



Material Safety Data Sheet

# CELLCEPT (R) Powder for Oral Suspension

## 1. Product and Company Identification

Product name	CELLCEPT (R) Powder for Oral Suspension
Product code	2501481
Use	- Therapeutic Category: Immunosuppressant
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America  Phone 001-973/235 50 00 E-Mail info.sds@roche.com  US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300
Roche Nutley Inventory Code	25753196

## 2. Hazard identification

### Emergency Overview

Form	powder
Color	white to off-white
Hazard Overview	<ul style="list-style-type: none"><li>- Harmful if swallowed.</li><li>- May cause blood system changes.</li><li>- May cause lymphatic system effects.</li><li>- May cause birth defects based on animal data.</li><li>- Possible dust explosion hazard based on information on related materials</li></ul>
Potential Health Effects	<ul style="list-style-type: none"><li>- Exposure: Inhalation, Ingestion, Skin contact, Eye contact</li><li>- Target Organs: gastrointestinal system, Hematopoietic/blood system, Lymphatic system, Immune System</li><li>- Acute Effects: This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients., May cause gastrointestinal effects.</li><li>- Chronic Effects: May cause blood system changes., May cause lymphatic system effects., May cause immune system suppression.</li><li>- Carcinogenicity: formulation not listed by NTP, IARC or OSHA</li></ul>

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## GHS Classification

### Health Hazards:

- 3.1 oral Acute toxicity (Category 4)  
H302 Harmful if swallowed.
- 3.5 Germ cell mutagenicity (Category 2)  
H341 Suspected of causing genetic defects.
- 3.7 D Reproductive toxicity (Category 1B)  
H360D May damage the unborn child.
- 3.9 Specific target organ toxicity - Repeated exposure (Category 1)  
H372 Causes damage to organs.

Signalword: Danger

Label:



### Precautionary statements:

- P201 Obtain special instructions before use.
- P260 Do not breathe dust
- P273 Avoid release to the environment.
- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- P308 + P313 IF exposed or concerned: Get medical advice/attention.
- P405 Store locked up.

## Additional Health Information

- Reproduction Toxicity: May cause birth defects. Since this material may affect the developing fetus, females planning to have a child and pregnant women should exercise caution regarding exposure.
- It is also advisable for nursing mothers to exercise caution regarding exposure.

\*1 referring to: Mycophenolate mofetil

## 3. Composition/Information on ingredients

Ingredients	Concentration
Mycophenolate mofetil CAS: 128794-94-5	30-40 %

## 4. First-aid measures

Eye contact	- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	- remove immediately contaminated clothes, wash affected skin with plenty of water
Inhalation	- in case of inhalation remove to fresh air and seek medical aid
Ingestion	- consult physician

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### 5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable
Specific hazards	- consider dust explosion hazard
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

### 6. Accidental release measures

Personal precautions	- ensure adequate ventilation
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### 7. Handling and storage

#### Handling

Technical measures	- Use with adequate ventilation - processing in closed systems, if possible superposed by inert gas (e.g. nitrogen) - avoid dust formation; consider dust explosion hazard - take precautionary measures against electrostatic charging
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#### Storage

Storage conditions	- room temperature - dry and ventilated place
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### 8. Exposure controls/Personal protection

Engineering Measures	- see 7.
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.01 mg/m <sup>3</sup> *1

#### Personal protective equipment

Respiratory protection	- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. - Respiratory protection is recommended for dusty operations. - Use of a negative pressure air purifying, half face respirator with a toxic/dust/mist/fume high efficiency filter in the laboratory or a supplied-air full facepiece respirator or supplied-air hood for production operations is recommended.
Hand protection	- protective gloves
Eye protection	- tightly fitting safety glasses

