5,600 - 10,000 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 (Chlorella vulgaris (Fresh water algae)): 18,000 - 32,000 mg/l

Exposure time: 96 h

Toxicity to microorganisms : EC50 (Bacteria): 1,800 - 3,200 mg/l
Exposure time: 8 h

Silica:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 5,000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 203
GLP: no

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 10,000 mg/l
End point: Immobilization
Exposure time: 24 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 173.1 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Lowest Observed Effect Concentration (Daphnia magna (Water flea)): 149.2 mg/l
End point: mortality
Exposure time: 21 d
Test Type: semi-static test
Analytical monitoring: yes
Method: OECD Test Guideline 211
GLP: yes

Toxicity to microorganisms : NOEC (activated sludge): 1,000 mg/l
End point: Respiration inhibition
Exposure time: 3 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 209
GLP: yes

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester:

Ecotoxicology Assessment

Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

Persistence and degradability

Components:

Mycophenolate mofetil:

Biodegradability	:	aerobic Inoculum: activated sludge, non-adapted Concentration: 100 mg/l Result: Not readily biodegradable. Biodegradation: < 6 % Exposure time: 28 d Method: OECD Test Guideline 301F GLP: no Remarks: Primary biodegradation Biodegradation: 82.2 % Testing period: 2.9 d Exposure time: 28 d Method: OECD Test Guideline 314 GLP: yes Remarks: Ultimate aerobic biodegradation The value is given in analogy to the following substances: Mycophenolic acid Testing period: 1.7 d Method: OECD Test Guideline 314 GLP: yes Remarks: Primary biodegradation The value is given in analogy to the following substances: Mycophenolic acid
Stability in water	:	Hydrolysis: 50 % at 37 °C(118 h) Hydrolysis: 50 % at 37 °C(19 h)

Sodium citrate dihydrate:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 97 % Exposure time: 28 d Method: OECD Test Guideline 301B Remarks: Based on data from similar materials

Silica:

Biodegradability	:	Remarks: Not applicable

L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester:

Biodegradability	:	Remarks: Expected to be biodegradable

Bioaccumulative potential

Components:

Mycophenolate mofetil:

Partition coefficient: n-octanol/water	:	log Pow: 1.45 pH: 7.4 log Pow: 0.47 pH: 7.0

Sodium citrate dihydrate:

Bioaccumulation	:	Bioconcentration factor (BCF): 3.2 Remarks: Based on data from similar materials
Partition coefficient: n-octanol/water	:	Remarks: No data available

Silica:

Partition coefficient: n-octanol/water	:	Remarks: Not applicable

L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester:

Partition coefficient: n-octanol/water	:	Remarks: No data available

Mobility in soil

Components:

Mycophenolate mofetil:

Distribution among environmental compartments	:	Medium: Soil Koc: 168 - 557 ml/g Kd: 2.2 - 5.5 ml/g Method: OECD Test Guideline 106 Remarks: Mobile in soils Not expected to adsorb on soil. Medium: Sludge Koc: 30 - 37 ml/g Kd: 9.3 - 13 ml/g Method: OECD Test Guideline 106

Other adverse effects

Product:

Ozone-Depletion Potential	:	Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the

U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information	:	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	The product should not be allowed to enter drains, water courses or the soil. Do not contaminate ponds, waterways or ditches with chemical or used container. Send to a licensed waste management company.
Contaminated packaging	:	Empty remaining contents. Dispose of as unused product. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mycophenolate-mofetil)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	no

IATA-DGR

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Mycophenolate-mofetil)
Class	:	9
Packing group	:	III
Labels	:	Class 9 - Miscellaneous dangerous substances and articles
Packing instruction (cargo aircraft)	:	964
Packing instruction (passenger aircraft)	:	964
Environmentally hazardous	:	yes

IMDG-Code

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mycophenolate-mofetil)
Class	:	9

Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

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

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Mycophenolate-mofetil)
Class	:	9
Packing group	:	III
Labels	:	Class 9 - Miscellaneous dangerous substances and articles
ERG Code	:	171
Marine pollutant	:	no

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)

SARA 311/312 Hazards : Acute toxicity (any route of exposure)
Germ cell mutagenicity
Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

Silica	7631-86-9

Pennsylvania Right To Know

D-Glucitol	50-70-4
Water	7732-18-5
Mycophenolate mofetil	128794-94-5
Silica	7631-86-9

Maine Chemicals of High Concern

Silica	7631-86-9
Benzoic acid, 4-hydroxy-, methyl ester	99-76-3

Vermont Chemicals of High Concern

Benzoic acid, 4-hydroxy-, methyl ester	99-76-3

Washington Chemicals of High Concern

Benzoic acid, 4-hydroxy-, methyl ester	99-76-3

California Prop. 65

WARNING: This product can expose you to chemicals including Silica, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

Silica	7631-86-9

California Regulated Carcinogens

Silica	7631-86-9

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

AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Mycophenolate mofetil non hazardous compounds
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory

TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory

TSCA list

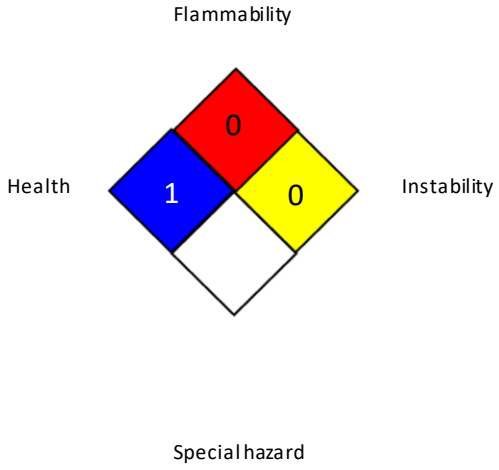
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

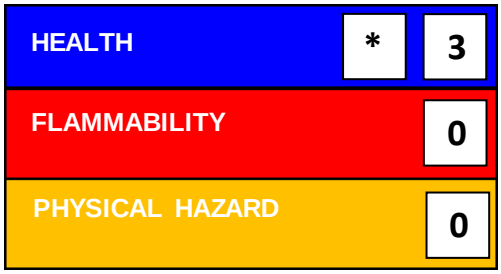
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA CARC	:	OSHA Specifically Regulated Chemicals/Carcinogens
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA CARC / PEL	:	Permissible exposure limit (PEL)

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide;

GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 06/15/2025

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.

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