Safety Data Sheet (SDS) According to the OSHA Hazard Communication Standard 29 CFR 1910.1200

Issuing Date: 2015-01-12 **Revision Date:** 2018-03-26 **Version:** 3

SECTION 1. Identification

Product identifier

Product No 12017
Product name Everolimus

Recommended use of the chemical and restrictions on use

Identified uses This product is intended for research purposes only.

Manufacturer, importer, supplier

Manufacturer address 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
Email address support@cellsignal.com
Emergency telephone number In case of emergency call CHEMTREC 1-800-424-9300

SECTION 2. Hazard(s) identification

Classification

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

Reproductive toxicity	Category 1B
Effects on or via lactation	Effects on or via lactation
Specific target organ toxicity - repeated exposure (STOT RE)	Category 1

GHS Label elements, including precautionary statements

Signal Word
Danger

Hazard statement(s)
May damage fertility or the unborn child. May cause harm to breast-fed children. Causes damage to organs through prolonged or repeated exposure.

Precautionary Statement(s)
Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact during pregnancy/while nursing. Wash face, hands and any exposed skin thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.
IF exposed or concerned: Get medical advice/attention.
Store locked up.
Dispose of contents/container to an approved waste disposal plant.

Supplementary Hazard Information

No information available.
Hazards not otherwise classified (HNOC)
Harmful to aquatic life with long lasting effects.

SECTION 3. Composition/information on ingredients

Formula $C_{53}H_{83}NO_{14}$
Molecular Weight 958.22 g/mol
Chemical nature Monoconstituent substance
Synonyms Everolimus;
42-O-(2-hydroxyethyl)-rapamycin (9CI);
Afinitor®;
Zortress®;
(1R,9S,12S,15R,16E,18R,19R,21R,23S,24E,26E,28E,30S,32S,35R)-1,18-dihydroxy-12-{(1R)-2-[(1S,3R,4R)-4-(2-hydroxyethoxy)-3-methoxycyclohexyl]-1-methylethyl}-19,30-dimethoxy-15,17,21,23,29,35-hexamethyl-11,36-dioxa-4-aza-tricyclo[30.3.1.$0^{4,9}$]-hexatriaconta-16,24,26,28-tetraene-2,3,10,14,20-pentaone

Chemical Name	CAS No	Weight %
Everolimus	159351-69-6	100

SECTION 4. First-aid measures

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.
Inhalation Move to fresh air.
Ingestion Clean mouth with water and afterwards drink plenty of water.

Most important symptoms and effects, both acute and delayed

Fatigue. stomatitis. infection. rash. Diarrhea. Edema. Abdominal pain. Nausea. Fever. Asthenia. Shortness of breath or cough. Headache. Loss of appetite.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Advice for emergency responders

General advice For further assistance, contact your local Poison Control Center.
Protection of first-aiders Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

SECTION 5. Fire-fighting measures

Extinguishing media

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

No information available.

Explosion Data

Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Ensure adequate ventilation.
Other information	No information available.

Environmental precautions

See Section 12 for additional 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.

SECTION 7. Handling and storage

Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical measures/Storage conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.
Packaging material	No information available.
Incompatible products	None known based on information supplied.

SECTION 8. Exposure controls/personal protection

Control parameters

Appropriate engineering controls

Showers, eyewash stations, and ventilation systems.

Individual protection measures, such as personal protective equipment

Personal protective equipment (PPE) needs to be selected depending on the implemented engineering controls, frequency/duration of work activities and the concentrations of the hazardous substance.

Eye/face protection	Safety glasses with side-shields
Skin and body protection	Wear protective gloves/clothing.
Respiratory protection	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid		
Appearance	Powder	**Color**	White to off-white
Odor	No information available	**Odor Threshold**	No information available

Property	**Values**	**Remarks Method**
pH	5.1 - 5.2	@ 10 g/L in water
Melting point/freezing point		
Initial boiling point and boiling range		
Flash point		-
Evaporation rate	No information available	
Flammability (solid, gas)	No information available	
Upper flammability limit	No information available	
Lower flammability limit	No information available	
Vapor pressure	No information available	
Vapor density	No information available	
Relative density	No information available	
Solubility	No information available.	
Solubility in other solvents	No information available.	
Partition coefficient: n-octanol/water	No information available	
Autoignition temperature	No information available	No information available
Decomposition temperature	No information available	
Viscosity	No information available	
Viscosity, dynamic	No information available	
Explosive properties	No information available	
Oxidizing properties	No information available	

Other information

Softening point	No information available
Molecular Weight	958.22 g/mol
VOC content	No information available
Density	No information available.
Bulk Density VALUE	No information available.

