



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

|                                                                            |                                           |                                     |
|----------------------------------------------------------------------------|-------------------------------------------|-------------------------------------|
| <b>SDS Title:</b><br>Mycophenolate Mofetil for Injection Safety Data Sheet | <b>SDS Number:</b><br>SDS-000039          | <b>Page Number:</b><br>Page 1 of 18 |
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## Section 1. Identification

**GHS product identifier** : Mycophenolate Mofetil for Injection

**Other means of identification** : 2-morpholinoethyl (E)-6-(1,3dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4hexenoate

**Product type** : Powder.

### Relevant identified uses of the substance or mixture and uses advised against

**Product use** : Pharmaceuticals (For intended use only).  
Observe technical data sheet/instructions for use.  
Specific Treatments: Immunosuppressive agent.

**Area of application** : Professional applications.

**Supplier's details** : Meitheal Pharmaceuticals, Inc.  
8700 W. Bryn Mawr, Suite 600S  
Chicago, IL 60631

Telephone: 224-443-4617  
www.meithealpharma.com

**e-mail address of person responsible for this SDS** : info@meithealpharma.com

**Emergency telephone number (with hours of operation)** : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

## Section 2. Hazards identification

**OSHA/HCS status** : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

**Classification of the substance or mixture** :  
H302 COMBUSTIBLE DUSTS  
H319 ACUTE TOXICITY (oral) - Category 4  
EYE IRRITATION - Category 2A  
Percentage of the mixture consisting of ingredient(s) of unknown acute oral toxicity: 11.7%

### GHS label elements

**Hazard pictograms** :



**Signal word** : Warning



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## Section 2. Hazards identification

|                                         |                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Hazard statements</b>                | : H302 - Harmful if swallowed.<br>H319 - Causes serious eye irritation.<br>May form combustible dust concentrations in air.                                                                                                                                                                                                                |
| <b>Precautionary statements</b>         |                                                                                                                                                                                                                                                                                                                                            |
| <b>Prevention</b>                       | : P280 - Wear eye or face protection.<br>P270 - Do not eat, drink or smoke when using this product.<br>P264 - Wash thoroughly after handling.                                                                                                                                                                                              |
| <b>Response</b>                         | : P301 + P312, P330 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. Rinse mouth.<br>P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P337 + P313 - If eye irritation persists: Get medical advice or attention. |
| <b>Storage</b>                          | : Not applicable.                                                                                                                                                                                                                                                                                                                          |
| <b>Disposal</b>                         | : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.                                                                                                                                                                                                                 |
| <b>Supplemental label elements</b>      | : Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Prevent dust accumulation.                                                                                                                                                                                 |
| <b>Hazards not otherwise classified</b> | : None known.                                                                                                                                                                                                                                                                                                                              |
| <b>Hazards identified when used</b>     | : No known significant effects or critical hazards.                                                                                                                                                                                                                                                                                        |

## Section 3. Composition/information on ingredients

|                                      |                                                                                                                  |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------|
| <b>Substance/mixture</b>             | : Mixture                                                                                                        |
| <b>Other means of identification</b> | : 2-morpholinoethyl (E)-6-(1,3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4hexenoate |

| Ingredient name                                                                                                                     | Synonyms       | %         | Identifiers      |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------|-----------|------------------|
| 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)- | -              | ≥80       | CAS: 128794-94-5 |
| Hydrochloric acid                                                                                                                   | -              | ≥5 - ≤10  | CAS: 7647-01-0   |
| Sorbitan monooleate, ethoxylated                                                                                                    | Polysorbate 80 | ≥1 - ≤5   | CAS: 9005-65-6   |
| citric acid                                                                                                                         | Citric acid    | ≥0.1 - ≤1 | CAS: 77-92-9     |
| sodium hydroxide                                                                                                                    | -              | ≥0.1 - ≤1 | CAS: 1310-73-2   |

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

**There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.**



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## Section 4. First aid measures

### Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : Harmful if swallowed.

#### Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:  
pain or irritation  
watering  
redness
- Inhalation** : Adverse symptoms may include the following:  
respiratory tract irritation  
coughing
- Skin contact** : No specific data.
- Ingestion** : No specific data.



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## Section 4. First aid measures

### Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

## Section 5. Fire-fighting measures

### Extinguishing media

- Suitable extinguishing media** : Use dry chemical powder.
- Unsuitable extinguishing media** : Do not use water jet.

**Specific hazards arising from the chemical** : May form explosible dust-air mixture if dispersed.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:  
carbon dioxide  
carbon monoxide  
nitrogen oxides  
halogenated compounds

**Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

**Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

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## Section 6. Accidental release measures

**Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### Methods and materials for containment and cleaning up

- Small spill** : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor.

## Section 7. Handling and storage

### Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Storage temperature: 25°C (77°F). Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.



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## Section 8. Exposure controls/personal protection

### Control parameters

#### Occupational exposure limits

| <b>Ingredient name</b>                                                                                                                                   | <b>Exposure limits</b>                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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)-<br>Hydrochloric acid | None.<br><br><b>ACGIH TLV (United States, 1/2025) A4.</b><br>C: 2 ppm.<br><b>NIOSH REL (United States, 10/2020)</b><br>CEIL: 5 ppm.<br>CEIL: 7 mg/m <sup>3</sup> .<br><b>OSHA PEL (United States, 5/2018)</b><br>CEIL: 5 ppm.<br>CEIL: 7 mg/m <sup>3</sup> .<br><b>CAL OSHA PEL (United States, 1/2025)</b><br>C: 2 ppm.<br>TWA 8 hours: 0.45 mg/m <sup>3</sup> .<br>TWA 8 hours: 0.3 ppm. |
| Sorbitan monooleate, ethoxylated<br>citric acid<br>sodium hydroxide                                                                                      | None.<br>None.<br><b>ACGIH TLV (United States, 1/2025)</b><br>C: 2 mg/m <sup>3</sup> .<br><b>NIOSH REL (United States, 10/2020)</b><br>CEIL: 2 mg/m <sup>3</sup> .<br><b>OSHA PEL (United States, 5/2018)</b><br>TWA 8 hours: 2 mg/m <sup>3</sup> .<br><b>CAL OSHA PEL (United States, 1/2025)</b><br>C: 2 mg/m <sup>3</sup> .                                                             |

#### Biological exposure indices

None known.

#### **Appropriate engineering controls**

- : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

#### **Environmental exposure controls**

- : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

#### Individual protection measures

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## Section 8. Exposure controls/personal protection

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles. If operating conditions cause high dust concentrations to be produced, use dust goggles.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

## Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

### Appearance

- Physical state** : Solid. [Powder.]
- Color** : White to off-white.
- Odor** : Odorless.
- Odor threshold** : Not available.
- pH** : 2.7 to 4.1 (Reconstitution solution)
- Melting point** : Not available.
- Boiling point or initial boiling point and boiling range** : Not available.
- Flash point** : Not applicable.
- Evaporation rate** : Not available.



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## Section 9. Physical and chemical properties

**Flammability** : Not available.

**Lower and upper explosion limit/flammability limit** : Not applicable.

**Vapor pressure** : Not available.

**Relative vapor density** : Not applicable.

**Relative density** : Not available.

**Density** : Not available.

|                          |                         |                                  |
|--------------------------|-------------------------|----------------------------------|
| <b>Solubility(ies)</b> : | <b>Media</b>            | <b>Result</b>                    |
|                          | cold water<br>hot water | Easily soluble<br>Easily soluble |

**Miscible with water** : Yes.

**Partition coefficient: n-octanol/water** : Not applicable.

**Auto-ignition temperature** : Not applicable.

**Decomposition temperature** : Not available.

**SADT** : Not available.

**Viscosity** : Dynamic (room temperature): Not available.  
Kinematic (room temperature): Not available.  
Kinematic (40°C (104°F)): Not available.

