



SAFETY DATA SHEET

74152 74154 - FK506

Revision Date 10-May-2023

Revision Number 1.1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name FK506

Other means of identification

Catalog Number 74152 74154

UN/ID no. UN2811

Document Number DX23200

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

Recommended use of the chemical and restrictions on use

Recommended Use Laboratory chemicals

Details of the supplier of the safety data sheet

Manufacturer/Supplier

STEMCELL Technologies Canada Inc.
Suite 500 - 1618 Station Street
Vancouver, British Columbia V6A 1B6 Canada

Emergency telephone number

Emergency Telephone 1-800-667-0322

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

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



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Hazards not otherwise classified (HNOC)

Label elements

Danger

Hazard statements

Toxic if swallowed
Suspected of damaging fertility or the unborn child
Causes damage to organs through prolonged or repeated exposure



Appearance Crystalline

Physical state Solid

Odor No data available

Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe dust/fume/gas/mist/vapors/spray
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Precautionary statements - Response

IF exposed or concerned: Get medical advice/attention
IF SWALLOWED: Immediately call a POISON CENTER or doctor
Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other Information

Unknown acute toxicity 0 % 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)



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100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

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.

Chemical name	CAS No.	Weight-%
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

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

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.
- 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.

Most important symptoms and effects, both acute and delayed

Symptoms

Indication of any immediate medical attention and special treatment needed



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Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the chemical

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

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

6. ACCIDENTAL RELEASE MEASURES

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.

Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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 Pick up and transfer to properly labeled containers.

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

7. HANDLING AND STORAGE

Precautions for safe handling



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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.

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. Store locked up.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES



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Information on basic physical and chemical properties

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

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
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 in other solvents	~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	No data available	
Oxidizing properties		

Other Information

Molecular weight	804.0
Molecular formula	C44H69NO12
VOC Content (%)	

10. STABILITY AND REACTIVITY

Reactivity

Chemical stability	Stable under recommended transport or storage conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.



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Incompatible materials Strong oxidizing agents.

Hazardous decomposition products Carbon oxides. Nitrogen oxides (NO_x).

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
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) 6.00 mg/kg

Unknown acute toxicity 0 % 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)

0 % 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



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Respiratory or skin sensitization

Product Information

Germ cell mutagenicity

Product Information

Carcinogenicity

Reproductive toxicity

Classification based on data available for ingredients.

Product Information

STOT - single exposure

Product Information

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Product Information

Aspiration hazard

RTECS #

KD4200000

12. ECOLOGICAL INFORMATION

Ecotoxicity

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

Product Information

Persistence and degradability

Bioaccumulation

There is no data for this product.

Other adverse effects

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

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.



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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.

DOT

UN/ID no.	UN2811
Proper shipping name	Toxic solids, organic, n.o.s. (FK-506)
Hazard class	6.1 Toxic substances
Packing Group	III

TDG

Not regulated

MEX

Not regulated

ICAO (air)

Not regulated

IATA

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

IMDG

UN Number	2811
UN proper shipping name	TOXIC SOLID, ORGANIC, N.O.S. (FK-506)
Transport hazard class(es)	6.1 Toxic substances
Packing Group	III

RID

Not regulated

ADR

Not regulated

ADN

Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Does not comply
DSL/NDL	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



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Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - 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

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	Yes
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information



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16. OTHER INFORMATION, INCLUDING DATE OF PREPARATION OF THE LAST REVISION

Prepared By, Quality Control. STEMCELL Technologies Canada Inc.

Revision Date 10-May-2023

Revision Note

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.

End of Safety Data Sheet