

CELLCEPT(R) Capsules (250 mg)

Version
0.0

Revision Date:
02-19-2020

Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

SECTION 1. IDENTIFICATION

Product name : CELLCEPT(R) Capsules (250 mg)

Product code : 00010133839

Common name(s), syno- : CELLCEPT Capsules (hard) 250 mg
nym(s) of the substance

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.

Address : DNA Way 1
94080 South San Francisco
CA
USA

Telephone : 001-(650) 225-1000

E-mail address : info.sds@roche.com

Emergency telephone

Emergency telephone num- : US Chemtrec phone (800)-424-9300
ber

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Acute toxicity (Oral) : Category 4

Germ cell mutagenicity : Category 2

Carcinogenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity : Category 1
- repeated exposure

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.
H341 Suspected of causing genetic defects.

CELLCEPT(R) Capsules (250 mg)Version
0.0Revision Date:
02-19-2020Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

H351 Suspected of causing cancer.
 H360D May damage the unborn child.
 H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Mycophenolate mofetil	128794-94-5	66.1
Starch	9005-25-8	7.9
Croscarmellose sodium	74811-65-7	3.1
2-Pyrrolidinone, 1-ethenyl-, homo-polymer	9003-39-8	1.6
Octadecanoic acid, magnesium salt (2:1)	557-04-0	1.2
Titanium oxide (TiO ₂)	13463-67-7	<= 1.0
non hazardous compounds	Not Assigned	19.1

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
 Show this material safety data sheet to the doctor in attendance.
 Do not leave the victim unattended.

CELLCEPT(R) Capsules (250 mg)

Version	Revision Date:	Date of last issue: 06-10-2017
0.0	02-19-2020	Date of first issue: 06-10-2017

- If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
Suspected of causing genetic defects.
Suspected of causing cancer.
May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
Carbon oxides
Nitrogen oxides (NOx)
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

CELLCEPT(R) Capsules (250 mg)

Version
0.0

Revision Date:
02-19-2020

Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Avoid exposure
Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.
- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Mycophenolate mofetil The value is given in analogy to the following substances:	128794-94-5	IOEL	0.01 mg/m ³	Roche Industrial Hygiene Com-

SAFETY DATA SHEET

CELLCEPT(R) Capsules (250 mg)

Version
0.0

Revision Date:
02-19-2020

Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

Mycophenolic acid				mittee (RIHC)
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable fraction)	10 mg/m3	ACGIH
		TWA (Respirable fraction)	3 mg/m3	ACGIH
Titanium oxide (TiO2)	13463-67-7	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA	10 mg/m3 (Titanium dioxide)	ACGIH

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Mycophenolate mofetil	Surface waters	0.58 µg/l
	Remarks: Based on chronic data	
	Surface waters	64 µg/l
	Remarks: Based on chronic data, Provisional antibiotic resistance PNEC	

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
Effective dust mask

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles

Skin and body protection : Choose body protection according to the amount and

CELLCEPT(R) Capsules (250 mg)

Version
0.0

Revision Date:
02-19-2020

Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

concentration of the dangerous substance at the work place.

Protective measures : Instruction of employees recommended

Hygiene measures : When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : capsules
- Color : brown
light blue
- Odor : Not applicable
- Odor Threshold : Not applicable
- pH : Not applicable
- Melting point/range : No data available
- Boiling point/boiling range : No data available
- Flash point : No data available
- Evaporation rate : No data available
- Self-ignition : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapor pressure : No data available
- Relative vapor density : Not applicable
- Relative density : No data available
- Solubility(ies)
Water solubility : No data available
Solubility in other solvents : No data available
- Partition coefficient: n-octanol/water : No data available
- Autoignition temperature : No data available
- Decomposition temperature : No data available

CELLCEPT(R) Capsules (250 mg)Version
0.0Revision Date:
02-19-2020Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

Viscosity
 Viscosity, dynamic : Not applicable
 Viscosity, kinematic : Not applicable
 Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.
 Chemical stability : Stable under normal conditions.
 Possibility of hazardous reactions : No decomposition if stored and applied as directed.
 Incompatible materials : No data available
 Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 532.36 mg/kg
 Method: Calculation method
 Acute inhalation toxicity : Acute toxicity estimate: > 200 mg/l
 Exposure time: 4 h
 Test atmosphere: dust/mist
 Method: Calculation method

