

Safety Data Sheet: Mycophenolate Mofetil

Section 1. Identification of the substance/mixture and of the Company

Product identifiers

| | | | |
|--------------|-----------------------|-------------|-----------|
| Product name | Mycophenolate Mofetil | EC Number # | 627-027-6 |
| Product Code | MM | Formula | C23H31NO7 |
| CAS # | 128794-94-5 | RTECS | MP7746700 |
| | | M.W. | 433.49 |

Intended uses of the substance or mixture and uses advised against

| Intended use | Uses advised against: |
|---|--|
| Only for Research and/or Development | Not for drug, Not to be used in humans or animals. Not food additive |

Details of the supplier of the safety data sheet

FERMENTEK Ltd
 4 Yatziv street, POB 47120
 Jerusalem 97800,
 Israel

Tel: +972 2 5853953
 Fax: +972 2 5853943
 eMail: fermentek@fermentek.com
 Website: www.fermentek.com

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

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

Reach: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

Section 2. Hazards identification


Classification of the substance or mixture

2.1. Classification of the substance or mixture / Regulation (EC) No 1272/2008

And: GHS Classification:

| | | | |
|------------------------|--------------|------|----------------------------|
| Acute Toxicity, Oral | (Category 4) | H302 | Harmful if swallowed |
| Acute aquatic toxicity | (Category 1) | H400 | Very toxic to aquatic life |

GHS Label elements, including precautionary statements

| | | |
|------------|---|------------------------|
| Pictogram: |  | Signal word: {Warning} |
|------------|---|------------------------|

GHS Hazard Statements

| | |
|------|----------------------------|
| H302 | Harmful if swallowed |
| H400 | Very toxic to aquatic life |

GHS Precautionary Statements

| | |
|-------------|---|
| | EU (§28, 1272/2008) |
| P264 | Wash face, hands and any exposed skin thoroughly after handling |
| P270 | Do not eat, drink or smoke when using this product |
| P301 + P312 | IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell |
| P330 | Rinse mouth |
| P501 | Dispose of contents/ container to an approved waste disposal plant |
| P273 | Avoid release to the environment |
| P391 | Collect spillage |

Section 3. *Composition/information on ingredients*

Substance

| | |
|-----------------|---|
| Substance name: | Mycophenolate Mofetil |
| | CAS Registry #:128794-94-5 EC#: 627-027-6 |
| | Molecular Formula: C ₂₃ H ₃₁ NO ₇ Molecular Weight: 433.49 |
| | Acute Toxicity, Oral (Category 4) H302 Harmful if swallowed |
| | Aquatic Toxicity, (Category 1) H400 Very toxic to aquatic life |
| Mixture | Not mixture. |

Section 4. *First Aid Measures*

4.1. Description of First Aid Measures

| | |
|-------------------------------------|--|
| General advice: | If symptoms persist, call a physician. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing. If medical attention is required, show this safety data sheet to the doctor. |
| Eye contact: | Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. If symptoms persist, call a physician. |
| Skin Contact: | Consult a physician if necessary. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes |
| Ingestion: | Rinse mouth. Drink plenty of water. If symptoms persist, call a physician. Do NOT induce vomiting. |
| Inhalation: | Remove to fresh air. Call a physician. If breathing is irregular or stopped, administer artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Artificial respiration and/or oxygen may be necessary. Call a physician. Move to fresh air in case of accidental inhalation of vapors. If symptoms persist, call a physician |
| Self-protection of the first aider: | Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. |

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

No information available.

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

Note to physicians Treat symptomatically.

Section 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 |

5.2. Special hazards arising from the substance

| | |
|-------------------------------|-------------------------------|
| Hazardous combustion products | Carbon oxides, Nitrous oxides |
|-------------------------------|-------------------------------|

5.3. Advice for firefighters

| | |
|---|---|
| Special protective equipment for firefighters | Wear self-contained breathing apparatus for fire fighting if necessary. Wear protective suit. |
|---|---|

Section 6. *Accidental release measures*

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions Use personal protective equipment as required. Keep people away from and upwind of spill/leak.

6.2 Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

| | |
|--------------------------|--|
| Methods for containment: | Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal. |
| Methods for cleaning up: | Cover liquid spill with sand, earth or other non-combustible absorbent material (e.g. sand, earth, diatomaceous earth, and vermiculite). Cover powder spill with plastic sheet or tarp to minimize spreading. Sweep up and shovel into suitable containers for disposal. |

Section 7. Handling and storage

7.1. Precautions for safe handling

Advice 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.

