



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 2501481

Use - Therapeutic Category: Immunosuppressant

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

Roche Nutley Inventory Code 25753196

2. Hazard identification

Emergency Overview

Form powder

Color white to off-white

Hazard Overview

- 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

- 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

CELLCEPT (R) Powder for Oral Suspension

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

- 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.

*1 referring to:

Mycophenolate mofetil

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

CELLCEPT (R) Powder for Oral Suspension

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
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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
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Storage

Storage conditions	- room temperature - dry and ventilated place
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8. Exposure controls/Personal protection

Engineering Measures	- see 7.
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.01 mg/m ³ *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

CELLCEPT (R) Powder for Oral Suspension

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

10. Stability and reactivity

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

11. Toxicological information

- | | | |
|-----------------------|---|----|
| Acute toxicity | - LD ₅₀ > 4'000 mg/kg (oral, mouse) | *1 |
| | - LD ₅₀ 250 to 500 mg/kg (oral, rat) | *1 |
| Local effects | - skin: non-irritant | *1 |
| | - eye: non-irritant | *1 |
| Sensitization | - non-sensitizing | *1 |
| Carcinogenicity | - not carcinogenic (several species) | *1 |
| Reproductive toxicity | - teratogenic (several species) | *1 |

*1 referring to: Mycophenolate mofetil

12. Ecological information

- | | | |
|---------------------------|--|----|
| 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 |
| | - inhibits anaerobic biodegradability at high concentrations (toxic to
bacteria)
complete primary degradation evidenced by HPLC
0 %, 62 d
(Ultimate anaerobic biodegradability, ISO 11734) | *1 |

CELLCEPT (R) Powder for Oral Suspension

Abiotic degradation	<ul style="list-style-type: none"> - hydrolysis 5 mg/l, river water $t_{1/2} \leq 5$ d, ~ 20 °C Identified decomp. products: Mycophenolic acid (CAS 24280-93-1) *1 - 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	<ul style="list-style-type: none"> - barely toxic for planktonic crustaceans (Daphnia magna) EC₅₀ ~ 755 mg/l *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 - 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 - 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
Mobility	<ul style="list-style-type: none"> - strong adsorption to activated sludge (water-activated sludge, 24 h, ~22 °C) K_d = 830000 l/kg (Adsorption to activated sludge in biodegradability test) *1
Air pollution	<ul style="list-style-type: none"> - observe local/national regulations *1
*1	referring to: Mycophenolate mofetil

CELLCEPT (R) Powder for Oral Suspension

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.

14. Transport information

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

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 - changes from previous version in sections 2, 8, 12, 13, 14

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.

**1. Product and Company Identification**

Product name	CELLCEPT (R) Oral Suspension
Product code	2502054
Use	- Therapeutic Category: Immunosuppressant
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
Roche Nutley Inventory Code	25753196

2. Hazard identification**Emergency Overview**

Form	liquid
Color	white to off-white
Hazard Overview	- Harmful if swallowed. - May cause blood system changes. - May cause lymphatic system effects. - May cause birth defects based on animal data.
Potential Health Effects	- 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

CELLCEPT (R) Oral Suspension

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

- 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.

*1 referring to:

Mycophenolate mofetil

3. Composition/Information on ingredients

Ingredients	Concentration
Mycophenolate mofetil CAS: 128794-94-5	10-20 %

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

CELLCEPT (R) Oral Suspension

5. Fire-fighting measures

- Suitable extinguishing media - water spray jet, dry powder, foam, carbon dioxide
- Flash point (liquid) (Flash point not established)
- Protection of fire-fighters - use self-contained breathing apparatus

6. Accidental release measures

- Personal precautions - ensure adequate ventilation

7. Handling and storage

Handling

- Technical measures - Use with adequate ventilation
- Note - Store constituted suspension at 25 C (77 F); excursions permitted to 15 to 30 C (59 to 86 F) for 60 days. Storage in a refrigerator at 2 to 8 C (36 to 46 F) is acceptable.

