

**CELLCEPT Powder for suspension 200 mg/ml**Version  
1.1Revision Date:  
08/05/2025Date of last issue: 07/16/2025  
Date of first issue: 07/16/2025**SECTION 1. IDENTIFICATION**

Product name : CELLCEPT Powder for suspension 200 mg/ml

Product code : RO106-1443/F06-00

Common name(s),  
synonym(s) of the substance : CELLCEPT Powder for 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)**

Combustible dust

Acute toxicity (Oral) : Category 4

Germ cell mutagenicity : Category 2

Carcinogenicity : Category 1A

Reproductive toxicity : Category 1B

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

Hazard pictograms :



Signal Word : Danger

Hazard Statements : May form combustible dust concentrations in air.  
H302 Harmful if swallowed.

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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 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	31.8
D-Glucitol	50-70-4	63.55
Sodium citrate dihydrate	6132-04-3	1.59
Silica	7631-86-9	1.59
Benzoic acid, 4-hydroxy-, methyl ester	99-76-3	0.48
Lecithins	8002-43-5	0.32
non hazardous compounds	Not Assigned	0.32
Xanthan gum	11138-66-2	0.16
L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester	22839-47-0	0.16
1,2,3-Propanetricarboxylic acid, 2-hydroxy-	77-92-9	0.03

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**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	: No information available. 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.

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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	: Carbon oxides Nitrogen oxides (NOx)

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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.

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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.  
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.

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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.

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Storage temperature : to 30 °C  
 Keep in a dry place.  
 Keep in a well-ventilated place.

Further information on storage stability : Keep in a dry place.  
 No decomposition if stored and applied as directed.

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

**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

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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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Color : white

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : Not applicable

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
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

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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. Dust may form explosive mixture in air.
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.

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

Harmful if swallowed.

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Acute oral toxicity : Acute toxicity estimate: 1,111 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

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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.
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**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

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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.

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- 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

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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.

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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 7631-86-9  
(crystalline silica)

**NTP** Known to be human carcinogen  
Silica 7631-86-9  
(Silica, Crystalline (Respirable Size))

**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

**Silica:**

Effects on fertility : Species: Rat, male and female  
Application Route: Oral  
Dose: 100, 300, 1000 mg/kg bw/day  
General Toxicity Parent: NOAEL:  $\geq$  1,000 mg/kg body weight  
General Toxicity F1: NOAEL:  $\geq$  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:  $\geq$  1,340 mg/kg bw/day  
Embryo-fetal toxicity.: NOAEL:  $\geq$  1,340  $\mu$ g/kg body weight  
Method: No information available.  
GLP: No information available.

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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

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- 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

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	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
<b>Sodium citrate dihydrate:</b>	
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

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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

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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:**

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Biodegradability : Remarks: Expected to be biodegradable

**Bioaccumulative potential****Components:****Mycophenolate mofetil:**Partition coefficient: n-  
octanol/water : log Pow: 1.45  
pH: 7.4log Pow: 0.47  
pH: 7.0**Sodium citrate dihydrate:**Bioaccumulation : Bioconcentration factor (BCF): 3.2  
Remarks: Based on data from similar materialsPartition 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

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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.  
Do not re-use empty containers.

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**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**

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

**Genentech**  
A Member of the Roche Group

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

Not applicable

## 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

## 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.

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

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 SOCM1 Intermediate or Final VOC's (40 CFR 60.489).

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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
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**Pennsylvania Right To Know**

D-Glucitol	50-70-4
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
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**Washington Chemicals of High Concern**

Benzoic acid, 4-hydroxy-, methyl ester	99-76-3
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**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](http://www.P65Warnings.ca.gov).

**California List of Hazardous Substances**

Silica	7631-86-9
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**California Regulated Carcinogens**

Silica	7631-86-9
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**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

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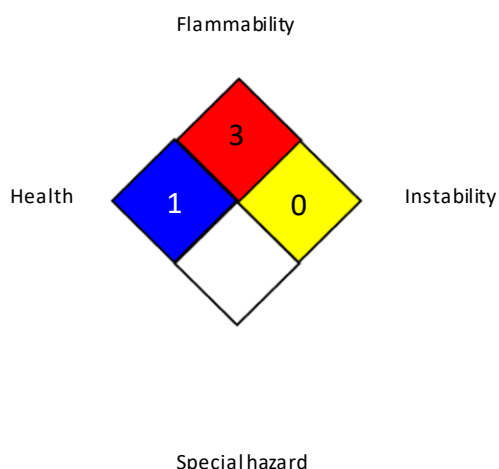
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PICCS	: Not in compliance with the inventory
IECSC	: Not in compliance with the inventory
TCSI	: Not in compliance with the inventory
TSCA	: Product contains substance(s) not listed on TSCA inventory.
TECI	: Not in compliance with the inventory

**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:**

<b>HEALTH</b>	*	<b>3</b>
<b>FLAMMABILITY</b>		<b>3</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**

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 -

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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; TECl - 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

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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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