### Particle characteristics

**Median particle size** : Not available.

### Other information

**Physical/chemical properties comments** : No additional information.

## Section 10. Stability and reactivity

**Reactivity** : No specific test data related to reactivity available for this product or its ingredients.

**Chemical stability** : The product is stable.

**Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.  
Under normal conditions of storage and use, hazardous polymerization will not occur.

**Conditions to avoid** : Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Prevent dust accumulation. Avoid high temperatures.



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## Section 10. Stability and reactivity

**Incompatible materials** : Reactive or incompatible with the following materials:  
oxidizing materials  
Reactive or incompatible with the following materials: acids.

**Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

##### **Product/ingredient name**

Sorbitan monooleate, ethoxylated

citric acid

##### **Result**

**Rat - Oral - LD50**

34500 ul/kg

**Rat - Oral - LD50**

3 g/kg

**Rat - Male, Female - Dermal - LD50**

>2000 mg/kg

OECD [Acute Dermal Toxicity]

**Conclusion/Summary [Product]** : Not available.

#### Skin corrosion/irritation

##### **Product/ingredient name**

citric acid

##### **Result**

**Rabbit - Skin - Mild irritant**

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 500 mg

**Rabbit - Skin - Moderate irritant**

Amount/concentration applied: 0.5 ml

**Rabbit - Skin - Severe irritant**

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 500 mg

**Conclusion/Summary [Product]** : Not available.

#### Serious eye damage/eye irritation

##### **Product/ingredient name**

##### **Result**



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## Section 11. Toxicological information

|                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hydrochloric acid                | <b>Rabbit - Eyes - Mild irritant</b><br>Duration of treatment/exposure: 0.5 minutes<br>Amount/concentration applied: 5 mg                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Sorbitan monooleate, ethoxylated | <b>Rabbit - Eyes - Mild irritant</b><br>Amount/concentration applied: 150 mg                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| citric acid                      | <b>Rabbit - Eyes - Severe irritant</b><br>Duration of treatment/exposure: 24 hours<br>Amount/concentration applied: 750 ug                                                                                                                                                                                                                                                                                                                                                                                                                          |
| sodium hydroxide                 | <b>Rabbit - Eyes - Mild irritant</b><br>Amount/concentration applied: 400 ug<br><b>Rabbit - Eyes - Severe irritant</b><br>Duration of treatment/exposure: 24 hours<br>Amount/concentration applied: 50 ug<br><b>Rabbit - Eyes - Severe irritant</b><br>Amount/concentration applied: 1 %<br><b>Rabbit - Eyes - Severe irritant</b><br>Duration of treatment/exposure: 24 hours<br>Amount/concentration applied: 1 mg<br><b>Rabbit - Eyes - Severe irritant</b><br>Duration of treatment/exposure: 0.5 minutes<br>Amount/concentration applied: 1 mg |

**Conclusion/Summary [Product]** : Not available.

### Respiratory corrosion/irritation

**Conclusion/Summary [Product]** : Not available.

### Respiratory or skin sensitization

#### **Skin**

**Conclusion/Summary [Product]** : Not available.

#### **Respiratory**

**Conclusion/Summary [Product]** : Not available.

### Germ cell mutagenicity

**Conclusion/Summary [Product]** : Not available.

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## Section 11. Toxicological information

### Carcinogenicity

**Conclusion/Summary [Product]** : Not available.

### Classification

| Product/ingredient name | OSHA | IARC | NTP |
|-------------------------|------|------|-----|
| Hydrochloric acid       | -    | 3    | -   |

### Reproductive toxicity

**Conclusion/Summary [Product]** : Not available.

### Specific target organ toxicity (single exposure)

#### **Product/ingredient name**

Hydrochloric acid

citric acid

sodium hydroxide

#### **Result**

SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)  
(Respiratory tract irritation) - Category 3  
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)  
(Respiratory tract irritation) - Category 3  
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)  
(Respiratory tract irritation) - Category 3

### Specific target organ toxicity (repeated exposure)

Not available.