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Body protection	- protective clothing	
General protective and hygiene measures	- instruction of employees mandatory - shower after work recommended	
*1 referring to:	Mycophenolate mofetil	
<b>9. Physical and chemical properties</b>		
Color	white to off-white	
Form	powder	
<b>10. Stability and reactivity</b>		
Stability	- stable under normal conditions	
Materials to avoid	- strong oxidizing agents	
<b>11. Toxicological information</b>		
Acute toxicity	- LD <sub>50</sub> > 4'000 mg/kg (oral, mouse)	*1
	- LD <sub>50</sub> 250 to 500 mg/kg (oral, rat)	*1
Local effects	- skin: non-irritant	*1
	- eye: non-irritant	*1
Sensitization	- non-sensitizing	*1
Carcinogenicity	- not carcinogenic (several species)	*1
Reproductive toxicity	- teratogenic (several species)	*1
*1 referring to:	Mycophenolate mofetil	
<b>12. Ecological information</b>		
Ready biodegradability	- not readily biodegradable ~ 14 %, 64 d (FDA Technical Assistance Document No. 3.11)	*1
	- not readily biodegradable primary degradation evidenced by HPLC < 6 %, 28 d (Manometric Respirometry Test, OECD No. 301 F)	*1
Inherent biodegradability	- evidence for medium-term biodegradation in surface waters (analogous to OECD 308, Transformation in natural water/sediment systems)	*1
	- inhibits anaerobic biodegradability at high concentrations (toxic to bacteria) complete primary degradation evidenced by HPLC 0 %, 62 d (Ultimate anaerobic biodegradability, ISO 11734)	*1

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Abiotic degradation	<ul style="list-style-type: none"> <li>- hydrolysis 5 mg/l, river water  <math>t_{1/2} \leq 5</math> d, ~ 20 °C                      Identified decomp. products:                      Mycophenolic acid (CAS 24280-93-1) <span style="float: right;">*1</span></li> <li>- rapid degradation, photodegradation, hydrolysis 22.3 mg/l, water;                      HPLC                      ~ 37 %, 120 h, ~ 22 °C, dark                      ~ 67 %, 120 h, ~ 22 °C, under illumination <span style="float: right;">*1</span></li> </ul>
Ecotoxicity	<ul style="list-style-type: none"> <li>- barely toxic for planktonic crustaceans (Daphnia magna)                      EC<sub>50</sub> ~ 755 mg/l <span style="float: right;">*1</span></li> <li>- highly toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)                      ErC<sub>50</sub> (72 h) 0.6 mg/l (average measured concentration)                      EbC<sub>50</sub> (72 h) 0.2 mg/l (average measured concentration)                      NOEC (72 h) 0.1 mg/l (nominal concentration)                      (OECD No. 201) <span style="float: right;">*1</span></li> <li>- adaptation/recovery of organisms upon prolongation of test duration (Scenedesmus (=Desmodesmus) subspicatus)                      LOEC (14 d) 1.6 mg/l (nominal concentration)                      (OECD No. 201, prolonged) <span style="float: right;">*1</span></li> <li>- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Daphnia magna)                      EC<sub>50</sub> (48 h) &gt; 100 mg/l (nominal concentration)                      NOEC (48 h) 27.7 mg/l (average measured concentration)                      (OECD No. 202) <span style="float: right;">*1</span></li> <li>- acute fish toxicity in a limit test is lower than daphnid or algal toxicity, hence not relevant for classification (guppy)                      NOEC (96 h) 1.7 mg/l (highest tested concentration)                      (OECD No. 203) <span style="float: right;">*1</span></li> <li>- no adverse influence on substrate biodegradation (activated sludge)                      concentration (14 d) 100 mg/l (nominal concentration)                      (Manometric Respirometry Test, OECD No. 301 F) <span style="float: right;">*1</span></li> </ul>
Mobility	<ul style="list-style-type: none"> <li>- strong adsorption to activated sludge (water-activated sludge, 24 h, ~22 °C)                      K<sub>d</sub> = 830000 l/kg                      (Adsorption to activated sludge in biodegradability test) <span style="float: right;">*1</span></li> </ul>
Air pollution	<ul style="list-style-type: none"> <li>- observe local/national regulations <span style="float: right;">*1</span></li> </ul>
*1	referring to: Mycophenolate mofetil

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### 13. Disposal considerations

Waste from residues

- observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing
- DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

### 14. Transport information

DOT	Class	UN/ID	PG	PI	RQ	Label	Haz.no
	9	3077	III			9	

DOT Remark:

- NON-REGULATED IN NON-BULK PACKAGINGS TRANSPORTED BY MOTOR VEHICLES, RAIL CARS OR AIRCRAFT (49CFR 171.4(c)).

Proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Technical name

Mycophenolate mofetil

### 15. Regulatory information

TSCA Status

- FDA Exemption - not on inventory

Reporting Requirements

- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

### 16. Other information

Edition documentation

- changes from previous version in sections 2, 8, 12, 13, 14

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.