Storage

- Storage conditions - room temperature
- dry and ventilated place
- do not freeze

8. Exposure controls/Personal protection

- Engineering Measures - see 7.
- Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³ *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
- 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

CELLCEPT (R) Oral Suspension

9. Physical and chemical properties	
Color	white to off-white
Form	liquid
10. Stability and reactivity	
Stability	- stable under normal conditions
Materials to avoid	- strong oxidizing agents
11. Toxicological information	
Acute toxicity	- LD ₅₀ > 4'000 mg/kg (oral, mouse) *1 - LD ₅₀ 250 to 500 mg/kg (oral, rat) *1
Local effects	- skin: non-irritant *1 - eye: non-irritant *1
Sensitization	- non-sensitizing *1
Carcinogenicity	- not carcinogenic (several species) *1
Reproductive toxicity	- teratogenic (several species) *1
*1 referring to:	Mycophenolate mofetil
12. Ecological information	
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 - inhibits anaerobic biodegradability at high concentrations (toxic to bacteria) complete primary degradation evidenced by HPLC 0 %, 62 d (Ultimate anaerobic biodegradability, ISO 11734) *1
Abiotic degradation	- hydrolysis 5 mg/l, river water t _{1/2} ≤ 5 d, ~ 20 °C Identified decomp. products: Mycophenolic acid (CAS 24280-93-1) *1

CELLCEPT (R) Oral Suspension

	<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
Ecotoxicity	<ul style="list-style-type: none"> - barely toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC₅₀ ~ 755 mg/l - highly toxic for algae (<i>Scenedesmus (=Desmodesmus) subspicatus</i>) 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) - adaptation/recovery of organisms upon prolongation of test duration (<i>Scenedesmus (=Desmodesmus) subspicatus</i>) LOEC (14 d) 1.6 mg/l (nominal concentration) (OECD No. 201, prolonged) - barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (<i>Daphnia magna</i>) EC₅₀ (48 h) > 100 mg/l (nominal concentration) NOEC (48 h) 27.7 mg/l (average measured concentration) (OECD No. 202) - 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) - no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 100 mg/l (nominal concentration) (Manometric Respirometry Test, OECD No. 301 F) 	*1 *1 *1 *1 *1 *1
Mobility	<ul style="list-style-type: none"> - strong adsorption to activated sludge (water-activated sludge, 24 h, ~22 °C) K_d = 830000 l/kg (Adsorption to activated sludge in biodegradability test) 	*1
Air pollution	<ul style="list-style-type: none"> - observe local/national regulations 	*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.

CELLCEPT (R) Oral Suspension

14. Transport information							
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, LIQUID, N.O.S.					
Technical name		Mycophenolate mofetil					
15. Regulatory information							
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							
Edition documentation		- changes from previous version in sections 2, 8, 12, 13, 14					
<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>							



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	0341266
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 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. Hazard identification

Emergency Overview

Form	lyophilized powder
Color	white
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) Lyophilized Vials (500 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.

*1 referring to:

Mycophenolate mofetil

3. Composition/Information on ingredients

Characterization

final product

Ingredients

Concentration

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

CELLCEPT(R) Lyophilized Vials (500 mg)

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

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 - Secure the drum cover and move the container to a safe holding area - Clean spill area thoroughly - 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

7. Handling and storage

Handling

Technical measures	- local exhaust ventilation necessary
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Storage

Storage conditions	- keep containers tightly closed - room temperature - store in a dry place - protected from light
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8. Exposure controls/Personal protection

Engineering Measures	- see 7.
Threshold value (USA) air	- STEL: 7.5 mg/m ³ (STEL=ceiling limit)

*2

CELLCEPT(R) Lyophilized Vials (500 mg)

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³ *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

Hand protection - protective gloves

Eye protection - safety glasses

Body protection - protective clothing

*1 referring to: Mycophenolate mofetil
*2 referring to: Hydrochloric acid (1.0 N)

