

Safety Data Sheet (SDS) According to the REACH Regulation (EC) No. 1907/2006

Issuing Date: 2018-03-14

Revision Date: 2025-01-02

Version: 2

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product No 9974
Product name FK-506

Contains

Chemical name	Index No.	CAS No
15,19-Epoxy-3H-pyrido(2,1-c)(1,4)oxaazacyclotricosine-1,7,20,21-(4H,23H)-tetrone, 5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-(2-(4-hydroxy-3-methoxycyclohexyl)-14,16-dimethoxy-4,10,12,18-tetramethyl-8-(2-propenyl)-, (3S-(3R*(E(1S*,3S*,4S*)),4S*,5R*,8S*,9E,12R*,14R*,15S*,16R*,18S*,19S*,26aR*))-(90 - 100%)		104987-11-3

Formula C₄₄H₆₉NO₁₂
Molecular Weight 804.02

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

Identified uses For Research Use Only. Not for Use in Diagnostic Procedures.

1.3. Details of the supplier of the safety data sheet

Importer	Manufacturer
Cell Signaling Technology Europe B.V. Dellaertweg 9b 2316 WZ Leiden The Netherlands TEL: +31 (0)71 7200 200 FAX: +31 (0)71 891 0019	Cell Signaling Technology, Inc. 3 Trask Lane Danvers, MA 01923 United States TEL: +1 978 867 2300 FAX: +1 978 867 2400

Website www.cellsignal.com
E-mail Address info@cellsignal.eu

1.4. Emergency telephone number

CHEMTREC 24 hours a day, 7 days a week, 365 days a year
+1 703 527 3887 (INTERNATIONAL) +1 800 424 9300 (NORTH AMERICA)

Europe 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Acute oral toxicity	Category 3 - (H301)
Reproductive toxicity	Category 2 - (H361)
Specific target organ toxicity - single exposure (STOT SE)	Category 3 - (H335)
Specific target organ toxicity - repeated exposure (STOT RE)	Category 1 - (H372)

2.2. Label elements



Signal word

Danger

Hazard statement(s)

H301 - Toxic if swallowed.

H335 - May cause respiratory irritation.

H361 - Suspected of damaging fertility or the unborn child.

H372 - Causes damage to organs through prolonged or repeated exposure.

Precautionary statement(s)

P201 - Obtain special instructions before use.

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

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

P264 - Wash face, hands and any exposed skin thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P271 - Use only outdoors or in a well-ventilated area.

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

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

P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

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

P314 - Get medical advice/attention if you feel unwell.

P330 - Rinse mouth.

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.

P405 - Store locked up.

P501 - Dispose of contents/container to an approved waste disposal plant.

2.3. Other hazards

Avoid contact during pregnancy and while nursing.

For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16

SECTION 3: Composition/information on ingredients

3.1 Substances

Formula

C₄₄H₆₉NO₁₂

Chemical name	CAS No	Weight-%	EC No	Classification (1272/2008)	REACH Registration Number
15,19-Epoxy-3H-pyrido(2	104987-11-3	100	-	Acute Tox. 3 (H301)	no data available

,1-c)(1,4)oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone, 5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-(2-(4-hydroxy-3-methoxycyclohexyl)-14,16-dimethoxy-4,10,12,18-tetramethyl-8-(2-propenyl)-, (3S-(3R*(E(1S*,3S*,4S*)),4S*,5R*,8S*,9E,12R*,14R*,15S*,16R*,18S*,19S*,26aR*))-				Repr. Cat. 2 (H361fd) STOT SE. 3 (H335) STOT RE. 1 (H372)	
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For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice	Use first aid treatment according to the nature of the injury. When symptoms persist or in all cases of doubt seek medical advice.
Inhalation	Move to fresh air. If symptoms persist, call a physician.
Skin contact	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention immediately if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Call a physician immediately.

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

Respiratory irritation. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

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

Notes to physician Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Dry chemical, CO ₂ , water spray or alcohol-resistant foam
Unsuitable Extinguishing Media	No information available

5.2. Special hazards arising from the substance or mixture

May emit toxic fumes under fire conditions.

Hazardous Combustion Products	Carbon oxides (CO _x), Nitrogen oxides (NO _x)
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5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing dust/fume/gas/mist/vapors/spray.
For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Should not be released into the environment. Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages cannot be contained.

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 Avoid dust formation. Take up mechanically, placing in appropriate containers for disposal. Clean contaminated surface thoroughly.

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid dust formation. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Wash thoroughly after handling. Avoid contact during pregnancy/while nursing.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Keep in properly labeled containers. Recommended storage temperature -20 °C.

7.3. Specific end use(s)

Use as a laboratory reagent.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Contains no substances with occupational exposure limit values.

8.2. Exposure controls

Appropriate engineering controls
Showers, eyewash stations, and ventilation systems

Individual protection measures, such as personal protective equipment
Eye/face protection Tightly fitting safety goggles.
Skin protection Wear protective gloves and protective clothing.

Hand protection	Impervious gloves.
Other	Wear suitable protective clothing.
Respiratory protection	In case of inadequate ventilation wear respiratory protection.

