

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**SECTION 1. IDENTIFICATION**

Product name : CELLCEPT Capsules 250 mg

Product code : RO106-1443/V01-00

Common name(s),
synonym(s) of the substance : CELLCEPT Capsules (hard) 250 mg**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 2

Reproductive toxicity : Category 1B

Specific target organ toxicity : Category 1
- repeated exposure**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.
H341 Suspected of causing genetic defects.
H351 Suspected of causing cancer.
H360D May damage the unborn child.

CELLCEPT Capsules 250 mg

Version
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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 dust.

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)
Mycophenolate mofetil	128794-94-5	66.1
Starch	9005-25-8	7.9
Croscarmellose sodium	74811-65-7	3.1
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8	1.6
Octadecanoic acid, magnesium salt (2:1)	557-04-0	1.2
Titanium oxide (TiO ₂)	13463-67-7	1
non hazardous compounds	Not Assigned	19.1

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.

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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. Suspected of causing 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 (NO _x)
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.

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

Special protective equipment : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Avoid exposure
Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.
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 : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.
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 : Protect from moisture.
Protect from heat and light

Further information on storage stability : No decomposition if stored and applied as directed.

Packaging material : Suitable material: Stainless steel, glass

CELLCEPT Capsules 250 mg

 Version
 1.0

 Revision Date:
 06/13/2025

 Date of last issue: -
 Date of first issue: 06/13/2025

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)
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
Titanium oxide (TiO2)	13463-67-7	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA (Respirable particulate matter)	0.2 mg/m3 (Titanium dioxide)	ACGIH
		TWA (Respirable particulate matter)	2.5 mg/m3 (Titanium dioxide)	ACGIH
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

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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

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

In case of contact through splashing:

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

In case of full contact:

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 : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Protective measures : Instruction of employees recommended

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 : capsules

Color : brown
light blue

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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 : No data available

Upper explosion limit / Upper
flammability limit : No data availableLower explosion limit / Lower
flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

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 : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : No data available

Oxidizing properties : No data available

Particle characteristics

Particle Size Distribution : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No decomposition if stored and applied as directed.
Conditions to avoid	:	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: 532.36 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 200 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

Components:**Mycophenolate mofetil:**

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

Starch:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Expert judgment
Acute inhalation toxicity	:	Acute toxicity estimate: > 30 mg/l Test atmosphere: dust/mist Method: Expert judgment
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Expert judgment

Octadecanoic acid, magnesium salt (2:1):

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

Titanium oxide (TiO₂):Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 425Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation

Not classified due to lack of data.

Components:**Mycophenolate mofetil:**Species : laboratory animal
Result : No skin irritation**Titanium oxide (TiO₂):**Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation**Serious eye damage/eye irritation**

Not classified due to lack of data.

Components:**Mycophenolate mofetil:**Species : laboratory animal
Result : No eye irritation**Titanium oxide (TiO₂):**Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405**Respiratory or skin sensitization****Skin sensitization**

Not classified due to lack of data.

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**Respiratory sensitization**

Not classified due to lack of data.

Components:**Mycophenolate mofetil:**

Result : Did not cause sensitization on laboratory animals.

Titanium oxide (TiO₂):

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

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

Carcinogenicity

Suspected of causing cancer.

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**Components:****Mycophenolate mofetil:**Species : laboratory animal
Result : negative**Titanium oxide (TiO₂):**Carcinogenicity - : Limited evidence of a carcinogenic effect.
Assessment**IARC** Group 2B: Possibly carcinogenic to humans
Titanium oxide (TiO₂) 13463-67-7**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.**Reproductive toxicity**

May damage the unborn child.

Components:**Mycophenolate mofetil:**Effects on fetal development : Species: laboratory animal
Result: Teratogenic effects.Reproductive toxicity - : May damage the unborn child., Presumed human
Assessment reproductive toxicant**STOT-single exposure**

Not classified due to lack of data.

Components:**Starch:**

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

Octadecanoic acid, magnesium salt (2:1):

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.

