



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	25 0148 1	
Use	- Therapeutic Category: Immunosuppressant	
Company information	Enquiries:	Local representation:
	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. Hazards identification

Emergency Overview

Form	powder
Color	white to off-white
Hazard Overview	<ul style="list-style-type: none">- Harmful if swallowed.- May cause blood system changes.- May cause lymphatic system effects.- May cause birth defects based on animal data.- Possible dust explosion hazard based on information on related materials
Potential Health Effects	<ul style="list-style-type: none">- Exposure: Inhalation, Ingestion, Skin contact, Eye contact- Target Organs: gastrointestinal system, Hematopoietic/blood system, Lymphatic system, Immune System- 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.- Chronic Effects: May cause blood system changes., May cause lymphatic system effects., May cause immune system suppression.- Carcinogenicity: formulation not listed by NTP, IARC or OSHA

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- 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.

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

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
- Methods for cleaning up
- Scoop or shovel spilled material into a suitable labeled open head drum
 - Secure the drum cover and move the container to a safe holding area
 - Mop or flush the area with water
 - Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.
 - Check area for residual material and repeat clean up if detected

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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

Storage

- Storage conditions
- room temperature
 - dry and ventilated place

8. Exposure controls/Personal protection

- Engineering Measures
- see 7.

- Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 0.1 mg/m³ (Internal Occupational Exposure Limit, men) *1
 - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³ (women of childbearing age) *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

- Body protection
- protective clothing

- General protective and hygiene measures
- instruction of employees mandatory
 - shower after work recommended

*1 referring to: Mycophenolate mofetil

9. Physical and chemical properties

Color white to off-white

Form powder

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10. Stability and reactivity

- Stability - stable under normal conditions
- Materials to avoid - strong oxidizing agents

11. Toxicological information

- Acute toxicity - LD₅₀ > 4'000 mg/kg (oral, mouse) *1
- LD₅₀ 250 to 500 mg/kg (oral, rat) *1
- Local effects - skin: non-irritant *1
- eye: non-irritant *1
- Sensitization - non-sensitizing *1
- Mutagenicity - not mutagenic (various in vivo and in vitro test systems) *1
- Carcinogenicity - not carcinogenic (several species) *1
- Reproduction toxicity - teratogenic (several species) *1

*1 referring to: Mycophenolate mofetil

12. Ecological information

- Ecotoxicity - barely toxic for planktonic crustaceans (Daphnia magna)
EC₅₀ ~ 755 mg/l *1

*1 referring to: Mycophenolate mofetil

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.
- RCRA waste - not regulated under RCRA

14. Transport information

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

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15. Regulatory information

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|------------------------|--|
| TSCA Status | - FDA Exemption - not on inventory |
| Reporting Requirements | <ul style="list-style-type: none">- 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

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| Edition documentation | - changes from previous version in sections 13 |
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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.