

**1. Product and Company Identification**

Product name	CELLCEPT(R) Capsules (250 mg)
Product code	SAP-10133839
Use	- pharmaceutical active substance (immunosuppressant) *1
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
*1 referring to:	Mycophenolate mofetil

**2. Hazard identification****Emergency Overview**

Form	capsules
Color	brown blue
Hazard Overview	- May cause allergic reactions. - Harmful if swallowed. - May cause birth defects based on animal data.
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Target Organs: eye, skin, gastrointestinal system, Immune System  - 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.  - Chronic Effects: May cause allergic reactions., May cause immune system suppression.  - Carcinogenicity: formulation not listed by NTP, IARC or OSHA

## CELLCEPT(R) Capsules (250 mg)

### 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

- 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

pharmaceutical product not ready for use

### Ingredients

### Concentration

Mycophenolate mofetil CAS: 128794-94-5	~ 83 %
Starch CAS: 9005-84-9	~ 10 %
Povidone K 90 CAS: 9003-39-8	~ 2 %
Magnesium stearate CAS: 557-04-0	~ 2 %

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### 4. First-aid measures

Eye contact	- rinse immediately with tap water for 10 minutes - open eyelids forcibly
Skin contact	- drench affected skin with water
Inhalation	- remove the casualty to fresh air - in the event of symptoms get medical treatment
Ingestion	- consult physician
Note to physician	- treat symptomatically

### 5. Fire-fighting measures

Suitable extinguishing media	- adapt extinguishing media to surrounding fire conditions
Flash point (liquid)	not applicable
Specific hazards	- Toxic emissions may be given off in a fire
Protection of fire-fighters	- precipitate gases/vapours/mists with water spray

### 6. Accidental release measures

Environmental protection	- do not allow to enter drains or waterways - if the substance reaches waters or the sewer system, inform the competent authority - the solvent should be held back due to environmental protection
Methods for cleaning up	- collect spilled material (avoid dust formation) and hand over to waste removal in sealed containers

### 7. Handling and storage

#### Handling

Technical measures	- no special measures necessary if stored and handled as prescribed
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#### Storage

Storage conditions	- keep containers tightly closed - room temperature - store in a dry place - protected from light
Packaging materials	- drums - lined with polyethylene bag

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### 8. Exposure controls/Personal protection

**Engineering Measures** - see 7.

#### Monitoring

Threshold value (USA) air

- ACGIH-TLV: 10 mg/m<sup>3</sup> \*2
- ACGIH-TLV: 10 mg/m<sup>3</sup> (not classifiable as a human carcinogen) \*3
- OSHA-PEL: 5 mg/m<sup>3</sup> (respirable fraction) \*3
- OSHA-PEL: 15 mg/m<sup>3</sup> (total dust) \*3
- NIOSH-REL: 5 mg/m<sup>3</sup> (respirable fraction) \*3
- NIOSH-REL: 15 mg/m<sup>3</sup> (total dust) \*3

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m<sup>3</sup> \*1

Analytics - sampling on glass fibre filter, desorption with methanol; basify with NaOH, heat; neutralize with HCl, HPLC analysis \*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 not necessary during normal operations

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

\*1 referring to: Mycophenolate mofetil  
\*2 referring to: Magnesium stearate  
\*3 referring to: Starch

### 9. Physical and chemical properties

Color brown  
blue

Form capsules

Solubility ≤ 22 mg/l, water (~ 22 °C, pH 6.3, HPLC, 24 h) \*1  
≤ 36 mg/l, aquatic ecotoxicity media (~ 22 °C, HPLC, 24 h) \*1

