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

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

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

Storage

Storage conditions	-	keep containers tightly closed - room temperature - store in a dry place - protected from light

8. Exposure controls/Personal protection

Engineering Measures	-	see 7.	
Threshold value (USA) air	-	STEL: 7.5 mg/m3 (STEL=ceiling limit)	*2

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_{lo}	1’300	ppm	(inhal., man, 30 min)		*2
	-	LC_{lo}	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

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 (Daphnia magna) EC_{50} ~ 755 mg/l	*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
	- 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
	- 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	- 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	- 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	- 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:	- 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 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.