Environmental Exposure Controls

No information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid - Crystalline Powder
Color	White to off-white
Odor	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No information available	No information available
Melting point/freezing point	No information available	No information available
Boiling point or initial boiling point and boiling range	No information available	No information available
Flash point	No information available	No information available.
Evaporation rate	No information available	No information available
Flammability	No information available	No information available
Upper/lower flammability or explosive limits	/	No information available
Vapor pressure	No information available	No information available
Relative vapor density	No information available	No information available
Density and/or relative density	No information available	No information available
Solubility	No information available.	No information available
Partition coefficient: n-octanol/water	No information available	No information available
Autoignition temperature	No information available	No information available
Decomposition temperature	No information available	No information available.
Viscosity	No information available	No information available
Explosive properties	No information available	No information available
Oxidizing properties	No information available	No information available

9.2. Other information

Softening point	No information available
Molecular Weight	804.02
Solubility in other solvents	No information available
VOC content	No information available
Liquid Density	No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization	Hazardous polymerization does not occur.
Hazardous reactions	None under normal processing

10.4. Conditions to avoid

Protect from light. Excessive heat.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Thermal decomposition can lead to release of irritating and toxic gases and vapors: Carbon oxides (COx), Nitrogen oxides (NOx)

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

This material should only be handled by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals. It should be borne in mind that the toxicological and physiological properties of this compound is not well defined.

Chemical name	LD50 Oral	LD50 Dermal	LC50 Inhalation
15,19-Epoxy-3H-pyrido(2,1-c)(1,4)oxazacyclotricosine-1,7,20,21(4H,23H)-tetrone, 5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-(2-(4-hydroxy-3-methoxycyclohexyl)-14,16-dimethoxy-4,10,12,18-tetramethyl-8-(2-propenyl)-, (3S-(3R*(E(1S*,3S*,4S*)),4S*,5R*,8S*,9E,12R*,14R*,15S*,16R*,18S*,19S*,26aR*))-	134 mg/kg (Tacrolimus hydrate)	-	-

ATEmix (oral)

100.00 mg/kg

Information on likely routes of exposure**Inhalation**

May be harmful if inhaled. May cause irritation of respiratory tract.

Eye contact

There is no data available for this product.

Skin contact

There is no data available for this product.

Ingestion

Toxic if swallowed.

Symptoms

Respiratory irritation. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

Skin corrosion/irritation

No information available.

Serious eye damage/eye irritation

No information available.

Sensitization

No information available.

Mutagenic effects

Did not show mutagenic effects in animal experiments.

Carcinogenicity

Contains no ingredient listed as a carcinogen.

Reproductive toxicity

Product is or contains a chemical which is a known or suspected reproductive hazard.

STOT - single exposure

Respiratory system.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Aspiration Hazard

No information available.

11.2. Information on other hazards

No information available.

SECTION 12: Ecological information

12.1. Toxicity

Unknown Aquatic Toxicity 100% of the mixture consists of components of unknown hazards to the aquatic environment.

12.2. Persistence and degradability

No information available

12.3. Bioaccumulative potential

Bioaccumulation No information available.

Bioconcentration factor (BCF) No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Endocrine disrupting properties

This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects

No information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

Other information Waste codes should be assigned by the user based on the application for which the product was used.

SECTION 14: Transport information

This material is subject to regulation as a hazardous material for shipping:

IMDG/IMO

14.1 UN number	UN2811
14.2 UN proper shipping name	Toxic solid, organic, n.o.s. (FK-506)
14.3 Transport hazard class(es)	6.1
14.4 Packing group	III
14.5 Environmental hazards	None
14.6 Special precautions for user	None

14.7 Maritime transport in bulk according to IMO instruments Not regulated

ADR/RID

14.1 UN number UN2811
14.2 UN proper shipping name Toxic solid, organic, n.o.s. (FK-506)
14.3 Transport hazard class(es) 6.1
14.4 Packing group III
14.5 Environmental hazards None
14.6 Special precautions for user None

IATA

14.1 UN number UN2811
14.2 UN proper shipping name Toxic solid, organic, n.o.s. (FK-506)
14.3 Transport hazard class(es) 6.1
14.4 Packing group III
14.5 Environmental hazards None
14.6 Special precautions for user None

SECTION 15: Regulatory information

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

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

This product does not contain Substances of Very High Concern (SVHC).

SEVESO Directive Information

This product does not contain substances identified in the SEVESO Directive.

International inventories

TSCA 8(b) -
DSL/NDSL -
EINECS/ELINCS -
ENCS -
IECSC -
KECL -
PICCS -
AICS -

International inventories 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 Commercial Chemical Substances/EU 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

For this substance a chemical safety assessment has not been carried out

SECTION 16: Other information

Full text of H-Statements referred to under Sections 2 and 3

H301 - Toxic if swallowed

H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child

H335 - May cause respiratory irritation

H372 - Causes damage to organs through prolonged or repeated exposure if inhaled

Classification procedure: Expert judgment and weight of evidence determination.

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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.