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 ₅₀	900	mg/kg	(oral, rabbit)	*2
	- LC ₅₀	3'124	ppm	(inhal., rat, 1 h)	*2
	- LC ₁₀	1'300	ppm	(inhal., man, 30 min)	*2
	- LC ₁₀	3'000	ppm	(inhal., man, 5 min)	*2
	- LD ₅₀	250	to 500	mg/kg (oral, rat)	*1
Local effects	- skin:	non-irritant			*1
	- eye:	non-irritant			*1
Sensitization	-	non-sensitizing			*1
Carcinogenicity	-	not carcinogenic (several species)			*1

CELLCEPT(R) Lyophilized Vials (500 mg)

Reproductive toxicity	- teratogenic (several species)	*1
*1 referring to:	Mycophenolate mofetil	
*2 referring to:	Hydrochloric acid (1.0 N)	
12. Ecological information		
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
	- inhibits anaerobic biodegradability at high concentrations (toxic to bacteria) complete primary degradation evidenced by HPLC 0 %, 62 d (Ultimate anaerobic biodegradability, ISO 11734)	*1
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)	*1
	- 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	- barely toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC ₅₀ ~ 755 mg/l	*1
	- highly toxic for algae (<i>Scenedesmus (=Desmodesmus) subspicatus</i>) 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
	- adaptation/recovery of organisms upon prolongation of test duration (<i>Scenedesmus (=Desmodesmus) subspicatus</i>) 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 (<i>Daphnia magna</i>) EC ₅₀ (48 h) > 100 mg/l (nominal concentration) NOEC (48 h) 27.7 mg/l (average measured concentration) (OECD No. 202)	*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

CELLCEPT(R) Lyophilized Vials (500 mg)

Mobility	<ul style="list-style-type: none"> - no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 100 mg/l (nominal concentration) (Manometric Respirometry Test, OECD No. 301 F) *1 - strong adsorption to activated sludge (water-activated sludge, 24 h, ~22 °C) K_d = 830000 l/kg (Adsorption to activated sludge in biodegradability test) *1
*1 referring to:	Mycophenolate mofetil

13. Disposal considerations

Waste from residues	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - Empty containers must be triple rinsed prior to disposal, recycling or reuse.

14. Transport information

DOT	Class	UN/ID	PG	PI	RQ	Label	Haz.no
	9	3077	III			9	

DOT Remark:	<ul style="list-style-type: none"> - 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

15. Regulatory information

TSCA Status	<ul style="list-style-type: none"> - FDA Exemption - not on inventory
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CELLCEPT(R) Lyophilized Vials (500 mg)

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

- changes from previous version in sections 8, 14

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.



Material Safety Data Sheet

CELLCEPT(R) Film Coated Tablets (500 mg)

1. Product and Company Identification

Product name	CELLCEPT(R) Film Coated Tablets (500 mg)
Product code	SAP-10062347
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
Synonyms	- CELLCEPT Film Coated Tablets 500 mg - CELLCEPT F.C. Tablets 500 mg
*1 referring to:	Mycophenolate mofetil

2. Hazard identification

Emergency Overview

Form	tablets
Color	country-specific
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) Film Coated Tablets (500 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	~ 62 %
Microcrystalline cellulose CAS: 9004-34-6	~ 30 %
Povidone K 90 CAS: 9003-39-8	~ 3 %
Magnesium stearate CAS: 557-04-0	~ 2 %

CELLCEPT(R) Film Coated Tablets (500 mg)

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

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

Personal precautions	- ensure adequate ventilation - keep people away and stay on the upwind side
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	- provide suitable exhaust ventilation at the processing machines
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Storage

Storage conditions	- keep containers tightly closed - room temperature - store in a dry place - protected from light
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8. Exposure controls/Personal protection

Engineering Measures	- see 7.
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CELLCEPT(R) Film Coated Tablets (500 mg)

