SAFETY DATA SHEET



1. Identification

Product identifier MYCOPHENOLIC ACID

Other means of identification

Catalog number 1A06830 24280-93-1 **CAS** number

Chemical name (4E)-6-(4-Hydroxy-6-methoxy-7-methyl-3-oxo-1,3-dihydroisobenzofuran-5-yl)-4-methylhex-4-enoic

301-881-0666

Acid

Recommended use For analytical laboratory use only.

Not for use as a drug. Not for administration to humans or animals. **Recommended restrictions**

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

U. S. Pharmacopeia Company name **Address** 12601 Twinbrook Parkway

Rockville

MD

20852-1790 **United States**

Telephone **Customer Service**

Website www.usp.org E-mail AMTech@usp.org

CHEMTREC within US & **Emergency phone number** 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Acute toxicity, oral **Health hazards** Category 4

> Germ cell mutagenicity Category 2 Carcinogenicity Category 1 Reproductive toxicity Category 1 Specific target organ toxicity, repeated Category 1

exposure

Not classified. **Environmental hazards OSHA** defined hazards Not classified.

Label elements



Signal word Danger

Harmful if swallowed. Suspected of causing genetic defects. May cause cancer. May damage **Hazard statement** fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after

handling. Wear protective gloves/protective clothing/eye protection/face protection.

If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned: Response

Get medical advice/attention.

Store locked up. Storage

Material name: MYCOPHENOLIC ACID USP SDS US **Disposal**

Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
MYCOPHENOLIC ACID		24280-93-1	100

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Rinse with water. Get medical attention if irritation develops and persists. Eve contact

If ingestion of a large amount does occur, call a poison control center immediately. Rinse mouth. Ingestion

Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head

low so that stomach content doesn't get into the lungs.

Most important

symptoms/effects, acute and

delayed

Potent pharmacologically active material. Occupational exposure to small amounts may cause

physiological effects.

Indication of immediate medical attention and special

treatment needed

Provide general supportive measures and treat symptomatically.

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from General information an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is

1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must

receive immediate medical attention.

5. Fire-fighting measures

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding Suitable extinguishing media

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire fighting

Specific methods

equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Use standard firefighting procedures and consider the hazards of other involved materials.

Firefighters should use self-contained breathing equipment and protective clothing.

No unusual fire or explosion hazards noted. General fire hazards

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For

waste disposal, see section 13 of the SDS.

Avoid discharge into drains, water courses or onto the ground. **Environmental precautions**

Material name: MYCOPHENOLIC ACID USP SDS US 2/7 1A06830 Version #: 01 Issue date: 05-24-2024

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure

product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering

controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection

against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of

existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.

Form Crystalline solid.

Color White.

Odor Not available.
Odor threshold Not available.
pH Not available.
Melting point/freezing point Not available.
Initial boiling point and boiling Not available.

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure <0.0000001 kPa (77 °F (25 °C))

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Molecular formula C17H20O6
Molecular weight 320.34 g/mol

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.

Ingestion Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Gastrointestinal disturbances. Skin rash. Abdominal pain. Swelling. Fever. Chills. Infection. Back pain. Fast heartbeat. Pounding heartbeat. Irregular heartbeat. Tiredness. Joint pain. Headache. Insomnia. Confusion. Tremors. Bleeding or bruising. It is not known if this material causes the same effects.

Information on toxicological effects

Acute toxicity Harmful if swallowed. A related material showed oral toxicity in animals.

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete. **Skin sensitization** Knowledge about health hazard is incomplete.

Germ cell mutagenicity Suspected of causing genetic defects.

It is not known if this material causes the same effects.

Carcinogenicity May cause cancer.

It is not known if this material causes the same effects.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity May damage fertility or the unborn child.

A related material was shown to cause developmental toxicity in animal studies.

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Material name: MYCOPHENOLIC ACID USP SDS US

Specific target organ toxicity -

repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Based on available data, the classification criteria are not met. **Aspiration hazard**

Potent pharmacologically active material. Occupational exposure to small amounts may cause **Further information**

physiological effects.

12. Ecological information

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this substance.

Bioaccumulative potential

No data available. No data available.

Mobility in soil Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

UN number

UN3077

UN proper shipping name

Environmentally hazardous substance, solid, n.o.s. (MYCOPHENOLIC ACID), MARINE

POLLUTANT

Transport hazard class(es)

Class 9 Subsidiary risk **Packing group** Ш

Environmental hazards

Marine pollutant Yes Packaging exceptions 155 Packaging non bulk 213 Packaging bulk 240

IATA

UN3077 **UN** number

UN proper shipping name Transport hazard class(es) Environmentally hazardous substance, solid, n.o.s. (MYCOPHENOLIC ACID)

9 Class Subsidiary risk Packing group Ш

Other information

Passenger and cargo

aircraft

Allowed with restrictions.

Cargo aircraft only

Allowed with restrictions.

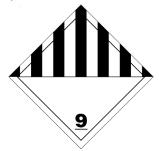
Transport in bulk according to Annex II of MARPOL 73/78 and

the IBC Code

Not applicable.

Material name: MYCOPHENOLIC ACID

DOT; IATA



Marine pollutant



General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Yes

Classified hazard

Acute toxicity (any route of exposure)

categories

Germ cell mutagenicity Carcinogenicity

Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

Material name: MYCOPHENOLIC ACID USP SDS US 6/7 1A06830 Version #: 01 Issue date: 05-24-2024

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No *A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing

16. Other information, including date of preparation or last revision

Issue date 05-24-2024

Version #

country(s).

USP materials are sold for analytical laboratory use only, and NOT for human consumption. The Disclaimer

information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been compiled by USP staff from sources considered to be scientifically reliable but has not been independently verified by USP. USP does not guarantee the accuracy or completeness of the information from these sources included herein nor should the statements contained herein be considered an official expression by USP. USP does not independently create or develop the information included in this safety data sheet. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained

herein.

USP SDS US 7/7 1A06830 Version #: 01 Issue date: 05-24-2024