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SDS Mycophenolate-Mofetil vers 8-2024

1. Identification of the Substance and the Manufacturer

1.1. Product identifiers

1.1. 1 <i>70uuct</i>				
Product name	Mycophenolate Mofetil 🖑	Formula	<i>C23H31NO7</i>	
Product Code	MYM-001	Molecular weight	433. g/mol	
<u>CAS</u>	128794-94-5 <i></i>	Mixture?	Substance	
<u>ECHA</u>	627-027-6 🕜	PUBCHEM 🖑	<u>CID 5281078</u>	
<u>HSDB</u>	<u>hsdb/7436</u>	<u>RTECS</u>	MP7746700	
Drug bank	<u>/drugs/DB00688</u>			
Comptox EPA	<u>DTXSID3023340 €</u>	<u>CHEBI</u>	<u>CHEBI:8764</u> ∕∂	
	Cellcept Mycophenolate	mofetil		
Synonyms and other names2-Morpholinoethyl (E)-6-(4-hydroxy-6-methoxy-7-methyl-3-oxo-5-phthalanyl)-4-methyl-4-hexenoate systematic name: 4-Hexenoic acid, 6-(1,3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5- isobenzofuranyl)-4-methyl-, 2-(4-morpholinyl)ethyl ester, (E)- 4-Hexenoic acid, 6-(1,3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-, (4-methyl-4-met			p-7-methyl-3-oxo-5-	
Source	(4-morpholinyl)ethyl ester, (E)- From: Synthetic	Version Date	10 October, 2024	
1.2. Intended uses of the Substance and uses advised against				

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1.2.1. Intended use:		1.2.2. Uses advised against:
Research and development.	Manufacturing of substances.	Not a drug,
Laboratory reagent.	To be used by professionals	Not a food additive
Reference material.	only	Not to be used in humans or animals.

1.3. Contacts

1.3.1. Details of the supplier of the SDS		
FERMENTEK ltd	Tel: +972 2 585	3953
4 Yatziv street, POB 47120	Fax: +972 2 585	53943
Jerusalem 97800,	eMail:	Fermentek@Fermentek.com
Israel		Safety@Fermentek.com
	Website:	Fermentek.com

This company is the manufacturer of the product and the supplier of the safety data sheet

1.3.2. Emergency Telephone number

For chemical emergency spill, leak, fire, exposure, or accident calls CHEMTREC day or night: Within USA and Canada: 1-800-424-9300. Outside USA and Canada: +1 703-527-3887





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2. Hazards' identification.

2.1. Classification of the Substance.

To our judgement, hazards of this substance have not been thoroughly investigated

Other authors have classified this substance as H300, H310, H330 (Fatal if swallowed, inhaled or in contact with skin, and H350 may cause cancer. To our opinion, these claims are neither proven experimentally, nor based on available literature

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2.1.1. GHS Classification: According to EU Reg. 1272/2008 and US OSHA 1910.1200)

Not hazardous, not classified according to EU Reg. 1272/2008 and US OSHA 1910.1200).

2.2. GHS Label elements, including precautionary statements

- 2.2.1. Pictogram: { None } Signal word: {None}
- 2.2.2. Hazard Statements

Not hazardous, not classified according to EU Reg. 1272/2008 and US OSHA 1910.1200).

	- / /	0 0 /
2.2.3.	GHS Precautionary St	atements
P203		Obtain, read and follow all safety instructions before use.
P261		Avoid breathing dust or mist.
P264		Wash {hands} thoroughly after handling.
P270		Do not eat, drink or smoke when using this product.
P272		Contaminated work clothing should not be allowed out of the workplace.
P280		Wear protective gloves/protective clothing/eye protection/face protection/hearing protection

2.2.4. GHS Response Phrases:

None

3. Composition/information on ingredients

Substance	
Substance Name:	Mycophenolate Mofetil
Concentration	<=100%
CAS Registry#:	128794-94-5
<i>EC#</i> :	627-027-6
Molecular Formula:	<i>C23H31NO7</i>
Molecular Weight:	433. g/mol
Classification	Not hazardous
Mixture?	Substance





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4. First Aid Measures.

4.1. Description of First Aid Measures.

1 0	
General advice:	First-aiders need to protect themselves. If medical attention is required, show this safety data sheet to the doctor in attendance.
Ingestion:	If swallowed: give water to drink (two glasses at most). Seek medical advice immediately.

