SECTION 1. IDENTIFICATION

Product name: CELLCEPT(R) Oral Suspension 200 mg/ml

Product code: RO106-1443/Z06

Common name(s), synonym(s) of the substance: CELLCEPT Oral Suspension (200 mg/ml)

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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral): Category 4
Germ cell mutagenicity: 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.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td>Mycophenolate mofetil</td>
<td>128794-94-5</td>
<td>20.0</td>
</tr>
<tr>
<td></td>
<td>D-Glucitol</td>
<td>50-70-4</td>
<td>39.9</td>
</tr>
<tr>
<td></td>
<td>Sodium citrate</td>
<td>6132-04-3</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>Silica</td>
<td>7631-86-9</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>Benzoic acid, 4-hydroxy-, methyl ester</td>
<td>99-76-3</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>Lecithins</td>
<td>8002-43-5</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>non hazardous compounds</td>
<td>Not Assigned</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Xanthan gum</td>
<td>11138-66-2</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>L-Phenylalanine, L-.alpha.-aspartyl-, 2-methyl ester</td>
<td>22839-47-0</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>Water</td>
<td>7732-18-5</td>
<td>&gt; 37.0</td>
</tr>
<tr>
<td></td>
<td>1,2,3-Propanetricarboxylic acid, 2-hydroxy-</td>
<td>77-92-9</td>
<td>0.02</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES
SAFETY DATA SHEET

CELLCEPT(R) Oral Suspension 200 mg/ml

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.
- 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:
- Carbon oxides
- In case of fire hazardous decomposition products may be produced such as:
  - Sodium oxides

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:
- Wear self-contained breathing apparatus for firefighting if...
for fire-fighters necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Refer to protective measures listed in sections 7 and 8.

Environmental precautions: Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion: Normal measures for preventive fire protection.

Advice on safe handling: 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: Do not freeze. Protected from heat and light

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

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters
SAFETY DATA SHEET

CELLCEPT(R) Oral Suspension 200 mg/ml

Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis
--- | --- | --- | --- | ---
Mycophenolate mofetil | 128794-94-5 | IOEL | 0.01 mg/m³ | Roche Industrial Hygiene Committee (RIHC)
Mycophenolic acid | | | | |
Silica | 7631-86-9 | TWA (Dust) | 20 Million particles per cubic foot (Silica) | OSHA Z-3
TWA | | | 80 mg/m³ / %SiO₂ (Silica) | OSHA Z-3
TWA | | | 6 mg/m³ (Silica) | NIOSH REL

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>
<tr>
<td>Remarks: Based on chronic data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surface waters</td>
<td></td>
<td>64 µg/l</td>
</tr>
<tr>
<td>Remarks: Based on chronic data, Provisional antibiotic resistance PNEC</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Engineering measures: No data available

Personal protective equipment

Respiratory protection: In the case of vapor formation use a respirator with an approved filter.

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: Impervious clothing. Choose body protection according to the amount and concentration of the dangerous substance at the work place.

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
**SAFETY DATA SHEET**

**CELLCEPT(R) Oral Suspension 200 mg/ml**

**Version**: 1.0  
**Revision Date**: 11-13-2020  
**Date of last issue**: -  
**Date of first issue**: 11-13-2020

**Appearance**: suspension  
**Color**: off-white, white  
**Odor**: No data available  
**Odor Threshold**: No data available  
**pH**: No data available  
**Melting point/range**: No data available  
**Boiling point/boiling range**: No data available  
**Flash point**: does not flash  
**Evaporation rate**: No data available  
**Self-ignition**: Not applicable  
**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**: No data available  
**Relative density**: No data available  
**Solubility(ies)**  
  **Water solubility**: No data available  
  **Solubility in other solvents**: No data available  
**Partition coefficient: n-octanol/water**: No data available  
**Autoignition temperature**: No data available  
**Decomposition temperature**: No data available  
**Viscosity**  
  **Viscosity, dynamic**: No data available  
  **Viscosity, kinematic**: No data available

---

**SECTION 10. STABILITY AND REACTIVITY**

**Reactivity**: No dangerous reaction known under conditions of normal use.  
**Chemical stability**: Stable under normal conditions.
SAFETY DATA SHEET

CELLCEPT(R) Oral Suspension 200 mg/ml

Possibility of hazardous reactions: No decomposition if stored and applied as directed.

Conditions to avoid: No data available

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: 1,753 mg/kg
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

Silica:
Acute oral toxicity: LD50 Oral (Rat): > 3,300 mg/kg

Acute inhalation toxicity: LC50 (Rat, male and female): > 5.01 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 436
GLP: yes
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity: LD50 Dermal (Rabbit): > 5,000 mg/kg
Method: No information available.
GLP: No information available.

Skin corrosion/irritation
Not classified based on available information.

Components:

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

Silica:
Species: Rabbit
Exposure time: 4 h
Method: OECD Test Guideline 404
Result: No skin irritation
GLP: No information available.

