

## CELLCEPT(R) Film Coated Tablets 500 mg

Version  
2.0

Revision Date:  
10-27-2022

Date of last issue: 02-19-2020  
Date of first issue: 06-10-2017

### SECTION 1. IDENTIFICATION

Product name : CELLCEPT(R) Film Coated Tablets 500 mg

Product code : 00010062347

Common name(s), syno- : CELLCEPT F.C. Tablets 500mg  
nym(s) of the substance CELLCEPT Film Coated Tablets

#### 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

Emergency telephone num- : US Chemtrec phone (800)-424-9300  
ber

#### Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

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### 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.

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H351 Suspected of causing 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 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	59.7
Cellulose	9004-34-6	29.1
Croscarmellose sodium	74811-65-7	3.9
2-Pyrrolidinone, 1-ethenyl-, homo-polymer	9003-39-8	2.9
Octadecanoic acid, magnesium salt (2:1)	557-04-0	1.5
Titanium oxide (TiO <sub>2</sub> )	13463-67-7	<= 0.9
non hazardous compounds	Not Assigned	2.0

**SECTION 4. FIRST AID MEASURES**

General advice : Move out of dangerous area.  
 Show this material safety data sheet to the doctor in attendance.

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- Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : 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.  
Rinse mouth with water.
- 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.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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**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 : In case of fire hazardous decomposition products may be produced such as:  
Carbon monoxide  
Carbon oxides  
Nitrogen oxides (NOx)
- 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.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Avoid exposure  
Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.
- 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.

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### 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.
- Further information on storage conditions : See label, package insert or internal guidelines
- Storage temperature : Protected from heat and light
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Polyethylene bag in metal drum, Plastic container of HDPE, Blister packages

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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

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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/m <sup>3</sup>	Roche Industrial Hygiene Committee (RIHC)
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	15 mg/m <sup>3</sup>	OSHA P0
		TWA (respirable dust fraction)	5 mg/m <sup>3</sup>	OSHA P0
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Titanium oxide (TiO <sub>2</sub> )	13463-67-7	TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	10 mg/m <sup>3</sup>	OSHA P0
		TWA (Respirable particulate matter)	2.5 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
		TWA (Respirable particulate matter)	0.2 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH

**Predicted No Effect Concentration (PNEC):**

Substance name	Environmental Compartment	Value
Mycophenolate mofetil	Surface waters	0.58 µg/l
	Remarks: Based on chronic data	

**Engineering measures** : No data available

**Personal protective equipment**

 Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.  
 Effective dust mask

Hand protection

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		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	:	Dust impervious protective suit Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Protective measures	:	Instruction of employees mandatory
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	:	tablet
Odor	:	Not applicable
Odor Threshold	:	Not applicable
pH	:	Not applicable
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Evaporation rate	:	No data available
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available

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Relative vapor density	:	Not applicable
Relative 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

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**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.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Harmful if swallowed.

**Product:**

Acute oral toxicity	:	Acute toxicity estimate: 588.96 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 178.08 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

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

**Cellulose:**

Acute oral toxicity : LD50 Oral (Rat): &gt; 5,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): &gt; 2,000 mg/kg

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

Acute oral toxicity : LD50 Oral (Rat): &gt; 2,000 mg/kg

**Titanium oxide (TiO<sub>2</sub>):**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): &gt; 5,000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Mycophenolate mofetil:**Species : laboratory animal  
Result : No skin irritation**Titanium oxide (TiO<sub>2</sub>):**Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Mycophenolate mofetil:**Species : laboratory animal  
Result : No eye irritation**Titanium oxide (TiO<sub>2</sub>):**Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405



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### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Components:

##### **Mycophenolate mofetil:**

Result : Did not cause sensitization on laboratory animals.

##### **Titanium oxide (TiO<sub>2</sub>):**

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.

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Result : negative**Cellulose:**

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  
Titanium oxide (TiO<sub>2</sub>) 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 - Assessment : May damage the unborn child., Presumed human reproductive toxicant

**STOT-single exposure**

Not classified based on available information.

**Components:****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.

**Components:****Mycophenolate mofetil:**

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

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

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

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Not classified based on available information.

**Components:****Octadecanoic acid, magnesium salt (2:1):**

No data available

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**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

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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

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

**Cellulose:****Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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**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.

Other organisms relevant to the environment : No data available

**Titanium oxide (TiO<sub>2</sub>):**

 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

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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 % at37 °C(118 h)  
 Hydrolysis: 50 % at37 °C(19 h)

**Titanium oxide (TiO<sub>2</sub>):**

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

**Cellulose:**

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 (TiO<sub>2</sub>):**

Partition coefficient: n- : Remarks: No data available

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octanol/water

**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.  
Very toxic to aquatic life with long lasting effects.

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**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.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**

**UNRTDG**

# SAFETY DATA SHEET

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UN number                                      : UN 3077  
Proper shipping name                        : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Mycophenolate mofetil mixture)  
Class    : 9  
Packing group                                : III  
Labels                                         : 9

### IATA-DGR

UN/ID No.                                     : UN 3077  
Proper shipping name                        : Environmentally hazardous substance, solid, n.o.s.  
(Mycophenolate mofetil mixture)  
Class    : 9  
Packing group                                : III  
Labels                                         : Miscellaneous  
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 mixture)  
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 mixture)  
Class    : 9  
Packing group                                : III  
Labels                                         : CLASS 9  
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.



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**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**

This material does not contain any components with a section 302 EHS TPQ.

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

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**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 I 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**

Cellulose 9004-34-6

**Pennsylvania Right To Know**

Mycophenolate mofetil 128794-94-5  
Cellulose 9004-34-6  
Croscarmellose sodium 74811-65-7

**Maine Chemicals of High Concern**

Product does not contain any listed chemicals

**Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

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**Washington Chemicals of High Concern**

Product does not contain any listed chemicals

**California Prop. 65**

WARNING: This product can expose you to chemicals including Titanium oxide (TiO<sub>2</sub>), which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**California List of Hazardous Substances**

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
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**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose	9004-34-6
Octadecanoic acid, magnesium salt (2:1)	557-04-0

**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
  - Croscarmellose sodium
  - 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.

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**SECTION 16. OTHER INFORMATION**

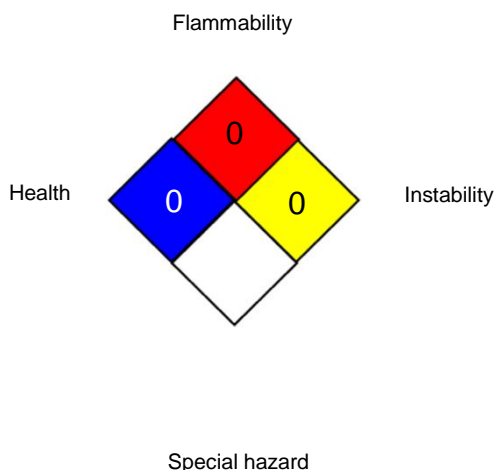
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**NFPA 704:**



**HMIS® IV:**

<b>HEALTH</b>	*	<b>3</b>
<b>FLAMMABILITY</b>		<b>0</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

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

AIC - 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; IECS - 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

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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 : 10-27-2022

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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