

Safety Data Sheet

CELLCEPT(R) Capsules (250 mg)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name CELLCEPT(R) Capsules (250 mg)

Product code SAP-10093418

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use - pharmaceutical active substance (immunosuppressant) *1

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries:	Local representation:
	Genentech, Inc.	
	1 DNA Way	
	South San Francisco	
	USA-CA 94080	
	United States of America	
	Phone 001-(650) 225-1000	
	E-Mail info.sds@roche.com	
	US Chemtrec phone:	
	(800)-424-9300	

1.4. Emergency telephone number

Emergency telephone number US Chemtrec phone: (800)-424-9300

*1 referring to: Mycophenolate mofetil

CELLCEPT(R) Capsules (250 mg)

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

- 3.1 Acute toxicity (Category 4)
H302 Harmful if swallowed.
- 3.5 Germ cell mutagenicity (Category 2)
H341 Suspected of causing genetic defects.
- 3.7 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 through prolonged or repeated exposure.

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.

Other hazards

Note - no information available

SECTION 3: Composition/information on ingredients

Characterization

Mycophenolate mofetil and other inactive ingredients

Ingredients

Concentration

GHS-Classification (pure ingredient)

Mycophenolate mofetil
128794-94-5

~ 83 %

- Combustible dust (No category), USH003
- Acute toxicity (Category 4), H302
- Germ cell mutagenicity (Category 2), H341
- Reproductive toxicity (Category 1B), H360D
- Specific target organ toxicity - Repeated exposure (Category 1), H372

Starch
9005-84-9

~ 10 %

CELLCEPT(R) Capsules (250 mg)

Magnesium stearate ~ 2 %
557-04-0

Povidone K 90 ~ 2 %
9003-39-8

For the full text of the H-phrases mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1. Description of 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

4.2. Most important symptoms and effects, both acute and delayed

Note - no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician - treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media - adapt extinguishing media to surrounding fire conditions

Flash point (liquid) not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards - Toxic emissions may be given off in a fire

5.3. Advice for firefighters

Protection of fire-fighters - precipitate gases/vapours/mists with water spray

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - ensure adequate ventilation

CELLCEPT(R) Capsules (250 mg)

6.2. Environmental precautions

Environmental protection	<ul style="list-style-type: none">- 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
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6.3. Methods and material for containment and cleaning up

Methods for cleaning up	<ul style="list-style-type: none">- collect spilled material (avoid dust formation) and hand over to waste removal in sealed containers
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures	<ul style="list-style-type: none">- no special measures necessary if stored and handled as prescribed
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	<ul style="list-style-type: none">- keep containers tightly closed- room temperature- store in a dry place- protected from light
Packaging materials	<ul style="list-style-type: none">- drums- lined with polyethylene bag

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (USA) air	<ul style="list-style-type: none">- ACGIH-TLV: 10 mg/m³ *2- ACGIH-TLV: 10 mg/m³ (not classifiable as a human carcinogen) *3- OSHA-PEL: 5 mg/m³ (respirable fraction) *3- OSHA-PEL: 15 mg/m³ (total dust) *3- NIOSH-REL: 5 mg/m³ (respirable fraction) *3- NIOSH-REL: 15 mg/m³ (total dust) *3
Threshold value (Roche) air	<ul style="list-style-type: none">- IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³ *1

8.2. Exposure controls

Respiratory protection	<ul style="list-style-type: none">- 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	<ul style="list-style-type: none">- protective gloves (eg made of neoprene, nitrile or butyl rubber)

CELLCEPT(R) Capsules (250 mg)

Eye protection	- safety glasses	
Analytics	- sampling on glass fibre filter, desorption with methanol; basify with NaOH, heat; neutralize with HCl, HPLC analysis	*1
*1 referring to:	Mycophenolate mofetil	
*2 referring to:	Magnesium stearate	
*3 referring to:	Starch	

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	brown blue	
Form	oblong 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 _{ow} 1.45 (n-octanol/water) pH 7.4	*1

9.2. Other information

Note	- no information available
*1 referring to:	Mycophenolate mofetil

SECTION 10: Stability and reactivity

10.1. Reactivity

Note	- no information available
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10.2. Chemical stability

Stability	- stable under the conditions mentioned in chapter 7
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10.3. Possibility of hazardous reactions

Note	- no information available
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10.4. Conditions to avoid

Conditions to avoid	- warming - light - humidity
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CELLCEPT(R) Capsules (250 mg)

10.5. Incompatible materials

Materials to avoid - strong oxidizing agents *1

10.6. Hazardous decomposition products

Note - no information available

*1 referring to: Mycophenolate mofetil

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD ₅₀ 353 mg/kg (oral, rat); females, "trimmed Spearman-Kärber method"	*1
	- LD ₅₀ 500 mg/kg (oral, rat); males, "trimmed Spearman-Kärber method"	*1
	- LD ₀ 250 mg/kg (oral, rat)	*1
	- LD ₅₀ > 2'000 mg/kg (oral, rat)	*2
Local effects	- skin: non-irritant	*1
	- eye: non-irritant	*1
Sensitization	- non-sensitizing	*1
Mutagenicity	- mutagenic (OECD No. 474 (Micronucleus Test)); threshold dose response	*4
	- mutagenic (mouse lymphoma cell mutation test; OECD No. 476 (Mammalian Cell Gene Mutation Test))	*4
	- does not induce chromosomal aberrations in vitro (OECD No. 473 (Mammalian Cytogenic Test))	*4
	- not mutagenic (Ames test)	*4
Carcinogenicity	- not carcinogenic (several species)	*1
Reproductive toxicity	- teratogenic (several species)	*1
Note	- immunosuppressive agent	*1
	- average therapeutic dose 1 g twice daily	*1
	- elimination half-life: 16-18 h	*1
	- excretion predominantly renal	*1
	- adverse effects at therapeutic dose: diarrhea, drop in white blood cell count, susceptibility to infections, vomiting	*1
	- high doses may irritate the digestive tract	*1
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact	
	- Carcinogenicity: not listed by NTP, IARC or OSHA	

*1 referring to: Mycophenolate mofetil
 *2 referring to: Magnesium stearate
 *4 referring to: Mycophenolic acid

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	<ul style="list-style-type: none"> - 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) EC₅₀ (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) ErC₅₀ (72 h) 0.6 mg/l (average measured concentration) EbC₅₀ (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
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12.2. Persistence and degradability

Ready biodegradability	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - evidence for medium-term biodegradation in surface waters (analogous to OECD 308, Transformation in natural water/sediment systems) *1
Abiotic degradation	<ul style="list-style-type: none"> - rapid degradation, photodegradation, hydrolysis 22.3 mg/l, water; HPLC ~ 37 %, 120 h, ~ 22 °C, dark ~ 67 %, 120 h, ~ 22 °C, under illumination *1

12.3. Bioaccumulative potential

Note	- no information available
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12.4. Mobility in soil

Note	- no information available
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CELLCEPT(R) Capsules (250 mg)

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Air pollution - observe local/national regulations

*1

*1 referring to: Mycophenolate mofetil

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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.

SECTION 14: Transport information

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

CELLCEPT(R) Capsules (250 mg)

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

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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.

SECTION 16: Other information

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

Full text of H-Statements referred to under section 3

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.
USH003	May form combustible dust concentrations in the air

Note - Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

Edition documentation - changes from previous version in sections 2, 3, 16

***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.