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

Components:

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

Silica:
Species: Rabbit
Result: No eye irritation
Exposure time: 24 h
GLP: no

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.

Silica:
Test Type: Maximization Test
Species: Guinea pig
Assessment: Does not cause skin sensitization.
Method: OECD Test Guideline 406
Result: Did not cause sensitization on laboratory animals.
GLP: yes

Germ cell mutagenicity
Suspected of causing genetic defects.

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

Silica:
Genotoxicity in vitro:
Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 490
Result: negative
GLP: yes

Genotoxicity in vivo:
Species: Rat (male)
Cell type: Bone marrow
Application Route: Oral
Exposure time: 6, 24, and 48 h
Dose: 1.4, 14, 140, 500, 5000 mg/kg
Method: OECD Test Guideline 475
Result: negative
Carcinogenicity
Not classified based on available information.

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

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

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

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

Reproductive toxicity
May damage the unborn child.

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

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

Silica:
Effects on fertility: Species: Rat, male and female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
General Toxicity Parent: NOAEL: >= 1,000 mg/kg body weight
General Toxicity F1: NOAEL: >= 1,000 mg/kg body weight
Method: OECD Test Guideline 416
GLP: yes

Effects on fetal development: Species: Mouse, female
Application Route: Oral
Dose: 13.4, 62.3, 289, 1340 mg/kg bw/day
Duration of Single Treatment: 6 - 15 d
General Toxicity Maternal: LOAEL: >= 1,340 mg/kg bw/day
Embryo-fetal toxicity: NOAEL: >= 1,340 µg/kg body weight
Method: No information available.
GLP: No information available.

STOT-single exposure
Not classified based on available information.
SAFETY DATA SHEET

CELLCEPT(R) Oral Suspension 200 mg/ml

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.

Aspiration toxicity
Not classified based on available information.

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

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:**

**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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycophenolic acid</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>End point: mortality</th>
</tr>
</thead>
</table>

**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

**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

**Silica**

**Toxicity to fish**

<table>
<thead>
<tr>
<th>End point: mortality</th>
</tr>
</thead>
</table>

**EC10 (Danio rerio (zebra fish)):** 10.000 mg/l
- **Exposure time:** 96 h
- **Test Type:** static test
- **Analytical monitoring:** no
- **Method:** OECD Test Guideline 203
- **GLP:** yes

**End point:** mortality

---
Toxicity to daphnia and other aquatic invertebrates: (Daphnia magna (Water flea)): > 10,000 mg/l
End point: Immobilization
Exposure time: 24 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 173.1 mg/l
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): Lowest Observed Effect Concentration (Daphnia magna (Water flea)): 149.2 mg/l
End point: mortality
Exposure time: 21 d
Analytical monitoring: yes
Method: OECD Test Guideline 211
GLP: yes

Toxicity to microorganisms: NOEC (activated sludge): 1,000 mg/l
Exposure time: 3 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 209
GLP: yes

Ecotoxicology Assessment
Toxicity Data on Soil: Not expected to adsorb on soil.

Other organisms relevant to the environment: No data available

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)  

Silica:  
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  

Silica:  
Partition coefficient: n-octanol/water  
Remarks: Not applicable  

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. Toxic to aquatic life. 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 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mycophenolate-mofetil)

Class: 9
Packing group: III
Labels: 9

IATA-DGR

UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Mycophenolate-mofetil)

Class: 9
Packing group: III
Labels: 
Packing instruction (cargo aircraft): 964
Packing instruction: 964
SAFETY DATA SHEET

CELLCEPT(R) Oral Suspension 200 mg/ml

Version: 1.0  
Revision Date: 11-13-2020 
Date of last issue: -  
Date of first issue: 11-13-2020

(passerger aircraft)  
Environmentally hazardous : yes  

IMDG-Code  
UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Mycophenolate-mofetil)  
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 for product as supplied.  

Domestic regulation  

49 CFR  
UN/ID/NA number : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Mycophenolate-mofetil)  
Class : 9  
Packing group : III  
Labels : CLASS 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.  

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  
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. 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. This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know
Silica 7631-86-9

Pennsylvania Right To Know
D-Glucitol 50-70-4
Water 7732-18-5
Mycophenolate mofetil 128794-94-5
Silica 7631-86-9

Maine Chemicals of High Concern
Benzoic acid, 4-hydroxy-, methyl ester 99-76-3

Vermont Chemicals of High Concern
Benzoic acid, 4-hydroxy-, methyl ester 99-76-3

Washington Chemicals of High Concern
Benzoic acid, 4-hydroxy-, methyl ester 99-76-3

California List of Hazardous Substances
Silica 7631-86-9

California Permissible Exposure Limits for Chemical Contaminants
Silica 7631-86-9

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

AICS: Not in compliance with the inventory

NZIoC: Not in compliance with the inventory

ENCS: 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:  
HMIS® IV:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
<th>Special hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>-</td>
<td>0</td>
<td>-</td>
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HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-3 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx -
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 / 1810