



Material Safety Data Sheet

# CELLCEPT(R) Lyophilized Vials (500 mg)

## 1. Product and Company Identification

Product name	CELLCEPT(R) Lyophilized Vials (500 mg)	
Product code	03 4126 6	
Use	- CELLCEPT(R) is a pharmaceutical product used to prevent organ transplant rejection.	
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	Local representation:
	Phone 001-973/235 50 00 E-Mail info.sds@roche.com	
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	

## 2. Hazards identification

### Emergency Overview

Form	lyophilized powder
Color	white
Hazard Overview	<ul style="list-style-type: none"><li>- May cause allergic reactions.</li><li>- Harmful if swallowed.</li><li>- May cause birth defects based on animal data.</li></ul>
Potential Health Effects	<ul style="list-style-type: none"><li>- Exposure: Inhalation, Ingestion, Skin contact, Eye contact</li><li>- Target Organs: eye, skin, gastrointestinal system, Immune System</li> <li>- Acute Effects: May cause eye irritation., May cause skin irritation., 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., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.</li> <li>- Chronic Effects: May cause allergic reactions., May cause immune system suppression.</li> <li>- Carcinogenicity: formulation not listed by NTP, IARC or OSHA</li></ul>

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- Additional Health Information
- Reproductive Toxicity: May cause birth defects based on animal data. 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.

### 3. Composition/Information on ingredients

Characterization	final product
<b>Ingredients</b>	<b>Concentration</b>
Mycophenolate mofetil CAS: 128794-94-5	~ 64 %
Hydrochloric acid (1.0 N) CAS: 7647-01-0	~ 15 %

### 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

### 5. Fire-fighting measures

- Suitable extinguishing media
- water spray jet, dry powder, foam, carbon dioxide
- Flash point (liquid)
- not applicable
- Specific hazards
- Toxic emissions may be given off in a fire
- Protection of fire-fighters
- use self-contained breathing apparatus
- Special method of fire-fighting
- cool endangered containers with water spray

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### 6. Accidental release measures

- |                          |  |
|--------------------------|--|
| Personal precautions     | - ensure adequate ventilation  |
| Environmental protection | - avoid release to the environment   |
| Methods for cleaning up  | - Scoop or shovel spilled material into a suitable labeled open head drum<br>- Secure the drum cover and move the container to a safe holding area<br>- Clean spill area thoroughly<br>- Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.<br>- Check area for residual material and repeat clean up if detected |

### 7. Handling and storage

#### Handling

- |                    |                                       |
|--------------------|---------------------------------------|
| Technical measures | - local exhaust ventilation necessary |
|--------------------|---------------------------------------|

#### Storage

- |                    |  |
|--------------------|--|
| Storage conditions | - keep containers tightly closed<br>- room temperature<br>- store in a dry place<br>- protected from light |
|--------------------|--|

### 8. Exposure controls/Personal protection

- |                             |   |          |
|-----------------------------|---|----------|
| <b>Engineering Measures</b> | - see 7.  |          |
| Threshold value (USA) air   | - STEL: 7.5 mg/m <sup>3</sup> (STEL=ceiling limit)  | *1       |
| Threshold value (Roche) air | - IOEL (Internal Occupational Exposure Limit): 0.1 mg/m <sup>3</sup> (Internal Occupational Exposure Limit, men)<br>- IOEL (Internal Occupational Exposure Limit): 0.01 mg/m <sup>3</sup> (women of childbearing age) | *2<br>*2 |

#### 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.<br>- respiratory protection not necessary |
| Hand protection        | - protective gloves   |
| Eye protection         | - safety glasses  |

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Body protection - protective clothing

\*1 referring to: Hydrochloric acid (1.0 N)

\*2 referring to: Mycophenolate mofetil

### 9. Physical and chemical properties

Color white

Form lyophilized powder

Solubility soluble, water

### 10. Stability and reactivity

Stability - stable under the conditions mentioned in chapter 7

Conditions to avoid - high temperatures

Materials to avoid - strong acids, oxidizing agents

Note - Hazardous Polymerization: Will not occur.

### 11. Toxicological information

Acute toxicity	- LD <sub>50</sub>	900	mg/kg	(oral, rabbit)	*1
	- LC <sub>50</sub>	3'124	ppm	(inhal., rat, 1 h)	*1
	- LC <sub>10</sub>	1'300	ppm	(inhal., man, 30 min)	*1
	- LC <sub>10</sub>	3'000	ppm	(inhal., man, 5 min)	*1
	- LD <sub>50</sub>	250	to 500	mg/kg (oral, rat)	*2

Local effects	- skin: non-irritant	*2
	- eye: non-irritant	*2

Sensitization	- non-sensitizing	*2
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Mutagenicity	- not mutagenic (various in vivo and in vitro test systems)	*2
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Carcinogenicity	- not carcinogenic (several species)	*2
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Reproduction toxicity	- teratogenic (several species)	*2
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\*1 referring to: Hydrochloric acid (1.0 N)

\*2 referring to: Mycophenolate mofetil

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### 12. Ecological information

Ready biodegradability	- not readily biodegradable ~ 14 %, 64 d (FDA Technical Assistance Document No. 3.11)	*2
	- not readily biodegradable primary degradation evidenced by HPLC < 6 %, 28 d (Manometric Respirometry Test, OECD No. 301 F)	*2
Inherent biodegradability	- evidence for medium-term biodegradation in surface waters (analogous to OECD 308, Transformation in natural water/sediment systems)	*2
	- inhibits anaerobic biodegradability at high concentrations (toxic to bacteria) complete primary degradation evidenced by HPLC 0 %, 62 d (Ultimate anaerobic biodegradability, ISO 11734)	*2
Abiotic degradation	- hydrolysis (5 mg/l, river water) $t_{1/2} \leq 5$ d, ~ 20 °C Identified decomp. products: Mycophenolic acid (CAS 24280-93-1)	*2
	- rapid degradation, photodegradation, hydrolysis (22.3 mg/l, water; HPLC) ~ 37 %, 120 h, ~ 22 °C, dark ~ 67 %, 120 h, ~ 22 °C, under illumination	*2
Ecotoxicity	- barely toxic for planktonic crustaceans ( <i>Daphnia magna</i> ) EC <sub>50</sub> ~ 755 mg/l	*2
	- highly toxic for algae ( <i>Scenedesmus (=Desmodesmus)</i> 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)	*2
	- adaptation/recovery of organisms upon prolongation of test duration ( <i>Scenedesmus (=Desmodesmus)</i> subspicatus) LOEC (14 d) 1.6 mg/l (nominal concentration) (OECD No. 201, prolonged)	*2
	- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions ( <i>Daphnia magna</i> ) EC <sub>50</sub> (48 h) > 100 mg/l (nominal concentration) NOEC (48 h) 27.7 mg/l (average measured concentration) (OECD No. 202)	*2
	- 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)	*2
	- no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 100 mg/l (nominal concentration) (Manometric Respirometry Test, OECD No. 301 F)	*2

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Mobility - strong adsorption to activated sludge (water-activated sludge, 24 h, ~22 °C)  
 $K_d = 830000 \text{ l/kg}$   
(Adsorption to activated sludge in biodegradability test) \*2

\*2 referring to: Mycophenolate mofetil

### 13. Disposal considerations

Waste from residues - incinerate in qualified installation with flue gas scrubbing  
- observe local/national regulations regarding waste disposal  
- 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.

Contaminated packaging - Empty containers must be triple rinsed prior to disposal, recycling or reuse.

RCRA waste - not regulated under RCRA

### 14. Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

### 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 - first edition

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.