



SAFETY DATA SHEET

SECTION 1 – IDENTIFICATION OF THE PRODUCT & THE COMPANY

- a) **Product Name** : Mycophenolate Mofetil Hydrochloride for Injection, 500mg of mycophenolate mofetil/vial
- b) **Common/Trade Name** : Mycophenolate Mofetil Hydrochloride for Injection
Chemical Names : 2-morpholinoethyl (E)-6-(1,3dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4hexenoate
- Chemical Family** : Immunosuppressive agent
- c) **Product Use** : Pharmaceutical, Injectable
Product Type : Regulated Prescription Drug
Container Information : Vial
- d) **Manufacturers Name & Address** : **Gland Pharma Limited**
: Survey No.: 143–148, 150&151
: Near Gandimaisamma Cross Roads,
: D.P.Pally, Quthbullapur Mandal
: Ranga Reddy District
: Hyderabad- 500043
: Telangana, India
- e) **Telephone Number for Info** : +91-40-30510999

SECTION 2 – HAZARDS IDENTIFICATION

a) **Classification**

NFPA Rating

Health Hazard : 2

Fire Hazard : 0

Reactivity Hazard : 0

b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	c) Description of Hazards:
Signal Word:	Warning
Hazard Statements: Harmful if swallowed	

d) **Unknown Acute Toxicity:** N/A



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SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

a) Chemical Name	b) Common Name/Synonym	%Composition or other measure	c) CAS Number	d) Impurities / Stabilizing Additives
2-morpholinoethyl (E)-6-(1,3dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4hexenoate	Mycophenolate Mofetil	100 mg/mL	128794-94-5	N/A
monooleate polyoxyethylene deriv	Polysorbate 80	5.0 mg/mL	9005-65-6	N/A
2-Hydroxy-1,2,3-propanetricarboxylic acid	Citric acid Anhydrous	1.0 mg/mL	77-92-9	N/A
Hydrochloric Acid	Hydrochloric acid	0.25 mL/mL	128794-94-5	N/A
Caustic Soda	Sodium hydroxide	q.s for pH adjustment	1310-73-2	N/A
Water	Water for Injection	q.s to 1.0mL	7732-18-5	N/A

SECTION 4 – FIRST AID MEASURES

- Eye Exposure** : In case of contact with eyes rinse thoroughly with plenty of water and get medical advice
- Skin Exposure** : Remove immediately contaminated clothes, wash affected skin with plenty of water
- Ingestion** : Consult physician
- Injection** : Under normal use with supervision of a physician.
- Inhalation** : In case of inhalation remove to fresh air and seek medical aid.
- Notes to Physician** : See patient package insert in shipping carton for complete information



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SECTION 5 – FIRE FIGHTING MEASURES

- a) **Extinguishing Media** : Water spray jet, dry powder, foam, carbon dioxide
- b) **Hazardous Combustion Products** : Cool endangered containers with water spray
- c) **Special Protective Equipment / Precautions** : Use self-contained breathing apparatus

SECTION 6 – ACCIDENTAL RELEASE MEASURES

- Spill** : Clean spill area thoroughly, ensure adequate ventilation
- Release to Air** : Avoid release to the environment
- Release to Water** : Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines

SECTION 7 – HANDLING AND STORAGE

- General Handling** : Gloves, masks and goggles are recommended during handling.
- Storage Conditions** : Store powder and reconstituted/infusion solution at 25°C(77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Mycophenolate Mofetil	-----	STEL	7.5 mg/m ³
	IOEL	-----	0.1mg/m ³
Polysorbate 80	NA	NA	NA
Citric acid Anhydrous	OSHA	PEL	NE
	ACGIH	TLV	NE
Sodium hydroxide	OSHA	PEL	(2mg/m ³)
	ACGIH	TLV	TWA
	-----	STEL	(2mg/m ³)
Hydrochloric acid	OSHA	PEL	(7mg/m ³)
	NIOSH	TWA	(7mg/m ³)
	-----	STEL	TWA(7mg/m ³)
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE



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(b) Engineering Controls

Ventilation : local exhaust ventilation necessary

(c) Individual Protection Measures

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting.

