

Safety Data Sheet

CellCept(R) Lyophilized Vials (500 mg)

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

1.1. Product identifier

Product name CellCept(R) Lyophilized Vials (500 mg)
Product code SAP-10051336
Synonyms - CELLCEPT(R) Vials (500 mg)
- Mycophenolate mofetil (87%) plus excipients

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

Use - pharmaceutical active substance (immunosuppressant)

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

CellCept(R) Lyophilized Vials (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.
- P273 Avoid release to the environment.
- P281 Use personal protective equipment as required.
- P309 + P311 IF exposed or you feel unwell: Call a POISON CENTER or doctor/physician.

Other hazards

Note - no information available

SECTION 3: Composition/information on ingredients

Characterization

Mycophenolate mofetil and other ingredients

Ingredients

Concentration

**GHS-Classification
(pure ingredient)**

Mycophenolate mofetil
128794-94-5

87 %

- 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

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

CellCept(R) Lyophilized Vials (500 mg)

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
- consult a physician |
| Skin contact | - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents |
| Inhalation | - remove the casualty to fresh air and keep him/her calm
- get medical treatment |

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
- after accidental exposure women should get medical advice from a physician |
|-------------------|---|

SECTION 5: Firefighting measures

5.1. Extinguishing media

- | | |
|------------------------------|---|
| Suitable extinguishing media | - water spray jet, dry powder, foam, carbon dioxide |
| Flash point (liquid) | not applicable |

5.2. Special hazards arising from the substance or mixture

- | | |
|------------------|---|
| Specific hazards | - consider dust explosion hazard
- consider danger for the environment: dike spilled liquid
- formation of toxic and corrosive combustion gases (nitrogen oxides (NO _x)) possible |
|------------------|---|

5.3. Advice for firefighters

- | | |
|---------------------------------|---|
| Protection of fire-fighters | - precipitate gases/vapours/mists with water spray |
| Special method of fire-fighting | - for reasons of environmental protection hold the extinguishing agent back |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- | | |
|----------------------|-------------------------------|
| Personal precautions | - ensure adequate ventilation |
|----------------------|-------------------------------|

CellCept(R) Lyophilized Vials (500 mg)

6.2. Environmental precautions

- Environmental protection
- if the substance reaches waters or the sewer system, inform the competent authority
 - dilute the leaked substance by a water spray jet as far as necessary in order to minimize the hazard; hold the draining water/mixture of substances back by all means available

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up
- collect solids (avoid dust formation) and hand over to waste removal
 - collect spilled solutions with inert adsorbent and hand over to waste removal

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Technical measures
- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
 - local exhaust ventilation necessary
 - avoid dust formation; consider dust explosion hazard
 - take precautionary measures against electrostatic charging

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions
- room temperature
- Validity
- see expiry date on the label

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

- Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³ *1

8.2. Exposure controls

- General protective and hygiene measures
- instruction of employees mandatory
- 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.
 - in case of open handling or accidental release: particle mask or respirator with independent air supply
- Hand protection
- protective gloves (neoprene, nitrile or butyl rubber)

CellCept(R) Lyophilized Vials (500 mg)

Eye protection	- safety glasses	
Body protection	- protective clothing	
Analytics	- sampling on glass fibre filter, desorption with methanol; basify with NaOH, heat; neutralize with HCl, HPLC analysis	*1

*1 referring to: Mycophenolate mofetil

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	white to off-white	
Form	powder	
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
Melting temperature	93 to 99 °C	*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 normal conditions

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

CellCept(R) Lyophilized Vials (500 mg)

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD ₅₀ 353 mg/kg (oral, rat); females, "trimmed Spearman-Karber method"	*1
	- LD ₅₀ 500 mg/kg (oral, rat); males, "trimmed Spearman-Karber method"	*1
	- LD ₀ 250 mg/kg (oral, rat)	*1
	- LD ₅₀ > 4'000 mg/kg (oral, mouse)	*1
Local effects	- skin: non-irritant	*1
	- eye: non-irritant	*1
Sensitization	- non-sensitizing	*1
Mutagenicity	- mutagenic (OECD No. 474 (Micronucleus Test)); threshold dose response	*2
	- mutagenic (mouse lymphoma cell mutation test; OECD No. 476 (Mammalian Cell Gene Mutation Test))	*2
	- does not induce chromosomal aberrations in vitro (OECD No. 473 (Mammalian Cytogenic Test))	*2
	- not mutagenic (Ames test)	*2
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
	- 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
	- excretion predominantly renal	*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: Mycophenolic acid

CellCept(R) Lyophilized Vials (500 mg)

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	<ul style="list-style-type: none">- 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- 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- 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	<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

12.4. Mobility in soil

Note - no information available

CellCept(R) Lyophilized Vials (500 mg)

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*1 referring to: Mycophenolate mofetil

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal
 - incinerate in qualified installation with flue gas scrubbing

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

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

CellCept(R) Lyophilized Vials (500 mg)

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

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

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.