





Sections 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 SDS FK506 vers 8-2024 Page 1 of 8

1. Identification of the Substance and the Manufacturer

| 1.1. Product i | dentifiers | | | | - | |
|------------------------------------|---|----------------------------|-------------|----------------------|----------------|-----------------------|
| Product name | <u>FK506</u> ~ | Ô | For | Formula | | C44H69NO12 |
| Product Code | FK5-001 | A | Mo | lecular | weight | 804.14 g/mol |
| <u>CAS</u> | <u>104987-</u> | <u>11-3</u> 🕭 | Mix | cture? | | Substance |
| ECHA | 658-056-2 | 2 1 | PU | PUBCHEM 🗇 | | <u>363905074</u> |
| HSDB | <u>8195</u> | | RTI | ECS | | KD4200000 |
| Drug bank | <u>DB00864</u> | Ð | <u>T3L</u> | <u>)</u> | | toxins/T3D4732 |
| Comptox EPA | DTXSID5 | 5 <u>046354</u> 🕀 | CH | <u>EBI</u> | | <u>CHEBI:93221</u> |
| Synonyms and other names | Fujimycin | Prograf | Tacı | rolimus | Tsukubaenolide | FR 900506 |
| Source From: Streptomyces tsukubae | | | ubaensis | aensis Version Date | | 24 September, 2024 |
| 1.2. Intended | uses of the | e Substance | and use | es advis | ed against | |
| 1.2.1. Intended | | | | dvised against: | | |
| Research and deve | elopment. | v | 0 1 | | Not a drug, | |
| Laboratory reagen | | | • • • | | Not a food add | |
| v | Reference material. only | | | | Not to be used | in humans or animals. |
| 1.3. Contacts | 1.3. Contacts | | | | | |
| 1.3.1. Details of | 1.3.1. Details of the supplier of the SDS | | | | | |
| FERMENTEK ltd | | <i>Tel:</i> +972 2 5853953 | | | | |
| 4 Yatziv street, POB 47120 | | <i>Fax:</i> +972 2 5853943 | | | | |
| Jerusalem 97800, | | | | Fermentek@Ferm | | |
| Israel | | | | Safety@Fermentek.com | | |
| | | Website: Fermentek.com | | Fermentek.com | | |
| | | | | | | |
| This company is th | e manufactu | rer of the prod | luct and th | | | ta sheet |

1.3.2. Emergency Telephone number

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





FK506

Sections 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

SDS FK506 vers 8-2024

Page 2 of 8

2. Hazards' identification.

Classification of the Substance. *2.1*.

| <i>2.1.1</i> . | GHS Classification: A | According to EU | Reg. 12 | 272/2008 and US OSHA 1910.1200) |
|----------------|-----------------------|-----------------|----------------|---------------------------------------|
| (TOT) | | Catagory 1 | 11272 | Causes damages to sup and through and |

| STOT/RE/, urogen.system | Category I | H372 | Causes damage to organs through prolonged or repeated exposure (Urogenital system, kidney) |
|-------------------------|------------|------|--|
| Reproductive toxicity | Category 2 | H361 | Suspected of damaging fertility or the unborn child |

GHS Label elements, including precautionary statements 2.2.

Pictogram . { Signal word · { Danger } 221

| <i>4.4.1.</i> | I cogram. [🗸 j Signai wora. [Danger] |
|---------------|--|
| 2.2.2. | Hazard Statements |
| H372 | Causes damage to organs through prolonged or repeated exposure (Urogenital system, kidney) |
| H361 | Suspected of damaging fertility or the unborn child |
| 2.2.3. | GHS Precautionary Statements |
| P203 | Obtain, read and follow all safety instructions before use. |
| P261 | Avoid breathing dust or mist. |
| P264 | Wash {hands} thoroughly after handling. |
| P270 | Do not eat, drink or smoke when using this product. |
| P272 | Contaminated work clothing should not be allowed out of the workplace. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection/hearing protection |
| 2.2.4. | GHS Response Phrases: |
| <i>P318</i> | If exposed or concerned, get medical advice. |
| P319 | Get medical help if you feel unwell |
| P308+ | |

IF exposed or concerned: Get medical advice/attention. P313

Composition/information on ingredients 3.

Substance

| Substance | |
|--------------------|--------------------------------|
| Substance Name: | <u>FK506</u> |
| Concentration | <=100% |
| CAS Registry#: | 104987-11-3 |
| <i>EC#</i> : | 658-056-2 |
| Molecular Formula: | C44H69NO12 |
| Molecular Weight: | 804.14 g/mol |
| Classification | REPR:3 (H361) STOT/RE 2 (H372) |
| Mixture? | Substance |
| | |

First Aid Measures. *4*.

Description of First Aid Measures. *4.1*.

