



# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 10-May-2023

Revision Number 1.1

74152 74154 - FK506

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Document Number DX23200

Product Name FK506

Synonym Tacrolimus;  
(3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-[(1E)-2-[(1R,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylethenyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-8-(2-propen-1-yl)-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone

Pure substance/mixture Substance

Contains 2-Amino-(N,N)-1-bis(hexadecahydro-6,13-diisopropyl-2,5,9-trimethyl-1,4,7,11,14-pentaoxo-1H-pyrrolo[2,1]-[1,4,7,10,13]oxatetraazacyclohexadecin-10-yl)-4,6-dimethyl-3-oxo-3H-phenoxazine-1,9-dicarboxamide

Molecular weight 804.0

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

Recommended Use Laboratory chemicals

Uses advised against

### 1.3. Details of the supplier of the safety data sheet

#### Manufacturer

STEMCELL Technologies SARL  
40 Rue des Berges, Miniparc Polytec, Bâtiment Sirocco, 38000 Grenoble, France  
+33 (0) 4 76 04 75 30  
STEMCELL Technologies Germany GmbH  
Stolberger Str. 200, 50933, Köln, Germany  
+33 (0) 4 76 04 75 30  
STEMCELL Technologies UK Ltd.  
Building 7100, Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, UK, CB25 9TL  
+33 (0) 4 76 04 75 30

For further information, please contact

### 1.4. Emergency telephone number

Emergency Telephone

Emergency Telephone - §45 - (EC)1272/2008

Europe 112



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## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 3 - (H301)
Reproductive toxicity	Category 2 - (H361)
Specific target organ toxicity (repeated exposure)	Category 1 - (H372)

### 2.2. Label elements

Contains 2-Amino-(N,N)-1-bis(hexadecahydro-6,13-diisopropyl-2,5,9-trimethyl-1,4,7,11,14-pentaoxo-1H-pyrrolo[2,1]-[1,4,7,10,13]oxatetraazacyclohexadecin-10-yl)-4,6-dimethyl-3-oxo-3H-phenoxazine-1,9-dicarboxamide



#### Signal word

Danger

#### Hazard statements

##### Hazard statements

H301 - Toxic if swallowed

H361 - Suspected of damaging fertility or the unborn child

H372 - Causes damage to organs through prolonged or repeated exposure

#### Precautionary Statements - EU (§28, 1272/2008)

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P314 - Get medical advice/attention if you feel unwell

P501 - Dispose of contents/container to industrial incineration plant

#### Additional information

This product requires child resistant fastenings if supplied to the general public This product requires tactile warnings if supplied to the general public

### 2.3. Other hazards



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## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Synonym

Chemical name	EC No.	CAS No.	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
2-Amino-(N,N)-1-bis(hexadecahydro-6,13-diisopropyl-2,5,9-trimethyl-1,4,7,11,14-pentaoxo-1H-pyrrolo[2,1]-[1,4,7,10,13]oxatetraazacyclohexadecin-10-yl)-4,6-dimethyl-3-oxo-3H-phenoxazine-1,9-dicarboxamide	-	104987-11-3	100	Acute Tox. 3 (H301) Repr. 2 (H361) STOT RE 1 (H372)	No data available

Full text of H- and EUH-phrases: see section 16

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.

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

Symptoms

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

Note to physicians Treat symptomatically.

## Section 5: FIRE-FIGHTING MEASURES



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### 5.1. Extinguishing media

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable Extinguishing Media**

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical**

### 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.

**Other Information** Refer to protective measures listed in Sections 7 and 8.

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** See Section 12 for additional Ecological Information.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Take up mechanically, placing in appropriate containers for disposal.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## Section 7: HANDLING AND STORAGE



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### 7.1. Precautions for safe handling

#### **Advice on safe handling**

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation.

#### **General hygiene considerations**

Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

#### **Storage Conditions**

Store in accordance with information listed on the Product Information Sheet (PIS). Keep out of the reach of children.

### 7.3. Specific end use(s)

#### **Identified Uses**

**Risk Management Methods (RMM)** The information required is contained in this Material Safety Data Sheet.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### **Exposure Limits**

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

#### **Derived No Effect Level (DNEL)**

#### **Predicted No Effect Concentration (PNEC)**

### 8.2. Exposure controls

#### **Personal protective equipment**

##### **Eye/face protection**

No special protective equipment required.

##### **Hand protection**

Wear suitable gloves.

##### **Skin and body protection**

Wear suitable protective clothing.



