

TACROLIMUSUM MONOHYDRICUM

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Tacrolimus
Tacrolimusum monohydricum
Tacrolimus
Tacrolimus
Tacrolimus

N° CAS: 104987-11-3

N° EC: 658-056-2

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient.

1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV
Neerlandweg 24
2610 Wilrijk
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 3	H301
Repr. 2	H361
STOT RE 1	H372

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H301	Toxic if swallowed.
H361	Suspected of damaging fertility or the unborn child.

TACROLIMUSUM MONOHYDRICUM

H372	Causes damage to organs through prolonged or repeated exposure.
Precautionary statements:	
P203	Obtain, read and follow all safety instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P264	Wash hands [and ...] thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P301+P316	IF SWALLOWED: Get emergency medical help immediately.
P318	If exposed or concerned, get medical advice.
P319	Get medical help if you feel unwell.
P321	Specific treatment (see section 4 on this label).
P330	Rinse mouth.
P405	Store locked up.
P501	Dispose of contents/container to local/regional/national/international regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Tacrolimus
IUPAC name:	(1R,9S,12S,13R,14S,17R,18E,21S,23S,24R,25S,27R)-1,14-dihydroxy-12-[(1Z)-1-[(1R,3R,4R)-4-hydroxy-3-methoxycyclohexyl]prop-1-en-2-yl]-23,25-dimethoxy-13,19,21,27-tetramethyl-17-(prop-2-en-1-yl)-11,28-dioxo-4-azatricyclo[22.3.1.0 ^{4,9}]octacos-18-ene-2,3,10,16-tetrone
Synonyms:	Prograf Fujimycin
N° CAS:	104987-11-3
N° EC:	658-056-2
Molecular Formula:	C ₄₄ H ₆₉ NO ₁₂
Content:	97.0 % to 102.0 % for the sum of tacrolimus, tacrolimus compound I and tacrolimus compound II (anhydrous substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

TACROLIMUSUM MONOHYDRICUM

General notes:	Consult a doctor. Show safety data sheet to doctor on duty.
After inhalation:	Remove to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including under eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam, dry powder, carbon dioxide, sand, water fog. Nearby fires (fire-exposed containers): Water spray or water fog.
Unsuitable extinguishing media:	Direct water jet.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to prevent decomposition of product and development of health hazards. Always use full fire protection. Collect water from entering sewage system. Dispose of contaminated water used to extinguish and the remains of the second in accordance with current regulations.
Protection against fire:	Helmet with visor, fireproof clothing (jacket and trousers with straps around the arms, legs and waist), gloves (fireproof and dielectric), a mask with face mask covering the entire face of the operator or self (self protector) in the case of large amounts of smoke.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

See section 7 for specific handling precautions.

For emergency responders

See section 7 for specific handling precautions.

TACROLIMUSUM MONOHYDRICUM

6.2 Environmental precautions

Prevent product from entering sewers, surface and ground water.

6.3 Methods and material for containment and cleaning up

Collect and prepare for disposal without creating dust.

Store in suitable, closed containers for disposal.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid contact with skin, eyes and clothing. Wash hands thoroughly after handling.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Wash hands thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed in a dry and well-ventilated place.
Storage – away from:	Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Unprotected handling is not recommended. Use appropriate control measures such as fume hood, isolator (e.g. glove bag, glove box) or closed material transfer systems.

Individual protection measures

Eye/face protection:	Protective face shields and safety goggles according to EN166.
Skin protection:	Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.
Hand protection:	Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

TACROLIMUSUM MONOHYDRICUM

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White, crystalline solid.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Not available.
Solubility in water:	Not available.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molecular weight: 882.03 g/mol

SECTION 10: STABILITY AND REACTIVITY

TACROLIMUSUM MONOHYDRICUM

10.1 Reactivity

The product is stable when used properly.

10.2 Chemical stability

Not available.

10.3 Possibility of hazardous reactions

None in particular.

10.4 Conditions to avoid

High temperatures.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Hazardous decomposition of the product under fire conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity (LD ₅₀ , mouse): > 200 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	RTECS: KD4200000

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Toxic if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

TACROLIMUSUM MONOHYDRICUM

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 2811
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), TOXIC SOLID, ORGANIC, N.O.S. (TACROLIMUS)
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 6.1
IATA/ICAO (Air) :

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Not available.
IATA/ICAO (Air) :

14.6 Special precautions for user

Not available.

TACROLIMUSUM MONOHYDRICUM

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

The product is classified according to the hazardous materials conventions.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Risk phrases:

R25 Toxic if swallowed.
R48 Danger of serious damage to health by prolonged exposure.
R62 Possible risk of impaired fertility.
R63 Possible risk of harm to the unborn child.

Safety phrases:

S23 Do not breathe dust/fume/gas/mist/vapours/spray.
S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
S46 If swallowed, seek medical advice immediately and show this container or label.
S53 Avoid exposure - obtain special instructions before use.
S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.
S64 If swallowed, rinse mouth with water (only if the person is conscious).

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail

TACROLIMUSUM MONOHYDRICUM

STOT: Specific Target Organ Toxicity
UN (number): United Nations (number)
vPvB: very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the Magis-Pharma NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. Magis-Pharma NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Magis-Pharma NV
info@magis-pharma.be