

Safety Data Sheet

CELLCEPT(R) Film Coated Tablets (500 mg)

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

1.1. Product identifier

Product name	CELLCEPT(R) Film Coated Tablets (500 mg)
Product code	SAP-10062347
Synonyms	- CELLCEPT F.C. Tablets - CELLCEPT Film Coated Tablets

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

Use	- pharmaceutical active substance (immunosuppressant)	*1
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1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: 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	Local representation:
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1.4. Emergency telephone number

Emergency telephone number	US Chemtrec phone: (800)-424-9300
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*1 referring to:	Mycophenolate mofetil
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CELLCEPT(R) Film Coated Tablets (500 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 further 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

~ 62 %

- 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

Microcrystalline cellulose
9004-34-6

~ 30 %

CELLCEPT(R) Film Coated Tablets (500 mg)

Povidone K 90 ~ 3 %
9003-39-8

Magnesium stearate ~ 2 %
557-04-0

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	- in case of inhalation remove to fresh air and seek medical aid
Ingestion	- consult physician

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

Note - no information available

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
	- keep people away and stay on the upwind side

CELLCEPT(R) Film Coated Tablets (500 mg)

6.2. Environmental precautions

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|--------------------------|---|
| 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 |
|--------------------------|---|

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 |
|-------------------------|---|

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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| Technical measures | <ul style="list-style-type: none">- provide suitable exhaust ventilation at the processing machines |
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7.2. Conditions for safe storage, including any incompatibilities

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|--------------------|---|
| Storage conditions | <ul style="list-style-type: none">- keep containers tightly closed- room temperature- store in a dry place- protected from light |
|--------------------|---|

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 *3- OSHA-PEL: 5 mg/m³ (respirable dust fraction) *3- OSHA-PEL: 15 mg/m³ (total dust) *3- NIOSH-REL: 5 mg/m³ (respirable dust fraction) *3- NIOSH-REL: 10 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.- in case of open handling or accidental release:<ul style="list-style-type: none">particle mask or respirator with independent air supply- 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) |
| Eye protection | <ul style="list-style-type: none">- safety glasses |

CELLCEPT(R) Film Coated Tablets (500 mg)

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: Microcrystalline cellulose

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color country-specific
Form capsule-shaped tablet
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

10.2. Chemical stability

Stability - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Note - no information available

10.5. Incompatible materials

Materials to avoid - strong oxidizing agents *1

CELLCEPT(R) Film Coated Tablets (500 mg)

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	- 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 ₅₀ (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 ₅₀ (72 h) 0.6 mg/l (average measured concentration) EbC ₅₀ (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

12.2. Persistence and degradability

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
	- inherently biodegradable	*3
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

12.3. Bioaccumulative potential

Note	- no information available
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CELLCEPT(R) Film Coated Tablets (500 mg)

12.4. Mobility in soil

Note - no information available

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
 *3 referring to: Microcrystalline cellulose

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues

- return to supplier or hand over to authorized disposal company
- 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.

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) Film Coated Tablets (500 mg)

DOT	Class	UN/ID	PG	PI	RQ	Label	Haz.no
	9	3077	III			9	
<p>DOT Remark: - NON-REGULATED IN NON-BULK PACKAGINGS TRANSPORTED BY MOTOR VEHICLES, RAIL CARS OR AIRCRAFT (49CFR 171.4(c)).</p> <p>Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.</p> <p>Technical name Mycophenolate mofetil</p>							
SECTION 15: Regulatory information							
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture							
<p>TSCA Status - FDA Exemption - not on inventory</p> <p>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.</p>							
SECTION 16: Other information							
<p>Safety-lab number - BS-8818 *1 - BS-9333 *1</p> <p>Full text of H-Statements referred to under section 3</p> <p style="margin-left: 40px;">H302 Harmful if swallowed.</p> <p style="margin-left: 40px;">H341 Suspected of causing genetic defects.</p> <p style="margin-left: 40px;">H360D May damage the unborn child.</p> <p style="margin-left: 40px;">H372 Causes damage to organs through prolonged or repeated exposure.</p> <p style="margin-left: 40px;">USH003 May form combustible dust concentrations in the air</p> <p>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.</p> <p>Edition documentation - changes from previous version in sections 3, 13, 16</p> <p>*1 referring to: Mycophenolate mofetil</p>							
<p>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.</p>							