SAFETY DATA SHEET

CELLCEPT(R) Capsules (250 mg)

SECTION 1. IDENTIFICATION

Product name : CELLCEPT(R) Capsules (250 mg)
Product code : 00010133839
Common name(s), synonym(s) of the substance : CELLCEPT Capsules (hard) 250 mg

Manufacturer or supplier's details
Company name of supplier : Genentech, Inc.
Address : DNA Way 1
94080 South San Francisco
CA
USA
Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com

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

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 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 - repeated exposure : Category 1

GHS label elements
Hazard pictograms
Signal Word : Danger
Hazard Statements : H302 Harmful if swallowed.
H341 Suspected of causing genetic defects.
H351 Suspected of causing cancer.
H360D May damage the unborn child.
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/ fume/ gas/ mist/ vapors/ spray.
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycophenolate moefitil</td>
<td>128794-94-5</td>
<td>66.1</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>7.9</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>3.1</td>
</tr>
<tr>
<td>2-Pyrrolidinone, 1-ethenyl-, homopolymer</td>
<td>9003-39-8</td>
<td>1.6</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>1.2</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>&lt;= 1.0</td>
</tr>
<tr>
<td>non hazardous compounds</td>
<td>Not Assigned</td>
<td>19.1</td>
</tr>
</tbody>
</table>

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:
- 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.

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 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.
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.

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

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycophenolate mofetil</td>
<td>128794-94-5</td>
<td>IOEL</td>
<td>0.01 mg/m3</td>
<td>Roche Industrial Hygiene Com-</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

CELLCEPT(R) Capsules (250 mg)

Version 0.0
Revision Date: 02-19-2020
Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
<th>Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycophenolic acid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium oxide (TiO₂)</td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>(Titanium dioxide) ACGIH</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC):

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycophenolate moftel</td>
<td>Surface waters</td>
<td>0.58 µg/l</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on chronic data</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Surface waters</td>
<td>64 µg/l</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on chronic data, Provisional antibiotic resistance PNEC</td>
<td></td>
</tr>
</tbody>
</table>

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

Material: Protective gloves

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

Eye protection: Eye wash bottle with pure water
Tightly fitting safety goggles

Skin and body protection: Choose body protection according to the amount and
Protective measures: Instruction of employees recommended
Hygiene measures: When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>capsules</td>
</tr>
<tr>
<td>Color</td>
<td>brown light blue</td>
</tr>
<tr>
<td>Odor</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not applicable</td>
</tr>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting point/range</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point/boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Self-ignition</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Viscosity
  Viscosity, dynamic: Not applicable
  Viscosity, kinematic: Not applicable
Oxidizing properties: No data available

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

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 532.36 mg/kg
  Method: Calculation method
Acute inhalation toxicity: Acute toxicity estimate: > 200 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

Components:
Mycophenolate mofetil:
Acute oral toxicity: LD50 Oral (Rat, female): 353 mg/kg
  LD50 Oral (Rat, male): 500 mg/kg
  LD0 (Rat): 250 mg/kg
  LD50 Oral (Mouse): > 4,000 mg/kg

Starch:
Acute oral toxicity: Acute toxicity estimate: > 5,001 mg/kg
  Method: Expert judgment
Acute inhalation toxicity: Acute toxicity estimate: > 30 mg/l
  Test atmosphere: dust/mist
Method: Expert judgment

Acute dermal toxicity: Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

Octadecanoic acid, magnesium salt (2:1):
Acute oral toxicity: LD50 Oral (Rat): > 2,000 mg/kg

Titanium oxide (TiO2):
Acute oral toxicity: LD50 (Rat): > 7,500 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 10,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:
Mycophenolate mofetil:
Species: laboratory animal
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

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.

Germ cell mutagenicity
Suspected of causing genetic defects.

Components:
Mycophenolate mofetil:
SAFETY DATA SHEET

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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

Carcinogenicity:
Suspected of causing cancer.

Components:

Mycophenolate mofetil:
- Species: laboratory animal
- Result: negative

IARC
Group 2B: Possibly carcinogenic to humans
Titanium oxide (TiO2) 13463-67-7

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity:
May damage the unborn child.

Components:

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

Reproductive toxicity - As: May damage the unborn child., Presumed human
STOT-single exposure
Not classified based on available information.