First-aiders need to protect themselves. General advice:







Sections <u>5 6 7 8 9 10 11 12 13 14 15 16</u> Page 3 of 8 SDS FK506 vers 8-2024 If medical attention is required, show this safety data sheet to the doctor in attendance. If swallowed: give water to drink (two glasses at most). Seek medical Ingestion: advice immediately. 4.2. Most important symptoms and effects, both acute and delayed See section 11 General symptoms Indication of any immediate medical attention and special treatment needed 4.3. No data available Note to physicians Fire-fighting measures. 5. 5.1. Extinguishing media. Suitable extinguishing media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. None known Unsuitable extinguishing media 5.2. Other information Hazardous combustion products Carbon oxides. Nitrogene oxides, C44H69NO12 Wear self-contained breathing apparatus for fire fighting if necessary. Advice for firefighters Wear protective suit. *6*. Accidental release measures *6.1*. Personal precautions, protective equipment, and emergency procedures Use personal protective equipment as required. Keep people away from Personal precautions 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 Prevent further leakage or spillage if safe to do so. Cover the powder spill Methods for containment: with a plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal. Clean-up should be dealt with only by qualified personnel familiar with *Methods for cleaning up:* the specific substance. Cover liquid spill with sand, earth or other noncombustible absorbent material (e.g., sand, earth, diatomaceous earth, and vermiculite). Cover the powder spill with a plastic sheet or tarp to minimize spreading. Sweep up and shovel into suitable containers for disposal.









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Sections 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

SDS FK506 vers 8-2024

Page 4 of 8

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. | |
| Suitable packaging | Must only be kept in original packaging. | |
| Incompatible materials: | None known based on information available. | |

8. Exposure Controls/Personal Protection

Attiention:

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

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

All recommendations included in this document are advisory in nature

8.1. Control parametersComponents with workplace control parametersControl parametersComponents with workplace control parameters8.2. Exposure controlsShowers, Eyewash stations, Ventilation systems
Avoid contact with skin, eyes, and clothing.NowersShowers before breaks and immediately after handling the product.
Use fume-hood for routine work.

8.3. Personal protective equipment

| [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). | |









Sections 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

SDS FK506 vers 8-2024

Page 5 of 8

| PPE: Hand Protection: | Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal techniques to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices, and wash and dry hands |
|-----------------------------------|---|
| PPE: Eye Protection: | Use a face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU) |
| PPE: Skin and Body Protection: | Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. |

9. Physical and chemical properties

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

9.1. Physical/chemical properties

| Physical State at room temperature | Solid |
|------------------------------------|--------------|
| Appearance | White powder |

No further safety relevant data are available

10. Stability and reactivity

| Reactivity: | No information available. |
|-------------------------------|------------------------------------|
| Chemical stability: | Stable under normal conditions. |
| Conditions to avoid | Heat, flames and sparks. Sunlight. |
| Incompatible materials | Strong reducers and exidizers |
| Possibility of Hazardous | None under normal processing |
| Reactions | |
| II lana a lanation and lanata | Section 5 |

Hazardous combustion products See section 5

11. Toxicological information

11.1. Information on toxicological effects

To the best of our knowledge, the toxicological effects of this product have not been thoroughly studied yet. *11.1.1.* Acute Toxicity

| Acute toxicity: | Oral, Mouse, LD50>2000 mg/kg Intrapetoneal, Mouse, LD50 >200 mg/kg |
|------------------------------------|---|
| Skin corrosion/irritation: | No data available |
| Serious eye damage/eye irritation: | No data available |



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Safety Data Sheet



Sections 7 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

SDS FK506 vers 8-2024

Page 6 of 8

| Respiratory or skin sensitization/corrosion: | No data available |
|--|--|
| 11.1.2. Chronic toxicity | |
| Chronic toxicity | No data available |
| 11.1.3. CRM (Carcinogene, Mutag | gene, Reproductive hazards) |
| Germ cell mutagenicity: | No data available |
| Carcinogenicity: | Not classified by IARC |
| <i>Reproductive toxicity / Teratogenicity:</i> | Oral, TRat, 14 mg/kg, 2W premating, paternal effects: spermatogenesis. Fetal death Intramusc., 2.7 mg/kg, 1-16 d postconcept., post implant. mortality Develop. Abnormal. musculoskeletal system. |

11.2. Additional information

| RTECS number | KD4200000 | |
|------------------|-----------------|---|
| General symptoms | RAT | · · · · · · · · · · · · · · · · · · · |
| | Behavioral | changes in motor activity (specific assay) analgesia |
| | Immunol. | decrease in cellular immune response. |
| | Cardiac | pulse rate increase, without fall in BP Vascular |
| | | BP elevation |
| | Human | |
| | Behavioral | headache ; muscle contraction or spasticity |
| | Gastrointestind | ıl: nausea or vomiting |
| | Endocrine | hypoglycemia |

