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 : 1 DNA Way
South San Francisco, CA 94080
USA

Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com
Emergency telephone : 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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 4
Germ cell mutagenicity : Category 2
Carcinogenicity : Category 2
Reproductive toxicity : Category 1B
Specific target organ toxicity - 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.
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

<table>
<thead>
<tr>
<th>Components</th>
<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>66.1</td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>7.9</td>
<td></td>
</tr>
<tr>
<td>Croskarmellose sodium</td>
<td>74811-65-7</td>
<td>3.1</td>
<td></td>
</tr>
<tr>
<td>2-Pyrollidinone, 1-ethenyl-, homopolymer</td>
<td>9003-39-8</td>
<td>1.6</td>
<td></td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>1.2</td>
<td></td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>non hazardous compounds</td>
<td>Not Assigned</td>
<td>19.1</td>
<td></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 firefighting
- Do not allow run-off from fire fighting to enter drains or water courses.

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

Further information
- Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
- Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Special protective equipment for fire-fighters
- Wear self-contained breathing apparatus for firefighting if necessary.
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 In-</td>
</tr>
</tbody>
</table>
The value is given in analogy to the following substances:
Mycophenolic acid

<table>
<thead>
<tr>
<th>Starch</th>
<th>9005-25-8</th>
<th>TWA</th>
<th>10 mg/m³</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>15 mg/m³</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<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>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2.5 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>0.2 mg/m³ (Titanium dioxide)</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>
</tr>
</thead>
<tbody>
<tr>
<td>Mycophenolate mofetil</td>
<td>Surface waters</td>
<td>0.58 µg/l</td>
</tr>
</tbody>
</table>

**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

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 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

Appearance: capsules

Color: brown
light blue

Odor: Not applicable

Odor Threshold: Not applicable

pH: Not applicable

Melting point/range: No data available

Boiling point/boiling range: No data available

Flash point: No data available

Evaporation rate: No data available

Self-ignition: No data available

Upper explosion limit / Upper flammability limit: 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
Components:

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

Starch:
- Acute oral toxicity: Acute toxicity estimate: > 5,000 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: > 5,000 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): > 5,000 mg/kg
  Method: OECD Test Guideline 425
- Acute inhalation toxicity: LC50 (Rat): > 6.82 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

Mycophenolate mofetil:
- Species: laboratory animal
- Result: No skin irritation

Titanium oxide (TiO2):
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Mycophenolate mofetil:
- Species: laboratory animal
Result : No eye irritation

Titanium oxide (TiO2):
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:
Mycophenolate mofetil:
Result : Did not cause sensitization on laboratory animals.

Titanium oxide (TiO2):
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406

Germ cell mutagenicity
Suspected of causing genetic defects.

Components:
Mycophenolate mofetil:
Genotoxicity in vitro : Test Type: Ames test
Result: negative
The value is given in analogy to the following substances:
Mycophenolic acid

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 473
Result: negative
The value is given in analogy to the following substances:
Mycophenolic acid

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: positive
The value is given in analogy to the following substances:
Mycophenolic acid

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Method: OECD Test Guideline 474
Result: positive
The value is given in analogy to the following substances:
Mycophenolic acid
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Revision Date: 10-27-2022
Date of last issue: 02-19-2020
Date of first issue: 06-10-2017

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 - Assessment : May damage the unborn child., Presumed human reproductive toxicant

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
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
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: no

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: no
Remarks: nominal concentration

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

Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): 0.6 mg/l
Exposure time: 72 h
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: no
Remarks: average measured concentration
<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (mg/l)</th>
<th>Exposure Time</th>
<th>Analytical Monitoring</th>
<th>Method</th>
<th>GLP</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EyC50 (Desmodesmus subspicatus (green algae))</td>
<td>0.2</td>
<td>72 h</td>
<td>yes</td>
<td>OECD Test Guideline 201</td>
<td>no</td>
<td>average measured concentration</td>
</tr>
<tr>
<td>NOEC (Desmodesmus subspicatus (green algae))</td>
<td>0.1</td>
<td>72 h</td>
<td>yes</td>
<td>OECD Test Guideline 201</td>
<td>no</td>
<td>nominal concentration</td>
</tr>
<tr>
<td>Lowest Observed Effect Concentration (Desmodesmus subspicatus (green algae))</td>
<td>1.6</td>
<td>14 d</td>
<td>yes</td>
<td>OECD Test Guideline 201</td>
<td>no</td>
<td>nominal concentration</td>
</tr>
<tr>
<td>ErC50 (Anabaena flos-aquae (cyanobacterium))</td>
<td>0.423</td>
<td>72 h</td>
<td>yes</td>
<td>OECD Test Guideline 201</td>
<td>yes</td>
<td>average measured concentration</td>
</tr>
<tr>
<td>ErC10 (Anabaena flos-aquae (cyanobacterium))</td>
<td>0.155</td>
<td>72 h</td>
<td>yes</td>
<td>OECD Test Guideline 201</td>
<td>yes</td>
<td>average measured concentration</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>EC10 (Danio rerio (zebra fish)): 0.0058 mg/l</td>
<td>34 d</td>
<td>Fish early-life stage (FELS) toxicity test (OECD 210)</td>
<td>OECD Test Guideline 210</td>
<td></td>
<td>Mycophenolic acid</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>EC10 (Daphnia magna (Water flea)): 0.929 mg/l</td>
<td>21 d</td>
<td></td>
<td>OECD Test Guideline 211</td>
<td></td>
<td>Mycophenolic acid</td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>(activated sludge): 100 mg/l</td>
<td>14 d</td>
<td>yes</td>
<td>OECD Test Guideline 301F</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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: LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
Exposure time: 96 h
Test Type: static test
LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: LC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h
Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l
Exposure time: 72 h
Method: ISO 10253

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

Persistence and degradability

Components:

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

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

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

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

Titanium oxide (TiO2):
Biodegradability : Remarks: Not applicable
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: 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
SAFETY DATA SHEET

CELLCEPT(R) Capsules 250 mg

Version 2.0
Revision Date: 10-27-2022
Date 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 : Acute toxicity (any route of exposure)
Germ cell mutagenicity
Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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

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

**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
- non hazardous compounds: Not Assigned
- Starch: 9005-25-8
- Croscarmellose sodium: 74811-65-7
- Titanium oxide (TiO2): 13463-67-7

**Maine Chemicals of High Concern**
Product does not contain any listed chemicals

**Vermont Chemicals of High Concern**
Product does not contain any listed chemicals

**Washington Chemicals of High Concern**
Product does not contain any listed chemicals

**California Prop. 65**
WARNING: This product can expose you to chemicals including Titanium oxide (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:

- **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
  - Croscarmellose sodium
- **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
SAFETY DATA SHEET

CELLCEPT(R) Capsules 250 mg

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

TSCA list
No substances are subject to a Significant New Use Rule.
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA 704:

HMIS® IV:

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average
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.

US / Z8 / 2104