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4.2. Most important symptoms and effects, both acute and delayed

General symptoms	See section 11
~ 1	

4.3. Indication of any immediate medical attention and special treatment needed

Note to	physicians	No	data	available

5. Fire-fighting measures.

5.1. Extinguishing media.

Suitable extinguishing media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media	None known
5.2. Other information	
Hazardous combustion products	Carbon oxides, Nitrogene oxides, C23H31NO7
Advice for firefighters	<i>Wear self-contained breathing apparatus for fire fighting if necessary.</i> <i>Wear protective suit.</i>

6. Accidental release measures

6.1. Personal precautions, protective equipment, and emergency procedures

Personal precautionsUse personal protective equipment as required. Keep people away
from and upwind of spill/leak.6.2. Environmental precautionsPrevent further leakage or spillage if safe to do so. Prevent product
from entering drains.6.3. Methods and material for containment and cleaning upPrevent further leakage or spillage if safe to do so. Cover the powder
spill with a plastic sheet or tarp to minimize spreading. Dike far ahead
of liquid spill for later disposal.





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Methods for cleaning up:Clean-up should be dealt with only by qualified personnel familiar
with the specific substance. Cover liquid spill with sand, earth or other
non-combustible absorbent material (e.g., sand, earth, diatomaceous
earth, and vermiculite). Cover the powder spill with a plastic sheet or
tarp to minimize spreading. Sweep up and shovel into suitable
containers for disposal.

7. Handling and storage

7.1. Precautions for safe handling

Adv	ice on safe handling:	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.
7)	Conditions for safe	stanges including any incompatibilities

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions:	Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children. Store at -20 °C.
Suitable packaging	Must only be kept in original packaging.
Incompatible materials:	None known based on information available.
9 Exposure Contr	pols/Dansonal Protection

8. Exposure Controls/Personal Protection

Attiention:

Usually, the product of concern would be present at the intended workplace in miniscule amounts, while surrounded by considerable amounts of other flammable, toxic or otherwise hazardous substances. Therefore, the employer/user should perform a risk assessment prior to the use of this product.

The type of protective equipment must be selected based on the amount and concentration of all dangerous materials being used in the workplace.

All recommendations included in this document are advisory in nature

8.1. Control parameters

Control parameters	Components with workplace control parameters	
8.2. Exposure controls		
Appropriate engineering controls	Showers, Eyewash stations, Ventilation systems Avoid contact with skin, eyes, and clothing. Wash hands before breaks and immediately after handling the product. Use fume-hood for routine work.	





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[PPE=Personal Protection Eq	uipment]
PPE: Respiratory protection	Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
PPE: Hand Protection:	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal techniques to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices, and wash and dry hands
PPE: Eye Protection:	Use a face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU)
PPE: Skin and Body Protection:	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

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8.3. Personal protective equipment

9. Physical and chemical properties

The information given here does not purport specification of warranty of any kind. It is designed only as guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification.

9.1. Physical/chemical properties

Physical State at room temperature	Solid
Appearance	White powder
No further safety relevant data are available	
10. Stability and reactivity	
Reactivity:	No information available.
Chemical stability:	Stable under normal conditions.
Conditions to avoid	Heat, flames and sparks. Sunlight.
Incompatible materials	Strong reducers and exidizers





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Possibility of hazardous reactions	None under normal processing
Hazardous combustion products	See section 5
11. Toxicological inform	
11.1. Information on toxicol	
-	xicological effects of this product have not been thoroughly studied yet.
11.1.1. Acute Toxicity	
Acute toxicity:	Oral, Mouse, TDL0= 7 gram/kg/day 10 weeks
	Human (Female) Oral, TDL0=200 mg/kg
	No fatalities reported among test population
Skin corrosion/irritation:	No data available
Serious eye damage/eye irritation:	No data available
Respiratory or skin sensitization/corrosion:	No data available
11.1.2. Chronic toxicity	
Chronic toxicity	No data available
11.1.3. CRM (Carcinogene, Mutag	gene, Reproductive hazards)
Germ cell mutagenicity:	No data available
Carcinogenicity:	Not classified by IARC
<i>Reproductive toxicity / Teratogenicity:</i>	No data available
11.2. Additional information	
RTECS number	MP7746700
General symptoms	Liver - change in gall bladder structure or function
	Behavioral - muscle contraction or spasticity Gastrointestinal - nausea or vomiting Gastrointestinal - other changes Behavioral - anorexia (human) Gastrointestinal - nausea or vomiting
	Blood - changes in erythrocyte (RBC) count
	changes in serum composition (e.g. TP, bilirubin, cholesterol)
	Gastrointestinal - hypermotility, diarrhea
12. Ecological Informat	tion

