

CELLCEPT Tablets 500 mg

Polyvinylpyrrolidone ~ 3 %
CAS: 9003-39-8

Magnesium stearate ~ 2 %
CAS: 557-04-0
EINECS: 209 150 3

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

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| Suitable extinguishing media | - adapt extinguishing media to surrounding fire conditions |
| 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

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

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| Technical measures | - provide suitable exhaust ventilation at the processing machines |
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Storage

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| 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.	
Monitoring		
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.1 mg/m ³ (Internal Occupational Exposure Limit, men) - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m ³ (women of childbearing age)	*1 *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	- 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	

9. Physical and chemical properties

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

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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"> - not mutagenic (various in vivo and in vitro test systems) *1
Carcinogenicity	<ul style="list-style-type: none"> - not carcinogenic (several species) *1
Reproduction 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/day *1 - elimination half-life: 16-18 h *1 - excretion predominantly renal *1 - Adverse effect at therapeutic dose: diarrhoea, drop of 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

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
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

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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 concentration tested) (OECD No. 203) *1- no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 100 mg/l (nominal concentration) (Manometric Respirometry Test, OECD No. 301 F) *1
Air pollution	<ul style="list-style-type: none">- observe local/national regulations *1
*1 referring to:	Mycophenolate mofetil
*3 referring to:	Cellulose

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
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14. Transport information

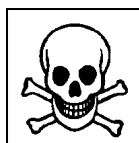
IATA	Class	UN/ID	PG		PI	Label	
	9	3077	III		911/911	9	
IMDG	Class	UN	PG	EmS	PI	Label	Mark
	9	3077	III	F-A S-F	P002/IBC08	9	marine pollutant
RID/ADR	Class	UN	PG	Haz.no	PI	Label	Classif.code
	9	3077	III	90	P002/IBC08	9	M7

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

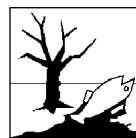
Technical name mixture with 62% Mycophenolate mofetil

15. Regulatory information

Classification and labelling according to EU directives



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R22	Harmful if swallowed.
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R61	May cause harm to the unborn child.
S22	Do not breathe dust.
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S53	Avoid exposure --- obtain special instructions before use.
S61	Avoid release to the environment. Refer to special instructions/Safety data sheets.

Water hazard class (Germany) 3: strongly hazardous for water (own classification according to directive VwVwS of 17.05.1999)