Partition coefficient log P<sub>ow</sub> 1.45 (n-octanol/water) pH 7.4 \*1

\*1 referring to: Mycophenolate mofetil

### 10. Stability and reactivity

Stability - stable under the conditions mentioned in chapter 7

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Conditions to avoid	- warming - light - humidity	
Materials to avoid	- strong oxidizing agents	*1
*1 referring to:	Mycophenolate mofetil	
<b>11. Toxicological information</b>		
Acute toxicity	- LD <sub>50</sub> 353 mg/kg (oral, rat); females, "trimmed Spearman-Karber method" - LD <sub>50</sub> 500 mg/kg (oral, rat); males, "trimmed Spearman-Karber method" - LD <sub>0</sub> 250 mg/kg (oral, rat) - LD <sub>50</sub> > 2'000 mg/kg (oral, rat)	*1 *1 *1 *2
Local effects	- skin: non-irritant - eye: non-irritant	*1 *1
Sensitization	- non-sensitizing	*1
Mutagenicity	- mutagenic (OECD No. 474 (Micronucleus Test)); threshold dose response - mutagenic (mouse lymphoma cell mutation test; OECD No. 476 (Mammalian Cell Gene Mutation Test)) - does not induce chromosomal aberrations in vitro (OECD No. 473 (Mammalian Cytogenic Test)) - not mutagenic (Ames test)	*4 *4 *4 *4
Carcinogenicity	- not carcinogenic (several species)	*1
Reproductive toxicity	- teratogenic (several species)	*1
Note	- immunosuppressive agent - average therapeutic dose 1 g twice daily - elimination half-life: 16-18 h - excretion predominantly renal - adverse effects at therapeutic dose: diarrhea, drop in white blood cell count, susceptibility to infections, vomiting - high doses may irritate the digestive tract	*1 *1 *1 *1 *1 *1
*1 referring to:	Mycophenolate mofetil	
*2 referring to:	Magnesium stearate	
*4 referring to:	Mycophenolic acid	
<b>12. Ecological information</b>		
Ready biodegradability	- not readily biodegradable ~ 14 %, 64 d (FDA Technical Assistance Document No. 3.11) - not readily biodegradable primary degradation evidenced by HPLC < 6 %, 28 d (Manometric Respirometry Test, OECD No. 301 F)	*1 *1

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Inherent biodegradability	- evidence for medium-term biodegradation in surface waters (analogous to OECD 308, Transformation in natural water/sediment systems)	*1
Abiotic degradation	- rapid degradation, photodegradation, hydrolysis 22.3 mg/l, water; HPLC ~ 37 %, 120 h, ~ 22 °C, dark ~ 67 %, 120 h, ~ 22 °C, under illumination	*1
Ecotoxicity	- 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) *1  - barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Daphnia magna) EC <sub>50</sub> (48 h) > 100 mg/l (nominal concentration) NOEC (48 h) 27.7 mg/l (average measured concentration) (OECD No. 202) *1  - 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) *1  - 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) *1  - no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 100 mg/l (nominal concentration) (Manometric Respirometry Test, OECD No. 301 F) *1	
Air pollution	- observe local/national regulations	*1
*1 referring to:	Mycophenolate mofetil	
<b>13. Disposal considerations</b>		
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.	

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<b>14. Transport information</b>								
IATA	Class	UN/ID	PG		PI	Label	Mark	
	9	3077	III		956/956	9	EHS	
IMDG	Class	UN	PG	EmS	PI	Label	Mark	
	9	3077	III	F-A S-F	P002/IBC08	9	marine pollutant	
RID/ADR	Class	UN	PG	Haz.no	PI	Label	Mark	Classif. code
	9	3077	III	90	P002/IBC08	9	EHS	M7
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						
<b>15. Regulatory information</b>								
TSCA Status		- FDA Exemption - not on inventory						
Reporting Requirements		<ul style="list-style-type: none"> <li>- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.</li> <li>- 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.</li> <li>- State and local regulations vary and may impose additional reporting requirements.</li> </ul>						

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### 16. Other information

Safety-lab number - BS-8818 \*1  
- BS-9333 \*1

Edition documentation - changes from previous version in sections 8

\*1 referring to: Mycophenolate mofetil

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.