

MATERIAL SAFETY DATA SHEET

Version No: MSDS/MMF-AUS/DP-001

Effective Date: 19th December 2020

Mycophenolate Mofetil for Injection, 500 mg/vial

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Mycophenolate Mofetil for Injection, 500 mg/vial

Intended Use:	It is a pharmaceutical product to prevent organ transplant rejection.
----------------------	---

Details of the Supplier of the Safety Data Sheet

Manufacturer: 1. Intas Pharmaceuticals Ltd. Plot No. 457, 458 Village-Matoda, Bavla Road, Ta. Sanand, Dist. Ahmedabad-382 210, Gujarat, India	2. Immacule Lifesciences Pvt. Ltd Village Thanthawal, Ropar Road, Nalagarh, District Solan, Himachal Pradesh, 174101, India	Sponsor: Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia
--	--	--

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Characterization Final product

Ingredients:

Active Ingredient	CAS Number	Concentration
Mycophenolate mofetil	128794-94-5	~ 64 %

Inactive Ingredient	CAS Number	Concentration
Hydrochloric acid	7647-01-0	~ 15 %

SECTION 3 - HAZARDS 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 Effect

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.

MATERIAL SAFETY DATA SHEET

Version No: MSDS/MMF-AUS/DP-001

Effective Date: 19th December 2020

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

SECTION 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

MATERIAL SAFETY DATA SHEET

Version No: MSDS/MMF-AUS/DP-001

Effective Date: 19th December 2020

SECTION 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

SECTION 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

SECTION 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

SECTION 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):

MATERIAL SAFETY DATA SHEET

Version No: MSDS/MMF-AUS/DP-001

Effective Date: 19th December 2020

- 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 glove
- Eye protection** : safety glasses.
- Body protection** : protective clothing
- *1 referring to** : Mycophenolate mofetil
- *2 referring to** : Hydrochloric acid (1.0 N)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

- Colour** : White
- Form** : lyophilized powder
- Solubility** : soluble, water

SECTION 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.

SECTION 11 - TOXICOLOGY INFORMATION

Acute toxicity

Species	Route	End Point	Dose/Concentration	Duration
*2 Rabbit	Oral	LD ₅₀	900 mg/kg	-
*2 Rat	Inhalational	LC ₅₀	3'124 ppm	1 h
*2 Man	Inhalational	LClo	1'300 ppm	30 min
*2 Man	Inhalational	LClo	3'000 ppm	5 min
*1 Rat	Oral	LD ₅₀	250 to 500 mg/kg	-

- Local effects** : - skin: non-irritant *1
- eye: non-irritant *1
- Sensitization** : - non-sensitizing *1
- Carcinogenicity** : - not carcinogenic (several species) *1

MATERIAL SAFETY DATA SHEET

Version No: MSDS/MMF-AUS/DP-001

Effective Date: 19th December 2020

Reproductive toxicity : teratogenic (several species) *1

*1 referring to : Mycophenolate mofetil

*2 referring to : Hydrochloric acid (1.0 N)

SECTION 12 - ENVIRONMENTAL IMPACT 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*) EC₅₀ ~ 755 mg/l *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*)

MATERIAL SAFETY DATA SHEET

Version No: MSDS/MMF-AUS/DP-001

Effective Date: 19th December 2020

(=Desmodemus) 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
- 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)
Kd = 830000 l/kg (Adsorption to activated sludge in biodegradability test) *1

*1 referring to:

: Mycophenolate mofetil

SECTION 13 - DISPOSAL INFORMATION

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.

MATERIAL SAFETY DATA SHEET

Version No: MSDS/MMF-AUS/DP-001

Effective Date: 19th December 2020

SECTION 14 - TRANSPORTATION 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

SECTION 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.

SECTION 16 - OTHER DATA

The information in this document is believed to be correct as of the date issued. HOWEVER, NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS EXPRESSED OR IS TO BE IMPLIED REGARDING THE ACCURACY OR COMPLETENESS OF THIS INFORMATION, THE RESULTS TO BE OBTAINED FROM THE USE OF THIS INFORMATION OR THE PRODUCT, THE SAFETY OF THIS PRODUCT, OR THE HAZARDS RELATED TO ITS USE. This information and product are furnished on the condition that the person receiving them shall make his own determination as to the suitability of the product for his particular purpose and on the condition that he assume the risk of his use thereof.