12. Ecological Information

| Eco-Toxicity | No data available | | |
|--|--------------------------|--------------------------|--------|
| Other adverse effects | No data available | | |
| 13. Disposal Considerations | | | |
| 13.1. Waste treatment methods | | | |
| Waste Disposal | Dispose of in accordance | e with local regulations | |
| Contaminated packaging Dispose of as unused product | | | |
| 14. Transport information | | | |
| 14.1. UN Number, Proper Shipping Name, Transport Hazard Class, packing group | | | |
| IATA | IMDG | ADR/RID | US/DOT |

| | IATA | IMDG | ADR/RID | US/DOT |
|---------------|------------------|------------------|------------------|------------------|
| UN Number, | UN 2811Toxic | UN 2811Toxic | UN 2811Toxic | UN 2811Toxic |
| Proper | solids, organic, | solids, organic, | solids, organic, | solids, organic, |
| shipment name | | | | |





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Safety Data Sheet

JFJK506

Sections 7 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

SDS FK506 vers 8-2024

Page 7 of 8

| | n.o.s (FK506) | n.o.s (FK506) | n.o.s (FK506) | n.o.s (FK506) |
|---------------|-------------------|---------------------|-------------------|-------------------|
| Transport | 6.1 poison | 6.1 poison | 6.1 poison | 6.1 poison |
| hazard Class, | | | | |
| Packing group | PGIII | PGIII | PGIII | PGIII |
| Comments | | Not marine polutant | | |

15. Regulatory information

15.1. Safety, health, and environmental regulations/legislation

| USA EPA / TSCA | This product is not listed on the USA EPA TSCA (it is for research) |
|----------------|---|
| EU ECHA Status | This product is registered with the EU ECHA, Number 658-056-2 REACH: Neither Registered nor PreRegistered. ANNEX III (criteria for 1 - 10 tonne registered substances): Not Listed |

16. Other information

16.1. Version information

Version date:8-2024

16.2. Department issuing this SDS

Quality systems and regulatory affairs

16.3. General Disclaimer

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

The information given here is designed only as guidance for safe handling, use, processing, storage, transportation, disposal, and release and **is not to be considered a warranty or quality specification**. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless explicitly specified in the text.

16.4. The users '/employers' responsibility:

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

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

All recommendations included in this document are advisory in nature.

16.5. No ©copyright



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Sections 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

SDS FK506 vers 8-2024

Page 8 of 8

16.7. Appendix A : Abbreviations and acronyms:

| | This symbol means, the text looking like a hyperlink, is a clickable link indeed. Of course, these are only active on glass screens, not on paper. | |
|-------------------------------|--|--|
| From /Synthetic | "From" means the compound was extracted from biomass, whether algal, fungal, microbial or plant material | |
| /Semisynthetic | "Synthetic" means this compound has been manufactured by chemical conversion of another compound. Often, certain product is made by the method of microbial fermentation, purified, and then chemically converted into another compound. It may be called "semisynthetic". | |
| | Substance means a single compound. | |
| Mixture/Substance/ Complex | Mixture means there are two or more pure substances mixed purposely. Complex is a mixture of two or more substances which naturally occur together and are sold unseparated | |
| Acute Tox.: | Acute toxicity | |
| CAS: | Chemical Abstracts Service | |
| ChEBI | Chemical Entities of Biological Interest | |
| Comptox | CompTox Chemicals Dashboard Resource Hub (EPA) | |
| DOT: | US Department of Transportation | |
| ЕСНА | European Chemicals Agency | |
| EINECS: | European Inventory of Existing Commercial Chemical Substances | |
| EPA | United States Environmental Protection Agency | |
| Eye Dam.: | Serious eye damage/eye irritation | |
| HSDB | Hazardous Substances Data Bank | |
| HMIS: | Hazardous Materials Identification System (USA) | |
| IATA: | International Air Transport Association | |
| IMDG: | International Maritime Code for Dangerous Goods | |
| LC50: | Lethal concentration, Median | |
| LD50: | Lethal dose, Median | |
| LDL0 | Letal dose, leatst published | |
| NDG | Not dangerous goods (for transport) | |
| NFPA: | National Fire Protection Association USA | |
| NIOSH: | National Institute for Occupational Safety | |
| NOAEL | No-Observed-Adverse-Effects-Level. Highest dose which yelded no results at toxisity test | |
| OSHA: | Occupational Safety & Health | |
| PBT: | Persistent, Bioaccumulative, and Toxic | |
| PEL: | Permissible Exposure Limit | |
| PubChem | An open chemistry database at the National Institutes of Health (NIH). " | |
| REL: | Recommended Exposure Limit | |
| Repr.: | Reproductive toxicity, incl. hazards to reproductive systems, and pregnancy and the offspring. | |
| RTECS: | Registry of Toxic Effects of Chemical Substances. Not free. | |
| Skin Irrit: | Skin corrosion/irritation | |
| STOT/SE | Specific target organ toxicity/Single exposure | |
| STOT/RE | Specific target organ toxicity/Repeated exposure | |
| T3DB | Toxin and Toxin Target Database | |
| TDL0 | Toxic dose, least published | |