### Aspiration hazard

Not available.

### Information on the likely routes of exposure

Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

### Potential acute health effects

#### **Eye contact**

: Causes serious eye irritation.

#### **Inhalation**

: Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.

#### **Skin contact**

: No known significant effects or critical hazards.

#### **Ingestion**

: Harmful if swallowed.

### Symptoms related to the physical, chemical and toxicological characteristics

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## Section 11. Toxicological information

|                     |                                                                                            |
|---------------------|--------------------------------------------------------------------------------------------|
| <b>Eye contact</b>  | : Adverse symptoms may include the following:<br>pain or irritation<br>watering<br>redness |
| <b>Inhalation</b>   | : Adverse symptoms may include the following:<br>respiratory tract irritation<br>coughing  |
| <b>Skin contact</b> | : No specific data.                                                                        |
| <b>Ingestion</b>    | : No specific data.                                                                        |

### Delayed and immediate effects and also chronic effects from short and long term exposure

#### Short term exposure

|                                    |                  |
|------------------------------------|------------------|
| <b>Potential immediate effects</b> | : Not available. |
| <b>Potential delayed effects</b>   | : Not available. |

#### Long term exposure

|                                    |                  |
|------------------------------------|------------------|
| <b>Potential immediate effects</b> | : Not available. |
| <b>Potential delayed effects</b>   | : Not available. |

### Potential chronic health effects

**Conclusion/Summary [Product]** : Not available.

|                              |                                                                                        |
|------------------------------|----------------------------------------------------------------------------------------|
| <b>General</b>               | : Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation. |
| <b>Carcinogenicity</b>       | : No known significant effects or critical hazards.                                    |
| <b>Mutagenicity</b>          | : No known significant effects or critical hazards.                                    |
| <b>Reproductive toxicity</b> | : No known significant effects or critical hazards.                                    |

### Numerical measures of toxicity

#### Acute toxicity estimates

| Product/ingredient name                                                                                                             | Oral (mg/kg) | Dermal (mg/kg) | Inhalation (gases) (ppm) | Inhalation (vapors) (mg/l) | Inhalation (dusts and mists) (mg/l) |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------|----------------|--------------------------|----------------------------|-------------------------------------|
| Mycophenolate Mofetil for Injection                                                                                                 | 505.7        | N/A            | N/A                      | N/A                        | N/A                                 |
| 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)- | 500          | N/A            | N/A                      | N/A                        | N/A                                 |
| citric acid                                                                                                                         | 3000         | 2500           | N/A                      | N/A                        | N/A                                 |



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|                                                                            |                                           |                                      |
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## Section 12. Ecological information

### Toxicity

#### **Product/ingredient name**

#### **Result**

Hydrochloric acid

**Acute - LC50 - Marine water**Effect: MortalityCrustaceans - Green crab - *Carcinus**maenas* - Adult

240 mg/l [48 hours]

**Acute - LC50 - Fresh water**Effect: MortalityFish - Western mosquitofish - *Gambusia**affinis* - Adult

282 ppm [96 hours]

citric acid

**Acute - LC50 - Marine water**Effect: MortalityCrustaceans - Green crab - *Carcinus**maenas* - Adult

160 mg/l [48 hours]

sodium hydroxide

**Acute - LC50 - Fresh water**Effect: MortalityFish - Western mosquitofish - *Gambusia**affinis* - Adult

125 ppm [96 hours]

**Acute - EC50 - Fresh water**Effect: Intoxication

Crustaceans - Water flea -

*Ceriodaphnia dubia* - NeonateAge: <24 hours

40.38 mg/l [48 hours]

#### **Conclusion/Summary [Product]**

: Not available.