7.2. 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.
Incompatible materials: None known based on information available.

Section 8. Exposure Controls/Personal Protection

8.1. Control parameters

Exposure limits

No occupational exposure limits are listed for this material.

OSHA Permissible Exposure Limits No Data Available

NIOSH Recommended Exposure Limits No Data Available

ACGIH Threshold Limit Values No Data Available

8.2. Exposure controls

Appropriate engineering controls

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 fumehood for routine work.

Personal protective equipment

The employer/end user, prior to use of this product should perform all recommendations below are advisory in nature and a risk assessment. The type of protective equipment must be selected based on the amount and concentration of the dangerous material being used in the workplace.

[PPE=Personal Protection Equipment]

| | |
|--------------------------------|--|
| 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. Wear protective clothing. Choose body protection according to the amount and concentration of the dangerous substance at the work place. When deemed needed according to the concentration and amount of this product, use a complete body suit |

Section 9. *Physical and chemical properties*

Physical / chemical properties

| | |
|------------------------------------|------------------------------|
| Physical State at room temperature | Solid / powder / crystalline |
| Color | |
| Melting/freezing point | 240-250oC |

No further safety relevant data are available

Section 10. *Stability and reactivity*

| | |
|---|--------------------------------------|
| Reactivity: | May form explosive peroxides. |
| Chemical stability: | Stable under normal conditions. |
| Conditions to avoid | Heat, flames and sparks. Sunlight. |
| Incompatible materials | Strong reducers and oxidizers |
| Possibility of Hazardous Reactions | None under normal processing |
| Hazardous decomposition products: | Carbon oxides, Nitrogen oxides |

Section 11. *Toxicological information*

Information on toxicological effects

The toxicological effects of this product have not been thoroughly studied.

| | | |
|--|---------------------------|--------------|
| Acute Toxicity | LD50 (oral - rat) | 120 mg/kg |
| | ATE-Mix Oral (estimated) | 500.00 mg/kg |
| Skin corrosion/irritation: | No data available | |
| Serious eye damage/eye irritation: | No data available | |
| Respiratory or skin sensitization: | No data available | |
| Germ cell mutagenicity: | No data available | |
| Carcinogenicity: | No data available. | |
| Reproductive toxicity / Teratogenicity: | No data available | |
| STOT-SE – single exposure (GHS): | No data available | |
| STOT-RE – repeated exposure (GHS): | No data available | |
| Aspiration hazard: | No data available | |
| Potential Health Effects | | |
| Inhalation: | No data available | |
| Skin | No data available | |
| Eyes: | No data available | |
| Ingestion | Harmful if swallowed | |
| Signs and Symptoms of Exposure | No information available. | |
| Additional information: | RTECS: MP7746700 | |

Section 12. *Ecological Information*

| | |
|------------------------------|---|
| Eco-Toxicity | May cause long lasting harmful effects to aquatic life. |
| Other adverse effects | No further relevant information available. |

Section 13. *Disposal Considerations*

Waste treatment methods

| | |
|--|---|
| Waste from residues / unused products | Dispose of in accordance with local regulations |
| Contaminated packaging | Dispose of as unused product |

Section 14. *Transport information*

UN number, Proper Shipping Name, Transport Hazard Class, packing group

| | US DOT | US IATA | RID / ADR | US IMDG |
|---|---|---|---|---|
| UN Number UN proper shipping name | UN 3077 Environmentally hazardous substance, solid, n.o.s (Mycophenolate Mofetil) | UN 3077 Environmentally hazardous substance, solid, n.o.s (Mycophenolate Mofetil) | UN 3077 Environmentally hazardous substance, solid, n.o.s (Mycophenolate Mofetil) | UN 3077 Environmentally hazardous substance, solid, n.o.s (Mycophenolate Mofetil) |
| Transport Hazard Class, & Packing Group | 9 Pg III | 9 Pg III | 9 Pg III | 9 Pg III |

Section 15. *Regulatory information*

Safety, health and environmental regulations/legislation

| | |
|----------------------------|--|
| USA EPA / TSCA | This product is not listed on the USA EPA TSCA |
| European Union regulations | Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at Work. |
| EU ECHA Status | On C/L inventory; EU number <627-027-6> |
| CA: DSL/NDSL Status | This product is not listed on the Canadian DSL/NDSL |

Section 16. *Other information*

Date of revision: 10 December, 2018

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 specified in the text.

End of SDS