0 0	
Eco-Toxicity	No data available
Other adverse effects	No data available





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13. Disposal Considerations

13.1. Waste treatment methods

Waste Disposal	Dispose of in accordance with local regulations
1	

Contaminated packaging Dispose of as unused product

14. Transport information

14.1. UN Number, Proper Shipping Name, Transport Hazard Class, packing group

	IATA	IMDG	ADR/RID	US/DOT
UN Number,	Not hazardous	Not hazardous	Not hazardous	Not hazardous
Proper	(Mycophenolate	(Mycophenolate	(Mycophenolate	(Mycophenolate
shipment name	Mofetil)	Mofetil)	Mofetil)	Mofetil)
Transport	Not hazardous for	Not hazardous for	Not hazardous for	Not hazardous for
hazard Class,	transport	transport	transport	transport
Packing group	Not regulated	Not regulated	Not regulated	Not regulated
Comments		Not marine polutant		

15. Regulatory information

15.1. Safety, health, and environmental regulations/legislation

USA EPA / TSCA	This product is not listed on the USA EPA TSCA (it is for research)
EU ECHA Status	This product is registered with the EU ECHA, Number 627-027-6 REACH: Neither Registered nor PreRegistered. ANNEX III (criteria for 1 - 10 tonne registered substances): Not Listed

16. Other information

16.1. Version information

Version date:8-2024

16.2. Department issuing this SDS

Quality systems and regulatory affairs

16.3. General Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication.

The information given here is designed only as 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 explicitly specified in the text.





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16.4. The users'/employers' responsibility:

Usually, the product of concern would be present at the intended workplace in miniscule amounts, while surrounded by considerable amounts of other flammable, toxic or otherwise hazardous substances.

Therefore, the employer/user should perform a risk assessment by prior to the use of this product. The type of protective equipment must be selected based on the amount and concentration of all dangerous materials being used in the workplace.

All recommendations included in this document are advisory in nature.

16.5. No © copyright



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16.6. End of SDS





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16.7. Appendix A : Abbreviations and acronyms:

Æ	This symbol means, the text looking like a hyperlink, is a clickable link indeed. Of course, these are only active on glass screens, not on paper.
	<i>"From" means the compound was extracted from biomass, whether algal, fungal, microbial or plant material</i>
From /Synthetic	"Synthetic" means this compound has been manufactured by chemical conversion of another compound.
/Semisynthetic	Often, certain product is made by the method of microbial fermentation, purified, and then chemically
	converted into another compound. It may be called "semisynthetic".
	Substance means a single compound. ,
Mixture/Substance/	Mixture means there are two or more pure substances mixed purposely.
Complex	Complex is a mixture of two or more substances which naturally occur together and are sold
Complex	unseparated
Acute Tox.:	Acute toxicity
CAS:	Chemical Abstracts Service
CAS. ChEBI	Chemical Entities of Biological Interest
CNS	Central nervous system
Comptox	CompTox Chemicals Dashboard Resource Hub (EPA)
DOT:	US Department of Transportation
ECHA	European Chemicals Agency
EINECS:	European Inventory of Existing Commercial Chemical Substances
ERVECS. EPA	United States Environmental Protection Agency
Er A Eye Dam.:	Serious eye damage/eye irritation
HSDB	Hazardous Substances Data Bank
HMIS:	Hazardous Substances Data Bank Hazardous Materials Identification System (USA)
IATA:	International Air Transport Association
IMDG:	International Maritime Code for Dangerous Goods
LC50:	Lethal concentration, Median
LD50:	Lethal dose, Median
LD50.	Letal dose, leatst published
NDG	Not dangerous goods (for transport)
NFPA:	National Fire Protection Association USA
NIOSH:	National Institute for Occupational Safety
NOAEL	No-Observed-Adverse-Effects-Level. Highest dose which yelded no results at toxisity test
OSHA:	Occupational Safety & Health
PBT:	Persistent, Bioaccumulative, and Toxic
PEL:	Permissible Exposure Limit
PubChem	An open chemistry database at the National Institutes of Health (NIH). "
REL:	Recommended Exposure Limit
Repr.:	<i>Reproductive toxicity, incl. hazards to reproductive systems, and pregnancy and the offspring.</i>
RTECS:	Registry of Toxic Effects of Chemical Substances. Not free.
Skin Irrit:	Skin corrosion/irritation
STOT/SE	Specific target organ toxicity/Single exposure
STOT/RE	Specific target organ toxicity/Repeated exposure
T3DB	Toxin and Toxin Target Database
	Toxic dose, least published