### Persistence and degradability

#### **Conclusion/Summary [Product]**

: Not available.

| <b>Product/ingredient name</b> | <b>Aquatic half-life</b> | <b>Photolysis</b> | <b>Biodegradability</b> |
|--------------------------------|--------------------------|-------------------|-------------------------|
| citric acid                    | -                        | -                 | Readily                 |

### Bioaccumulative potential

| <b>Product/ingredient name</b>                                                                                                      | <b>LogP<sub>ow</sub></b> | <b>BCF</b> | <b>Potential</b> |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------|------------|------------------|
| 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)- | 2.38                     | -          | Low              |
| citric acid                                                                                                                         | -1.8                     | -          | Low              |

|                                                                            |                                           |                                      |
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## Section 12. Ecological information

### Mobility in soil

**Soil/Water partition coefficient** : Not available.

### Other adverse effects

No known significant effects or critical hazards.

## Section 13. Disposal considerations

**Disposal methods** : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

## Section 14. Transport information

|                                   | <b>DOT Classification</b> | <b>IMDG</b>                                                                                                                                                                              | <b>IATA</b>                                                                                                                                                                              |
|-----------------------------------|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>UN number</b>                  | Not regulated.            | UN3077                                                                                                                                                                                   | UN3077                                                                                                                                                                                   |
| <b>UN proper shipping name</b>    | -                         | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (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)-) | Environmentally hazardous substance, solid, n.o.s. (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)-) |
| <b>Transport hazard class(es)</b> | -                         | 9<br>              | 9<br>          |
| <b>Packing group</b>              | -                         | III                                                                                                                                                                                      | III                                                                                                                                                                                      |
| <b>Environmental hazards</b>      | No.                       | Yes.                                                                                                                                                                                     | Yes.                                                                                                                                                                                     |

### Additional information

**DOT Classification** : **Remarks** 49 CFR 171.4 (c)



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## Section 14. Transport information

- IMDG** : This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.  
**Emergency schedules** F-A, S-F  
**Special provisions** 274, 335, 375, 966, 967, 969
- IATA** : This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.  
**Quantity limitation** Passenger and Cargo Aircraft: 400 kg. Packaging instructions: 956. Cargo Aircraft Only: 400 kg. Packaging instructions: 956. Limited Quantities - Passenger Aircraft: 30 kg. Packaging instructions: Y956.  
**Special provisions** A97, A158, A179, A197, A215
- Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport in bulk according to IMO instruments** : Not available.

## Section 15. Regulatory information

- U.S. Federal regulations** : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined  
**United States inventory (TSCA 8b):** All components are active or exempted.  
**Clean Water Act (CWA) 311:** Hydrochloric acid; sodium hydroxide  
**Clean Air Act (CAA) 112 regulated toxic substances:** Hydrochloric acid

### TSCA 12(b) - Chemical export notification

Not applicable.

- Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)** : Listed
- Clean Air Act Section 602 Class I Substances** : Not listed
- Clean Air Act Section 602 Class II Substances** : Not listed
- DEA List I Chemicals (Precursor Chemicals)** : Not listed
- DEA List II Chemicals (Essential Chemicals)** : Not listed

### SARA 302/304

### Composition/information on ingredients

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## Section 15. Regulatory information

| Name              | %        | EHS  | SARA 302 TPQ |           | SARA 304 RQ |           |
|-------------------|----------|------|--------------|-----------|-------------|-----------|
|                   |          |      | (lbs)        | (gallons) | (lbs)       | (gallons) |
| Hydrochloric acid | ≥5 - ≤10 | Yes. | 500          | -         | 5000        | -         |