Components:**Mycophenolate mofetil:**

Acute oral toxicity : LD50 Oral (Rat, female): 353 mg/kg
 LD50 Oral (Rat, male): 500 mg/kg
 LD0 (Rat): 250 mg/kg
 LD50 Oral (Mouse): > 4,000 mg/kg

Starch:

Acute oral toxicity : Acute toxicity estimate: > 5,001 mg/kg
 Method: Expert judgment
 Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
 Test atmosphere: dust/mist

CELLCEPT(R) Capsules (250 mg)

Version
0.0

Revision Date:
02-19-2020

Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

Octadecanoic acid, magnesium salt (2:1):

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

Titanium oxide (TiO₂):

Acute oral toxicity : LD50 (Rat): > 7,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Mycophenolate mofetil:

Species : laboratory animal
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Mycophenolate mofetil:

Species : laboratory animal
Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Mycophenolate mofetil:

Result : Did not cause sensitization on laboratory animals.

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:

Mycophenolate mofetil:

CELLCEPT(R) Capsules (250 mg)Version
0.0Revision Date:
02-19-2020Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

assessment reproductive toxicant

STOT-single exposure

Not classified based on available information.

Components:**Starch:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Octadecanoic acid, magnesium salt (2:1):

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:**Mycophenolate mofetil:**

Assessment : Causes damage to organs through prolonged or repeated exposure.

Starch:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Octadecanoic acid, magnesium salt (2:1):

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:**Starch:**

No data available

Octadecanoic acid, magnesium salt (2:1):

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Mycophenolate mofetil:**

Toxicity to fish : NOEC (Poecilia reticulata (guppy)): 1.7 mg/l

CELLCEPT(R) Capsules (250 mg)Version
0.0Revision Date:
02-19-2020Date of last issue: 06-10-2017
Date of first issue: 06-10-2017Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: no

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: no
Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): 27.7 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: no
Remarks: average measured concentration

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 0.6 mg/l
Exposure time: 72 h
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: no
Remarks: average measured concentration

EyC50 (Desmodesmus subspicatus (green algae)): 0.2 mg/l
Exposure time: 72 h
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: no
Remarks: average measured concentrationNOEC (Desmodesmus subspicatus (green algae)): 0.1 mg/l
Exposure time: 72 h
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentrationLowest Observed Effect Concentration (Desmodesmus subspicatus (green algae)): 1.6 mg/l
Exposure time: 14 d
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentrationErC50 (Anabaena flos-aquae (cyanobacterium)): 0.423 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: average measured concentration
The value is given in analogy to the following substances:
Mycophenolic acidErC10 (Anabaena flos-aquae (cyanobacterium)): 0.155 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

CELLCEPT(R) Capsules (250 mg)Version
0.0Revision Date:
02-19-2020Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

GLP: yes
 Remarks: average measured concentration
 The value is given in analogy to the following substances:
 Mycophenolic acid

Toxicity to fish (Chronic toxicity) : EC10 (Danio rerio (zebra fish)): 0.0058 mg/l
 Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
 Method: OECD Test Guideline 210
 The value is given in analogy to the following substances:
 Mycophenolic acid

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): 0.929 mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 211
 The value is given in analogy to the following substances:
 Mycophenolic acid

Toxicity to microorganisms : (activated sludge): 100 mg/l
 Exposure time: 14 d
 Analytical monitoring: yes
 Method: OECD Test Guideline 301F
 GLP: no
 Remarks: no adverse influence on substrate biodegradation
 nominal concentration

Starch:

Toxicity to fish : LC50: > 100 mg/l
 Exposure time: 96 h

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Octadecanoic acid, magnesium salt (2:1):**Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Titanium oxide (TiO₂):

CELLCEPT(R) Capsules (250 mg)

Version 0.0 Revision Date: 02-19-2020 Date of last issue: 06-10-2017
 Date of first issue: 06-10-2017

Toxicity to fish : LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
 Exposure time: 48 h

Toxicity to daphnia and other : EC0 (Daphnia magna (Water flea)): 3 mg/l
 aquatic invertebrates Exposure time: 720 h

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to : No data available
 the environment

Persistence and degradability**Components:****Mycophenolate mofetil:**

Biodegradability : aerobic
 Inoculum: activated sludge, non-adapted
 Concentration: 100 mg/l
 Result: Not readily biodegradable.
 Biodegradation: < 6 %
 Exposure time: 28 d
 Method: OECD Test Guideline 301F
 GLP: no
 Remarks: Primary biodegradation