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

Octadecanoic acid, magnesium salt (2:1):
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure
Causes damage to organs through prolonged or repeated exposure.

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

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

Octadecanoic acid, magnesium salt (2:1):
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity
Not classified based on available information.

Components:
Starch:
No data available

Octadecanoic acid, magnesium salt (2:1):
No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
Mycophenolate mofetil:
Toxicity to fish: NOEC (Poecilia reticulata (guppy)): 1.7 mg/l
Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: no
Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): 27.7 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: no
Remarks: average measured concentration

Toxicity to algae/aquatic plants:
ErC50 (Desmodesmus subspicatus (green algae)): 0.6 mg/l
Exposure time: 72 h
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: no
Remarks: average measured concentration

EyC50 (Desmodesmus subspicatus (green algae)): 0.2 mg/l
Exposure time: 72 h
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: no
Remarks: average measured concentration

NOEC (Desmodesmus subspicatus (green algae)): 0.1 mg/l
Exposure time: 72 h
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration

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

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

ErC10 (Anabaena flos-aquae (cyanobacterium)): 0.155 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
**Toxicity to fish (Chronic toxicity)**
- EC10 (Danio rerio (zebra fish)): 0.0058 mg/l
- Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
- Method: OECD Test Guideline 210
- The value is given in analogy to the following substances: Mycophenolic acid

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

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

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

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

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

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

**Titanium oxide (TiO2):**
Toxicity to fish: LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates: EC0 (Daphnia magna (Water flea)): 3 mg/l
Exposure time: 720 h

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

Persistence and degradability

Components:

Mycophenolate mofetil:
Biodegradability: aerobic
   Inoculum: activated sludge, non-adapted
   Concentration: 100 mg/l
   Result: Not readily biodegradable.
   Biodegradation: < 6 %
   Exposure time: 28 d
   Method: OECD Test Guideline 301F
   GLP: no
   Remarks: Primary biodegradation

   Biodegradation: 82.2 %
   Testing period: 2.9 d
   Exposure time: 28 d
   Method: OECD Test Guideline 314
   GLP: yes
   Remarks: Ultimate aerobic biodegradation
   The value is given in analogy to the following substances:
   Mycophenolic acid

   Testing period: 1.7 d
   Method: OECD Test Guideline 314
   GLP: yes
   Remarks: Primary biodegradation
   The value is given in analogy to the following substances:
   Mycophenolic acid

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

Bioaccumulative potential

Components:

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

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

Octadecanoic acid, magnesium salt (2:1):
Partition coefficient: n-octanol/water
log Pow: 0.8
Method: OECD Test Guideline 107

Titanium oxide (TiO2):
Partition coefficient: n-octanol/water
Remarks: No data available

Mobility in soil

Components:

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

Medium: Sludge
Koc: 30 - 37 ml/g
Kd: 9.3 - 13 ml/g
Method: OECD Test Guideline 106

Other adverse effects

Product:
Ozone-Depletion Potential
Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues
The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

Contaminated packaging:
Empty remaining contents.
Dispose of as unused product.
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**: 
- **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
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CELLCEPT(R) Capsules (250 mg)

Packing group : III
Labels : Class 9 - Miscellaneous dangerous substances and articles
ERG Code : 171
Marine pollutant : no

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

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know
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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component TPQ (lbs)</th>
</tr>
</thead>
</table>

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

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

Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know
Starch 9005-25-8
Titanium oxide (TiO2) 13463-67-7

Pennsylvania Right To Know
Mycophenolate mofetil 128794-94-5
Maine Chemicals of High Concern

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

California Prop. 65
WARNING: This product can expose you to chemicals including Titanium oxide (TiO2), which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
Starch 9005-25-8
Octadecanoic acid, magnesium salt (2:1) 557-04-0
Titanium oxide (TiO2) 13463-67-7

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

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

- AICS: Not in compliance with the inventory
- 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: Substance(s) not listed on TSCA 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

NFPA:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Special hazard</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
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HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>0</td>
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</tbody>
</table>

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. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
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

AICS - Australian Inventory of Chemical Substances; 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 Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of
SAFETY DATA SHEET

CELLCEPT(R) Capsules (250 mg)

Version 0.0  
Revision Date: 02-19-2020  
Date of last issue: 06-10-2017  
Date of first issue: 06-10-2017

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; 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 : 02-19-2020

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 1810