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.
Eye Protection	:	Safety glasses or goggles.
Skin Protection	:	Work uniform or lab coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suites) to avoid exposed skin surfaces.
Other Protective Equipment	:	Protective clothing.
Additional Exposure Precautions	:	Wash hands following use. No eating, drinking or smoking when handling this product.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

a)	Appearance	:	A white to off-white, lyophilized cake/powder
b)	Odor	:	No Odor
c)	Odor Threshold	:	None
d)	pH	:	2.7-4.1
e)	Melting Point	:	Not Applicable
f)	Initial Boiling Point	:	Approx to water
g)	Flash Point	:	Not applicable
h)	Evaporation Rate	:	Approx to water
i)	Flammability	:	Non-flammable
j)	Upper Lower Flammability or Explosion Limits	:	Not Applicable
k)	Vapor Pressure:	:	Approx to water
l)	Vapor Density	:	Approx to water
m)	Relative Density	:	Approx to water
n)	Solubility(ies)	:	Soluble in water



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o)	Partition Coefficient: n-octanol/water	:	Not Applicable
p)	Auto-ignition Temperature	:	Not available
q)	Decomposition Temperature	:	Not available
r)	Viscosity	:	Not available

SECTION 10 – STABILITY AND REACTIVITY

a)	Reactivity	Not Reactive
b)	Chemical Stability	Stable
c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur
d)	Conditions to Avoid	High temperatures
e)	Incompatible Materials	Strong acids, oxidizing agents
f)	Hazardous Decomposition Products	Decomposition products of this compound may include potentially hazardous byproduct of carbon monoxide and carbon dioxide oxides of nitrogen.

SECTION 11 – TOXICOLOGICAL INFORMATION

a)	Likely Routes of Exposure	Inhalation, eye/skin contact, or ingestion
b)	Symptoms related to the physical, chemical and toxicological characteristics	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Possible adverse reactions include: diarrhea, leucopenia, sepsis, vomiting



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c)	Delayed and immediate effects and also chronic effects from short and long term exposure	<p><i>Congenital Disorders:</i> Congenital malformations including ear malformations have been reported in offspring of patients exposed to mycophenolate mofetil during pregnancy. <i>Digestive:</i> Colitis, pancreatitis, isolated cases of intestinal villous atrophy.</p> <p><i>Hematologic and Lymphatic:</i> Cases of pure red cell aplasia (PRCA) have been reported in combination with other immunosuppressive agents.</p> <p><i>Respiratory:</i> Interstitial lung disorders, including fatal pulmonary fibrosis, have been reported rarely and should be considered in the differential diagnosis of pulmonary symptoms ranging from dyspnea to respiratory failure in posttransplant patients receiving system activity.</p>
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d) Acute Toxicity:

Component	Type	Route	Species	Dosage
Mycophenolate Mofetil	LD50	Oral	Rabbit	900 mg/kg
Mycophenolate Mofetil	LC50	Inhal	Rat (1Hr)	3124ppm
Mycophenolate Mofetil	LD50	Oral	Rat	250-500mg/kg

Reproductive Effects: Teratogenic (several species)

e) Hazardous Chemical Listings

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

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

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

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.



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SECTION 12 – ECOLOGICAL INFORMATION

a)	Ecotoxicity	<p>-Barely toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC50 ~ 755 mg/l -Highly toxic for algae (<i>Scenedesmus (=Desmodesmus) subspicatus</i>) 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) -Adaptation/recovery of organisms upon prolongation of test duration (<i>Scenedesmus (=Desmodesmus) subspicatus</i>) LOEC (14 d) 1.6 mg/l (nominal concentration) (OECD No. 201, prolonged) -Barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (<i>Daphnia magna</i>) EC50 (48 h) > 100 mg/l (nominal concentration) NOEC (48 h) 27.7 mg/l (average measured concentration) (OECD No. 202) *2 -Acute fish toxicity in a limit test is lower than daphnid or algal</p>
b)	Persistence and degradability	Not data available
c)	Bioaccumulative potential	No adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 100 mg/l (nominal concentration) (Manometric Respirometry Test, OECD No. 301 F)
d)	Mobility in soil	Strong adsorption to activated sludge (water-activated sludge, 24 h, ~22 °C) Kd = 830000 l/kg (Adsorption to activated sludge in biodegradability test)
e)	Other Adverse Effects	Not data available

SECTION 13 – DISPOSAL CONSIDERATIONS

Waste Disposal: - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use take back 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 take back 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.

Container Handling and Disposal: Dispose of container and unused contents in accordance with federal, state and local regulations.



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SECTION 14 – TRANSPORTATION INFORMATION

a)	UN Number	Not available
b)	UN Proper Shipping Name	Environmentally hazardous substance, solid, N.O.S.
c)	Transport Hazard Class(es)	Not available
d)	Packing Group	Not available
e)	Environmental Hazards	Not available
f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
g)	Special Precautions	Not available

DOT: (Class-9) NON-REGULATED IN NON-BULK PACKAGINGS TRANSPORTED BY MOTOR VEHICLES, RAIL CARS OR AIRCRAFT (49CFR 171.4(c)).

ICAO/IATA: (Class-9) EHS

IMDG: (Class-9) Marine pollutant

SECTION 15 – REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA – FDA Exemption - not on inventory

USEPA- Not on this list

SECTION 16 – OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.



SAFETY DATA SHEET

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
IOEL	International Occupational Exposure Limit
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)