Monitoring		
Threshold value (USA) air	- ACGIH-TLV: 10 mg/m ³	*2
	- ACGIH-TLV: 10 mg/m ³	*3
	- OSHA-PEL: 5 mg/m ³ (respirable dust fraction)	*3
	- OSHA-PEL: 15 mg/m ³ (total dust)	*3
	- NIOSH-REL: 5 mg/m ³ (respirable dust fraction)	*3
	- NIOSH-REL: 10 mg/m ³ (total dust)	*3
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.01 mg/m ³	*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	<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: particle mask or respirator with independent air supply - 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:	Microcrystalline cellulose	
9. Physical and chemical properties		
Color	country-specific	
Form	tablets	
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
*1 referring to:	Mycophenolate mofetil	
10. Stability and reactivity		
Stability	- stable under the conditions mentioned in chapter 7	
Materials to avoid	- strong oxidizing agents	*1
*1 referring to:	Mycophenolate mofetil	

CELLCEPT(R) Film Coated Tablets (500 mg)

11. Toxicological information

Acute toxicity	<ul style="list-style-type: none"> - LD₅₀ 353 mg/kg (oral, rat); females, "trimmed Spearman-Karber method" *1 - LD₅₀ 500 mg/kg (oral, rat); males, "trimmed Spearman-Karber method" *1 - LD₀ 250 mg/kg (oral, rat) *1 - LD₅₀ > 2'000 mg/kg (oral, rat) *2
Local effects	<ul style="list-style-type: none"> - skin: non-irritant *1 - eye: non-irritant *1
Sensitization	<ul style="list-style-type: none"> - non-sensitizing *1
Mutagenicity	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - not carcinogenic (several species) *1
Reproductive toxicity	<ul style="list-style-type: none"> - teratogenic (several species) *1
Note	<ul style="list-style-type: none"> - 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
*1 referring to:	Mycophenolate mofetil
*2 referring to:	Magnesium stearate
*4 referring to:	Mycophenolic acid

12. Ecological information

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 - inherently biodegradable *3

CELLCEPT(R) Film Coated Tablets (500 mg)

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						
15. Regulatory information								
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								
Safety-lab number		<ul style="list-style-type: none"> - BS-8818 - BS-9333 					*1 *1	
Edition documentation		- changes from previous version in sections 9, 13						
*1 referring to:		Mycophenolate mofetil						
<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>								

**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 %

CELLCEPT(R) Capsules (250 mg)

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

CELLCEPT(R) Capsules (250 mg)

8. Exposure controls/Personal protection

Engineering Measures - see 7.

Monitoring

Threshold value (USA) air

- 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 - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³ *1

Analytcs - 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 $\log P_{ow}$ 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

CELLCEPT(R) Capsules (250 mg)

Conditions to avoid	- warming - light - humidity	
Materials to avoid	- strong oxidizing agents	*1
*1 referring to:	Mycophenolate mofetil	
11. Toxicological information		
Acute toxicity	- LD ₅₀ 353 mg/kg (oral, rat); females, "trimmed Spearman-Karber method" - LD ₅₀ 500 mg/kg (oral, rat); males, "trimmed Spearman-Karber method" - LD ₀ 250 mg/kg (oral, rat) - LD ₅₀ > 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	
12. Ecological information		
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

CELLCEPT(R) Capsules (250 mg)

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 *1 ~ 37 %, 120 h, ~ 22 °C, dark ~ 67 %, 120 h, ~ 22 °C, under illumination
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) *1 EC₅₀ (48 h) > 100 mg/l (nominal concentration) NOEC (48 h) 27.7 mg/l (average measured concentration) (OECD No. 202) - highly toxic for algae (Scenedesmus (=Desmodesmus) subspicatus) *1 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) - acute fish toxicity in a limit test is lower than daphnid or algal toxicity, hence not relevant for classification (guppy) *1 NOEC (96 h) 1.7 mg/l (highest tested concentration) (OECD No. 203) - no adverse influence on substrate biodegradation (activated sludge) *1 concentration (14 d) 100 mg/l (nominal concentration) (Manometric Respirometry Test, OECD No. 301 F)
Air pollution	<ul style="list-style-type: none"> - observe local/national regulations *1
*1 referring to:	Mycophenolate mofetil
13. Disposal considerations	
Waste from residues	<ul style="list-style-type: none"> - 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.

CELLCEPT(R) Capsules (250 mg)

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
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						
15. Regulatory information								
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. 						

CELLCEPT(R) Capsules (250 mg)

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.