CellCept(R) Lyophilized Vials (500 mg)

Version	Revision Date:	Date of last issue: 06-10-2017
1.1	02-19-2020	Date of first issue: 06-10-2017

SECTION 1. IDENTIFICATION

Product name	:	CellCept(R) Lyophilized Vials (500 mg)
Product code	:	00010057786
Common name(s), synonym(s) of the substance	:	CELLCEPT Lyophilized Vials 500mg

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 number	:	US Chemtrec phone (800)-424-9300

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
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure	:	Category 1

GHS label elements

Hazard pictograms :

Signal Word	:	Danger
Hazard Statements	:	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.

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	87.4
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	9005-65-6	4.4
1,2,3-Propanetricarboxylic acid, 2-hydroxy-	77-92-9	0.9
non hazardous compounds	Not Assigned	7.3

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.

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. 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
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.

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
Storage temperature	:	Store at room temperature in the original container.
Further information on storage stability	:	No decomposition if stored and applied as directed.
Packaging material	:	Suitable material: Vials

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: Mycophenolic acid	128794-94-5	IOEL	0.01 mg/m3	Roche Industrial Hygiene Committee (RIHC)

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 concentration of the dangerous substance at the work place.

Protective measures : Instruction of employees mandatory

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 : lyophilized cake

Color : white, off-white

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

Melting point/range : No data available

Boiling point/boiling range : 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
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable

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: 403.84 mg/kg 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

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:

Genotoxicity in vitro	:	Test Type: Ames test Result: negative The value is given in analogy to the following substances: Mycophenolic acid
		Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 473

Result: negative
The value is given in analogy to the following substances:
Mycophenolic acid

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: positive
The value is given in analogy to the following substances:
Mycophenolic acid

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Method: OECD Test Guideline 474
Result: positive
The value is given in analogy to the following substances:
Mycophenolic acid

Germ cell mutagenicity - Assessment : In vitro tests showed mutagenic effects

Carcinogenicity

Not classified based on available information.

Components:

Mycophenolate mofetil:

Species : laboratory animal
Result : negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

May damage the unborn child.

Components:

Mycophenolate mofetil:

Effects on fetal development : Species: laboratory animal
Result: Teratogenic effects.

Reproductive toxicity - Assessment : May damage the unborn child., Presumed human reproductive toxicant

STOT-single exposure

Not classified based on available information.

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.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Mycophenolate mofetil:

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

NOEC (Desmodesmus subspicatus (green algae)): 0.1 mg/l
Exposure time: 72 h
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration

Lowest 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 concentration

ErC50 (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 acid

ErC10 (Anabaena flos-aquae (cyanobacterium)): 0.155 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 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

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-octanol/water : log Pow: 1.45
pH: 7.4

log Pow: 0.47
pH: 7.0

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 Pro-

tection 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.
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
Packing group	:	III
Labels	:	Class 9 - Miscellaneous dangerous substances and articles
ERG Code	:	171
Marine pollutant	:	no

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)

SARA 311/312 Hazards	:	Acute toxicity (any route of exposure) Germ cell mutagenicity Reproductive toxicity Specific target organ toxicity (single or repeated exposure)

Clean Air Act

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).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

Pennsylvania Right To Know

Mycophenolate mofetil	128794-94-5
non hazardous compounds	Not Assigned
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	9005-65-6

Maine Chemicals of High Concern

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

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
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

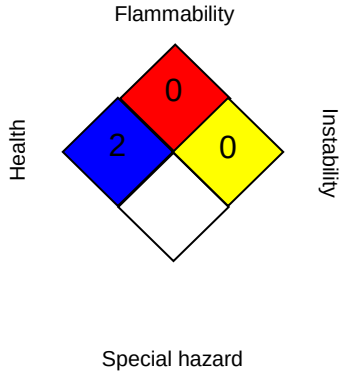
TSCA list

No substances are subject to a Significant New Use Rule.

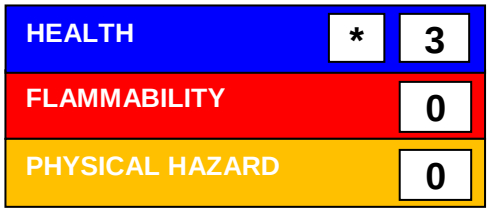
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA:



HMIS® IV:



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

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 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

CellCept(R) Lyophilized Vials (500 mg)

Version	Revision Date:	Date of last issue: 06-10-2017
1.1	02-19-2020	Date of first issue: 06-10-2017

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