**SARA 304 RQ** : 68493.2 lbs / 31095.9 kg

### SARA 311/312

**Classification** : COMBUSTIBLE DUSTS  
ACUTE TOXICITY (oral) - Category 4  
EYE IRRITATION - Category 2A

### Composition/information on ingredients

| Name                                                                                                                                 | %         | Classification                                                                                                                                                                                                                                      |
|--------------------------------------------------------------------------------------------------------------------------------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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)- | ≥80       | ACUTE TOXICITY (oral) - Category 4                                                                                                                                                                                                                  |
| Hydrochloric acid                                                                                                                    | ≥5 - ≤10  | CORROSIVE TO METALS - Category 1<br>SKIN CORROSION - Category 1B<br>SERIOUS EYE DAMAGE - Category 1<br>SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3<br>HNOC - Corrosive to digestive tract          |
| Sorbitan monooleate, ethoxylated                                                                                                     | ≥1 - ≤5   | EYE IRRITATION - Category 2B                                                                                                                                                                                                                        |
| citric acid                                                                                                                          | ≥0.1 - ≤1 | SKIN IRRITATION - Category 2<br>EYE IRRITATION - Category 2A<br>SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3                                                                                        |
| sodium hydroxide                                                                                                                     | ≥0.1 - ≤1 | CORROSIVE TO METALS - Category 1<br>SKIN CORROSION - Category 1A<br>SERIOUS EYE DAMAGE - Category 1<br>SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3<br>HNOC - Corrosive to digestive tract [severe] |

### SARA 313

|                                        | Product name      | CAS number | %        |
|----------------------------------------|-------------------|------------|----------|
| <b>Form R - Reporting requirements</b> | Hydrochloric acid | 7647-01-0  | ≥5 - ≤10 |
| <b>Supplier notification</b>           | Hydrochloric acid | 7647-01-0  | ≥5 - ≤10 |

SARA 313 notifications must not be detached from the SDS and any copying and redistribution of the SDS shall include copying and redistribution of the notice attached to copies of the SDS subsequently redistributed.

### State regulations

**Massachusetts** : The following components are listed: HYDROGEN CHLORIDE

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## Section 15. Regulatory information

- New York** : The following components are listed: Hydrochloric acid  
**New Jersey** : The following components are listed: HYDROGEN CHLORIDE  
**Pennsylvania** : The following components are listed: HYDROCHLORIC ACID  
**California Prop. 65**

This product does not require a Safe Harbor warning under California Prop. 65.

### International regulations

#### Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

#### Montreal Protocol

Not listed.

#### Stockholm Convention on Persistent Organic Pollutants

Not listed.

#### Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

#### UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

## Section 16. Other information

### Hazardous Material Information System (U.S.A.)

|                  |   |   |
|------------------|---|---|
| Health           | / | 2 |
| Flammability     |   | 3 |
| Physical hazards |   | 0 |

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

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### National Fire Protection Association (U.S.A.)



### Procedure used to derive the classification

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## Section 16. Other information

| Classification                                                                          | Justification                                                     |
|-----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| COMBUSTIBLE DUSTS<br>ACUTE TOXICITY (oral) - Category 4<br>EYE IRRITATION - Category 2A | On basis of test data<br>Calculation method<br>Calculation method |

### History

|                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Date of issue/Date of revision</b> | : 08/24/2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Date of previous issue</b>         | : 09/09/2024                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Version</b>                        | : 4.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Prepared by</b>                    | : Sphera Solutions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Key to abbreviations</b>           | : ATE = Acute Toxicity Estimate<br>BCF = Bioconcentration Factor<br>GHS = Globally Harmonized System of Classification and Labelling of Chemicals<br>IATA = International Air Transport Association<br>IBC = Intermediate Bulk Container<br>IMDG = International Maritime Dangerous Goods<br>IMO = International Maritime Organization<br>LogPow = logarithm of the octanol/water partition coefficient<br>MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)<br>N/A = Not available<br>SGG = Segregation Group<br>TDG = Transportation of Dangerous Goods<br>UN = United Nations |
| <b>References</b>                     | : HCS (U.S.A.)- Hazard Communication Standard<br>International transport regulations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

Indicates information that has changed from previously issued version.

### Notice to reader

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