SECTION 10. Stability and reactivity

Reactivity

No information available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

Hazardous reactions	None under normal processing.
Hazardous polymerization	None under normal processing.

Conditions to Avoid

No information available.

Incompatible Materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

SECTION 11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause irritation of respiratory tract.
Eye contact	Contact with eyes may cause irritation.
Skin contact	May cause irritation.
Ingestion	May be harmful if swallowed. Target Organ Effects.

Information on toxicological effects

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
Everolimus	> 2000 mg/kg (Rat)	-	-

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

Symptoms	Fatigue. stomatitis. infection. rash. Diarrhea. Edema. Abdominal pain. Nausea. Fever. Asthenia. Shortness of breath or cough. Headache. Loss of appetite.
Skin corrosion/irritation	not applicable.
Sensitization	Did not cause sensitization on laboratory animals.
Mutagenic effects	Not mutagenic in AMES Test. Negative in an in vivo rat micronucleus test. Negative in the chromosomal aberration assay.
Carcinogenicity	No component of this product present at levels greater than or equal to 0.1% is identifiable as probable, possible or confirmed carcinogen by IARC, ACGIH, NTP, or OSHA. Did not show carcinogenic effects in animal experiments
Reproductive toxicity	This material is classified as a Pregnancy Category D: Positive evidence of risk. In a male fertility study in rats, testicular morphology was affected at 0.5 mg/kg and above, and sperm motility, sperm head count, and plasma testosterone levels were diminished at 5 mg/kg. Female fertility was not affected, but everolimus crossed the placenta and was toxic to the foetus. Everolimus and/or its metabolites passed into the milk of lactating rats at a concentration 3.5 times higher than in maternal serum.
Teratogenicity	In rats, everolimus caused embryo/foetotoxicity at systemic exposure. This was manifested as mortality and reduced foetal weight. The incidence of skeletal variations and malformations (e.g. sternal cleft) was increased at 0.3 and 0.9 mg/kg. In rabbits, embryo toxicity was evident in an increase in late resorptions.
STOT - single exposure	No information available.
STOT - repeated exposure	The major target organs were male and female reproductive systems (testicular tubular degeneration, reduced sperm content in epididymides and uterine atrophy) in several species; lungs (increased alveolar macrophages) in rats and mice; pancreas (degranulation and vacuolation of exocrine cells in monkeys and minipigs, respectively, and degeneration of islet cells in monkeys), and eyes (lenticular anterior suture line opacities) in rats only.
Target Organ Effects	Immune system, Reproductive system, Lungs, Pancreas, Eyes.
Neurological effects	No information available.
Aspiration Hazard	No information available.

SECTION 12. Ecological information

Ecotoxicity

Harmful to aquatic life with long lasting effects

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates
Everolimus	-	LC50 >18.4 mg/L (Cyprinus carpio) 96 h	-

Persistence and degradability Not readily biodegradable. 2% 28 day period.
Bioaccumulation Not likely to bioaccumulate.
Mobility Is not likely mobile in the environment due its low water solubility

Chemical Name	Octanol-Water Partition Coefficient
Everolimus	4

Other adverse effects

No information available.

SECTION 13. Disposal considerations

Waste Disposal Methods

Dispose of in accordance with all applicable national environmental laws and regulations.

Disposal considerations

Do not empty into drains; dispose of this material and its container in a safe way.

SECTION 14. Transport information

This material is not subject to regulation as a hazardous material for shipping.

SECTION 15. Regulatory information

North American Inventory Listing

Chemical Name	TSCA 8(b)	TSCA 12(b)	DSL	NDSL
Everolimus	Not Listed	Not Listed	Not Listed	Not Listed

Canadian Workplace Hazardous Materials Information System (WHMIS) Classification

	Class D2A - Very Toxic Material at >= 0.1%

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	No
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

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.

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. FIFRA Label Information

This product does not contain any substances regulated as pesticides.

US Commerce Department - Export Administration Regulations Information

This product does not contain any substances regulated under the Chemical Weapons Convention (CWC).

U.S. Drug Enforcement Administration Information

This product does not contain any substances regulated under the DEA.

SECTION 16. Other information

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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.

End of Safety Data Sheet