

CELLCEPT(R) Lyophilized Vials 500 mgVersion
2.0Revision Date:
10-27-2022Date of last issue: 02-19-2020
Date of first issue: 06-10-2017**SECTION 1. IDENTIFICATION**

Product name : CELLCEPT(R) Lyophilized Vials 500 mg

Product code : 00010057786

Common name(s), syno- : CELLCEPT Lyophilized Vials 500mg
nym(s) of the substance**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.

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

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.

CELLCEPT(R) Lyophilized Vials 500 mgVersion
2.0Revision Date:
10-27-2022Date of last issue: 02-19-2020
Date of first issue: 06-10-2017

H341 Suspected of causing genetic defects.
 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	87.4
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	9005-65-6	4.4
1,2,3-Propanetricarboxylic acid, 2-hydroxy-	77-92-9	0.9
non hazardous compounds	Not Assigned	7.3

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(R) Lyophilized Vials 500 mg

Version 2.0	Revision Date: 10-27-2022	Date of last issue: 02-19-2020 Date of first issue: 06-10-2017
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- 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.
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.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protection : Avoid exposure

CELLCEPT(R) Lyophilized Vials 500 mg

Version 2.0 Revision Date: 10-27-2022 Date of last issue: 02-19-2020
 Date of first issue: 06-10-2017

- tive equipment and emergency procedures 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.

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 : Store at room temperature in the original container.
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Vials

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	128794-94-5	IOEL	0.01 mg/m ³	Roche Industrial Hy-

CELLCEPT(R) Lyophilized Vials 500 mg

Version
2.0

Revision Date:
10-27-2022

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

to the following substances: Mycophenolic acid				giene Com- mittee (RIHC)
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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

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.
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 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 : lyophilized cake

Color : white, off-white

Odor : Not applicable

CELLCEPT(R) Lyophilized Vials 500 mg

Version
2.0

Revision Date:
10-27-2022

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

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
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

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

CELLCEPT(R) Lyophilized Vials 500 mgVersion
2.0Revision Date:
10-27-2022Date of last issue: 02-19-2020
Date of first issue: 06-10-2017Hazardous decomposition : No data available
products**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Harmful if swallowed.

Product:Acute oral toxicity : Acute toxicity estimate: 403.84 mg/kg
Method: Calculation method**Components:****Mycophenolate mofetil:**

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

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

Acute oral toxicity : LD50 Oral (Rat): 63,840 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Mycophenolate mofetil:**Species : laboratory animal
Result : No skin irritation**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**Species : Rabbit
Exposure time : 72 h
Method : Draize Test
Result : No skin irritation
GLP : No information available.
Test substance : anhydrous substance**Serious eye damage/eye irritation**

Not classified based on available information.

Components:**Mycophenolate mofetil:**Species : laboratory animal
Result : No eye irritation**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**Species : Rabbit
Result : Mild eye irritation
Exposure time : 168 h
Method : Draize Test
GLP : No information available.

CELLCEPT(R) Lyophilized Vials 500 mg

 Version
 2.0

 Revision Date:
 10-27-2022

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

Test substance : anhydrous substance

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.

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

 Species : Humans
 Method : see user defined free text
 Result : Not a skin sensitizer.
 GLP : No information available.
 Test substance : anhydrous substance

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

CELLCEPT(R) Lyophilized Vials 500 mgVersion
2.0Revision Date:
10-27-2022Date of last issue: 02-19-2020
Date of first issue: 06-10-2017**Carcinogenicity**

Not classified based on available information.

Components:**Mycophenolate mofetil:**Species : laboratory animal
Result : negative**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

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 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.**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:**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

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.

CELLCEPT(R) Lyophilized Vials 500 mgVersion
2.0Revision Date:
10-27-2022Date of last issue: 02-19-2020
Date of first issue: 06-10-2017**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

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

Aspiration toxicity

Not classified based on available information.