Biodegradation: 82.2 %
 Testing period: 2.9 d
 Exposure time: 28 d
 Method: OECD Test Guideline 314
 GLP: yes
 Remarks: Ultimate aerobic biodegradation
 The value is given in analogy to the following substances:
 Mycophenolic acid

Testing period: 1.7 d
 Method: OECD Test Guideline 314
 GLP: yes
 Remarks: Primary biodegradation
 The value is given in analogy to the following substances:
 Mycophenolic acid

Stability in water : Hydrolysis: 50 % at37 °C(118 h)
 Hydrolysis: 50 % at37 °C(19 h)

Bioaccumulative potential**Components:****Mycophenolate mofetil:**

Partition coefficient: n- : log Pow: 1.45
 octanol/water pH: 7.4

CELLCEPT(R) Capsules (250 mg)Version
0.0Revision Date:
02-19-2020Date of last issue: 06-10-2017
Date of first issue: 06-10-2017log Pow: 0.47
pH: 7.0**Starch:**

Partition coefficient: n-octanol/water : Remarks: No data available

Octadecanoic acid, magnesium salt (2:1):Partition coefficient: n-octanol/water : log Pow: 0.8
Method: OECD Test Guideline 107**Titanium oxide (TiO₂):**

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil**Components:****Mycophenolate mofetil:**Distribution among environmental compartments : Medium: Soil
Koc: 168 - 557 ml/g
Kd: 2.2 - 5.5 ml/g
Method: OECD Test Guideline 106
Remarks: Mobile in soils
Not expected to adsorb on soil.Medium: Sludge
Koc: 30 - 37 ml/g
Kd: 9.3 - 13 ml/g
Method: OECD Test Guideline 106**Other adverse effects****Product:**Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Very toxic to aquatic life with long lasting effects.

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : The product should not be allowed to enter drains, water courses or the soil.

CELLCEPT(R) Capsules (250 mg)Version
0.0Revision Date:
02-19-2020Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Mycophenolate mofetil mixture)
Class : 9
Packing group : III
Labels : 9

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Mycophenolate mofetil mixture)
Class : 9
Packing group : III
Labels :
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Mycophenolate mofetil mixture)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation**49 CFR**

UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Mycophenolate mofetil mixture)
Class : 9

CELLCEPT(R) Capsules (250 mg)

Version 0.0	Revision Date: 02-19-2020	Date of last issue: 06-10-2017 Date of first issue: 06-10-2017
----------------	------------------------------	---

non hazardous compounds	Not Assigned
Starch	9005-25-8
Croscarmellose sodium	74811-65-7
Titanium oxide (TiO2)	13463-67-7

Maine Chemicals of High Concern

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

California Prop. 65

WARNING: This product can expose you to chemicals including Titanium oxide (TiO2), which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
--	-----------

California Permissible Exposure Limits for Chemical Contaminants

Starch	9005-25-8
Octadecanoic acid, magnesium salt (2:1)	557-04-0
Titanium oxide (TiO2)	13463-67-7

The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Mycophenolate mofetil

non hazardous compounds

Croscarmellose sodium

AICS : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Substance(s) not listed on TSCA inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

CELLCEPT(R) Capsules (250 mg)

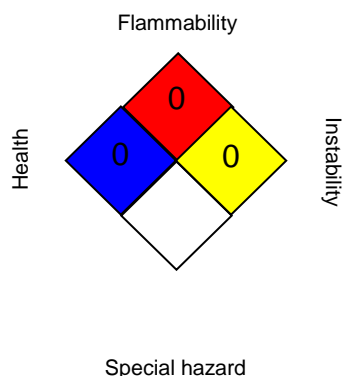
Version
0.0

Revision Date:
02-19-2020

Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

SECTION 16. OTHER INFORMATION

NFPA:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL : USA. NIOSH Recommended Exposure Limits
- OSHA P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA : 8-hour, time-weighted average
- NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA P0 / TWA : 8-hour time weighted average
- OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of

CELLCEPT(R) Capsules (250 mg)

Version
0.0

Revision Date:
02-19-2020

Date of last issue: 06-10-2017
Date of first issue: 06-10-2017

Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 02-19-2020

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 1810