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## Respiratory protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

## General hygiene considerations

Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

## Environmental exposure controls

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline
Color	
Odor	No data available.
Odor threshold	No data available

Property	Values	Remarks • Method
pH	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	Product is not flammable.	None known
Flammability Limit in Air		None known
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	~0.15 mg/mL in a 1:5 solution of EtOH:PBS (pH 7.2); ~30 mg/mL in EtOH; ~20 mg/mL in DMSO & DMF;	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties		

## Oxidizing properties

### 9.2. Other information



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**Molecular weight** 804.0  
**Molecular formula** C<sub>44</sub>H<sub>69</sub>NO<sub>12</sub>  
**VOC Content (%)**

### Section 10: STABILITY AND REACTIVITY

#### 10.1. Reactivity

**Reactivity**

#### 10.2. Chemical stability

**Stability** Stable under recommended transport or storage conditions.

#### **Explosion data**

**Sensitivity to Mechanical Impact** None.

**Sensitivity to Static Discharge** None.

#### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** None under normal processing.

#### 10.4. Conditions to avoid

**Conditions to avoid** None known based on information supplied.

#### 10.5. Incompatible materials

**Incompatible materials** Strong oxidizing agents.

#### 10.6. Hazardous decomposition products

**Hazardous decomposition products** Carbon oxides. Nitrogen oxides (NO<sub>x</sub>).

### Section 11: TOXICOLOGICAL INFORMATION

#### 11.1. Information on toxicological effects

#### Information on likely routes of exposure

#### **Product Information**

**Inhalation** Specific test data for the substance or mixture is not available.



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Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).

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

Symptoms

### Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 100.00 mg/kg

Unknown acute toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity.  
0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.  
100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.  
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).  
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).  
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Product Information

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation

Product Information

Serious eye damage/eye irritation

Product Information

Respiratory or skin sensitization

Product Information

Germ cell mutagenicity

Product Information

Carcinogenicity

Product Information

Reproductive toxicity Classification based on data available for ingredients.





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## Product Information

### STOT - single exposure

Product Information

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Product Information

Aspiration hazard

## Section 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### Ecotoxicity

The environmental impact of this product has not been fully investigated.

#### Unknown aquatic toxicity

Contains 0 % of components with unknown hazards to the aquatic environment.

Product Information

### 12.2. Persistence and degradability

#### Persistence and degradability

### 12.3. Bioaccumulative potential

#### Bioaccumulation

### 12.4. Mobility in soil

#### Mobility in soil

### 12.5. Results of PBT and vPvB assessment

#### PBT and vPvB assessment

### 12.6. Other adverse effects

#### Other adverse effects

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods



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**Waste from residues/unused products**

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging**

Do not reuse empty containers.

## Section 14: TRANSPORT INFORMATION

**Note:**

Transport in accordance with local, state, and federal regulations. When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted Quantity.

**IMDG**

14.1 UN Number	2811
14.2 UN proper shipping name	TOXIC SOLID, ORGANIC, N.O.S. (FK-506)
14.3 Transport hazard class(es)	6.1 Toxic substances
14.4 Packing Group	III
14.5 Marine pollutant	
14.6 Special Provisions	None
14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code	

**RID**

14.1 UN Number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing Group	Not regulated
14.5 Environmental hazard	
14.6 Special Provisions	None

**ADR**

14.1 UN Number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing Group	Not regulated
14.5 Environmental hazard	
14.6 Special Provisions	None

**IATA**

14.1 UN Number	2811
14.2 UN proper shipping name	Toxic solid, organic, n.o.s. (FK-506)
14.3 Transport hazard class(es)	6.1 Toxic substances
14.4 Packing Group	III
14.5 Environmental hazard	



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14.6 Special Provisions

None

## Section 15: REGULATORY INFORMATION

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

#### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### Persistent Organic Pollutants

#### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

##### International Inventories

TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply

##### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment



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### Chemical Safety Report

### Section 16: OTHER INFORMATION

#### Key or legend to abbreviations and acronyms used in the safety data sheet

##### **Full text of H-Statements referred to under section 3**

H301 - Toxic if swallowed

H361 - Suspected of damaging fertility or the unborn child

H372 - Causes damage to organs through prolonged or repeated exposure

##### **Legend**

SVHC: Substances of Very High Concern for Authorization:

##### **Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA

TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling

Maximum limit value

\*

Skin designation

**Revision Date**

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**This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**

##### **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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text. STEMCELL Technologies Inc. shall not be held liable for any damage resulting from handling or from contact with the product.