Components:**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

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
Method: OECD Test Guideline 202
GLP: no
Remarks: nominal concentrationNOEC (Daphnia magna (Water flea)): 27.7 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: no
Remarks: average measured concentrationToxicity 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 concentrationEyC50 (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 concentrationNOEC (Desmodesmus subspicatus (green algae)): 0.1 mg/l
Exposure time: 72 h
Analytical monitoring: yes
Method: OECD Test Guideline 201

CELLCEPT(R) Lyophilized Vials 500 mg
Version
2.0Revision Date:
10-27-2022Date of last issue: 02-19-2020
Date of first issue: 06-10-2017GLP: no
Remarks: nominal concentration

Lowest Observed Effect Concentration (Desmodesmus subspicatus (green algae)): 1.6 mg/l
 Exposure time: 14 d
 Analytical monitoring: yes
 Method: OECD Test Guideline 201
 GLP: no
 Remarks: nominal concentration

ErC50 (Anabaena flos-aquae (cyanobacterium)): 0.423 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 GLP: yes
 Remarks: average measured concentration
 The value is given in analogy to the following substances:
 Mycophenolic acid

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

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

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

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 471 mg/l
 Exposure time: 96 h
 Test Type: static test
 GLP: No information available.

CELLCEPT(R) Lyophilized Vials 500 mgVersion
2.0Revision Date:
10-27-2022Date of last issue: 02-19-2020
Date of first issue: 06-10-2017

Toxicity to daphnia and other aquatic invertebrates : LC50 (Mysidopsis bahia (opossum shrimp)): 165 mg/l
Exposure time: 96 h
Test Type: static test
GLP: No information available.

Ecotoxicology Assessment

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

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

Toxicity Data on Soil : Not expected to adsorb on soil.
Remarks: Expert judgment

Other organisms relevant to the environment : No data available
Remarks: Expert judgment

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

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

CELLCEPT(R) Lyophilized Vials 500 mgVersion
2.0Revision Date:
10-27-2022Date of last issue: 02-19-2020
Date of first issue: 06-10-2017

Biodegradability : Result: Biodegradable
Biodegradation: 64 %
Exposure time: 29 d
Method: OECD Test Guideline 301B
GLP: yes

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

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

log Pow: 0.47
pH: 7.0

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

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

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

Distribution among environ-
mental 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 Pro-
tection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: This product neither contains, nor was manufac-
tured 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 infor-
mation : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
Very toxic to aquatic life with long lasting effects.

CELLCEPT(R) Lyophilized Vials 500 mgVersion
2.0Revision Date:
10-27-2022Date of last issue: 02-19-2020
Date of first issue: 06-10-2017**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.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

- 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

CELLCEPT(R) Lyophilized Vials 500 mgVersion
2.0Revision Date:
10-27-2022Date of last issue: 02-19-2020
Date of first issue: 06-10-2017**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.

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 : Combustible dust
Acute toxicity (any route of exposure)
Germ cell mutagenicity
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/ 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.

CELLCEPT(R) Lyophilized Vials 500 mg

Version
2.0

Revision Date:
10-27-2022

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

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

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Mycophenolate mofetil	128794-94-5
non hazardous compounds	Not Assigned
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	9005-65-6

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

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

- AIIC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

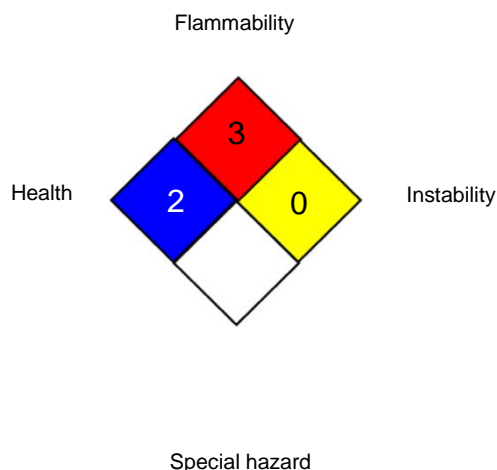
Mycophenolate mofetil

non hazardous compounds
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

CELLCEPT(R) Lyophilized Vials 500 mgVersion
2.0Revision Date:
10-27-2022Date of last issue: 02-19-2020
Date of first issue: 06-10-2017**SECTION 16. OTHER INFORMATION****NFPA 704:****HMIS® IV:**

HEALTH	*	3
FLAMMABILITY		3
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

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance

SAFETY DATA SHEET

CELLCEPT(R) Lyophilized Vials 500 mg

Version
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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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