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**Components:****Mycophenolate mofetil:**

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

Starch:

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

Octadecanoic acid, magnesium salt (2:1):

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

Aspiration toxicity

Not classified due to lack of data.

Components:**Starch:**

No data available

Octadecanoic acid, magnesium salt (2:1):

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: noToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

CELLCEPT Capsules 250 mg

Version
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

- 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

Starch:

- Toxicity to fish : LC50 : > 100 mg/l
Exposure time: 96 h

Ecotoxicology Assessment

- Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

Octadecanoic acid, magnesium salt (2:1):**Ecotoxicology Assessment**

- Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

Other organisms relevant to the environment : No data available

Titanium oxide (TiO₂):

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
Exposure time: 96 h
Test Type: static test

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201

EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h
Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l
Exposure time: 72 h
Method: ISO 10253

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

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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)

Titanium oxide (TiO₂):

Biodegradability : Remarks: Not applicable

Bioaccumulative potential**Components:****Mycophenolate mofetil:**

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

log Pow: 0.47
pH: 7.0

Starch:

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

Octadecanoic acid, magnesium salt (2:1):

Partition coefficient: n- : log Pow: 0.8
octanol/water Method: OECD Test Guideline 107

Titanium oxide (TiO₂):

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

Mobility in soil**Components:****Mycophenolate mofetil:**

Distribution among : Medium: Soil

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

environmental compartments 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.
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 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Mycophenolate-mofetil)
Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : no

IATA-DGR

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Mycophenolate-mofetil)
Class : 9
Packing group : III
Labels : Class 9 - Miscellaneous dangerous substances and articles
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
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

Domestic regulation**49 CFR**

UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, 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

Remarks : No data available

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)

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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 SOCM 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**

Starch	9005-25-8
Titanium oxide (TiO ₂)	13463-67-7

Pennsylvania Right To Know

Mycophenolate mofetil	128794-94-5
non hazardous compounds	Not Assigned
Starch	9005-25-8
Croscarmellose sodium	74811-65-7
Titanium oxide (TiO ₂)	13463-67-7

Maine Chemicals of High Concern**Vermont Chemicals of High Concern****Washington Chemicals of High Concern****California Prop. 65**

WARNING: This product can expose you to chemicals including Titanium oxide (TiO₂), 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

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
--	-----------

California Permissible Exposure Limits for Chemical Contaminants

Starch	9005-25-8
Octadecanoic acid, magnesium salt (2:1)	557-04-0
Titanium oxide (TiO ₂)	13463-67-7

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

AIIC : Not in compliance with the inventory

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Mycophenolate mofetil non hazardous compounds Croscarmellose sodium
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.

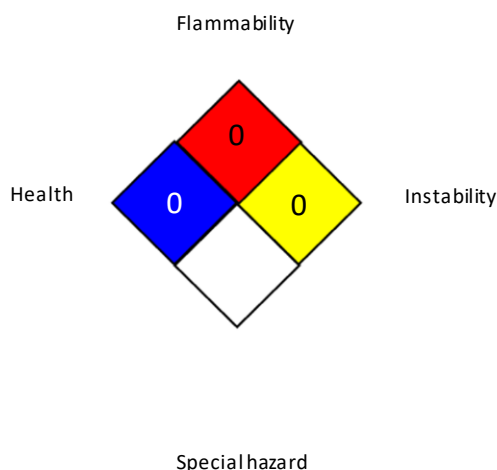
SECTION 16. OTHER INFORMATION**Further information**

CELLCEPT Capsules 250 mg

 Version
 1.0

 Revision Date:
 06/13/2025

 Date of last issue: -
 Date of first issue: 06/13/2025

NFPA 704:

HMIS® IV:

HEALTH	*	3
FLAMMABILITY		0
PHYSICAL HAZARD		0

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

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIIC - 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

CELLCEPT Capsules 250 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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; TE CI - 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 : 06/13/2025

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.

US / EN / 2404