SAFETY DATA SHEET

CELLCEPT(R) Film Coated Tablets (500 mg)

SECTION 1. IDENTIFICATION

Product name : CELLCEPT(R) Film Coated Tablets (500 mg)
Product code : 00010062347
Common name(s), synonym(s) of the substance : CELLCEPT F.C. Tablets 500mg
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 : US Chemtrec phone (800)-424-9300
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 : [Diagram]
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 mofetil</td>
<td>128794-94-5</td>
<td>59.7</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>29.1</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>3.9</td>
</tr>
<tr>
<td>2-Pyrrolidinone, 1-ethenyl-, homopolymer</td>
<td>9003-39-8</td>
<td>2.9</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>1.5</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>&lt;= 0.9</td>
</tr>
<tr>
<td>non hazardous compounds</td>
<td>Not Assigned</td>
<td>2.0</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

Storage temperature:
- Protected from heat and light

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

Packaging material:
- Suitable material: Polyethylene bag in metal drum, Plastic container of HDPE, Blister packages

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameter</th>
<th>Basis</th>
</tr>
</thead>
</table>

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CELLCEPT(R) Film Coated Tablets (500 mg)

Version 1.1
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>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycophenolate mofetil</td>
<td>Surface waters</td>
<td>0.58 µg/l</td>
<td>Based on chronic data</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Remarks: Provisional antibiotic resistance PNEC</td>
</tr>
<tr>
<td>Cellulose</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></td>
<td>TWA (Total dust)</td>
<td>15 mg/m³</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable dust fraction)</td>
<td>5 mg/m³</td>
<td>OSHA P0</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 (Titanium dioxide)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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

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

**Engineering measures**

<table>
<thead>
<tr>
<th>Engineering measures</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Personal protective equipment**

**Respiratory protection**

<table>
<thead>
<tr>
<th>Respiratory protection</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the case of dust or aerosol formation use respirator with an approved filter.</td>
<td></td>
</tr>
<tr>
<td>Effective dust mask</td>
<td></td>
</tr>
</tbody>
</table>

**Hand protection**

<table>
<thead>
<tr>
<th>Material</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protective gloves</td>
<td>Wear appropriate protective gloves to prevent skin contact.</td>
</tr>
</tbody>
</table>
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Eye protection : Eye wash bottle with pure water
: Tightly fitting safety goggles

Skin and body protection : Dust impervious protective suit
: Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Protective measures : Instruction of employees mandatory

Hygiene measures : When using do not eat or drink.
: When using do not smoke.
: Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet
Odor : Not applicable
Odor Threshold : Not applicable
pH : Not applicable
Melting point/range : No data available
Boiling point/boiling range : No data available
Evaporation rate : No data available
Self-ignition : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
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
SAFETY DATA SHEET

CELLCEPT(R) Film Coated Tablets (500 mg)

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
Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Harmful if swallowed.

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

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

Cellulose:
Acute oral toxicity : LD50 Oral (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg
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:
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

Cellulose:  
Remarks: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC  
Group 2B: Possibly carcinogenic to humans  
Titanium oxide (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 - Ass.: May damage the unborn child., Presumed human
STOT-single exposure
Not classified based on available information.

Components:

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

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

Components:

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

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

Aspiration toxicity
Not classified based on available information.

Components:

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
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
Toxicity to algae/aquatic plants:

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

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

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

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

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

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

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:

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

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

Cellulose:

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

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 % at 37 °C (118 h)
Hydrolysis: 50 % at 37 °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

Cellulose:
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:

<table>
<thead>
<tr>
<th>Medium</th>
<th>Koc (ml/g)</th>
<th>Kd (ml/g)</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soil</td>
<td>168 - 557</td>
<td>2.2 - 5.5</td>
<td>OECD Test Guideline 106</td>
<td>Mobile in soils, not expected to adsorb on soil.</td>
</tr>
<tr>
<td>Sludge</td>
<td>30 - 37</td>
<td>9.3 - 13</td>
<td>OECD Test Guideline 106</td>
<td></td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>UN number</th>
<th>Proper shipping name</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 3077</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,</td>
</tr>
</tbody>
</table>

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SAFETY DATA SHEET

CELLCEPT(R) Film Coated Tablets (500 mg)

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: 9
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

Domestic regulation

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

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: 9
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.
SAFETY DATA SHEET

CELLCEPT(R) Film Coated Tablets (500 mg)

Version 1.1
Revision Date: 02-19-2020
Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

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. Clean Water Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water 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
- Cellulose 9004-34-6

Pennsylvania Right To Know
- Mycophenolate mofetil 128794-94-5
- Cellulose 9004-34-6
- Croskarmellose sodium 74811-65-7

Maine Chemicals of High Concern

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

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

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

California Permissible Exposure Limits for Chemical Contaminants
- Cellulose 9004-34-6
- Octadecanoic acid, magnesium salt (2:1) 557-04-0
The ingredients of this product are reported in the following inventories:

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

- **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.

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**SECTION 16. OTHER INFORMATION**
NFPA:

HMIS® IV:

<table>
<thead>
<tr>
<th>Category</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEALTH</td>
<td>* 3</td>
</tr>
<tr>
<td>FLAMMABILITY</td>
<td>0</td>
</tr>
<tr>
<td>PHYSICAL HAZARD</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 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;
SAFETY DATA SHEET

CELLCEPT(R) Film Coated Tablets (500 mg)

Version 1.1
Revision Date: 02-19-2020
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Date of first issue: 06-10-2017

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