

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

Issuing Date: 2015-02-05

Revision Date: 2017-09-13

Version: 2

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

1.1. Product identifier

Product No 15021
Product name Actinomycin D
Reach registration number This substance/mixture contains only ingredients which have been registered, or are exempt from registration, according to Regulation (EC) No. 1907/2006.

Contains

Formula $C_{62}H_{86}N_{12}O_{16}$
Molecular Weight 1255.4 g/mol
Other means of identification 15021S, 15021L

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

Identified uses For research use only

1.3. Details of the supplier of the safety data sheet

Importer (Applicable in EU only)	Manufacturer
Cell Signaling Technology Europe B.V. Schuttersveld 2 2316 ZA Leiden The Netherlands TEL: +31 (0)71 7200 200 FAX: +31 (0)71 891 0098	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 2 - (H300)
Skin corrosion/irritation	Category 1 - (H314)
Serious eye damage/eye irritation	Category 1 - (H318)
Carcinogenicity	Category 1B - (H350)

15021 Actinomycin D

Reproductive toxicity

Category 2 - (H361)

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

2.2. Label elements



Signal word

Danger

Hazard statement(s)

H300 - Fatal if swallowed

H314 - Causes severe skin burns and eye damage

H361 - Suspected of damaging fertility or the unborn child

H350 - May cause cancer

Precautionary statement(s)

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

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

P201 - Obtain special instructions before use

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

P281 - Use personal protective equipment as required

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

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

P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

P280 - Wear eye protection/ face protection

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310 - Immediately call a POISON CENTER or doctor/physician

2.3. Other hazards

None under normal use conditions.

SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms

Actinomycin D;

Dactinomycin;

COSMEGEN®;

2-amino-4,6-dimethyl-3-oxo-1-N,9-N-bis[(3R,6S,7R,10S,16S)-7,11,14-trimethyl-2,5,9,12,15-pentaoxo-3,10-di(propan-2-yl)-8-oxa-1,4,11,14-tetrazabicyclo[14.3.0]nonadecan-6-yl]phenoxazine-1,9-dicarboxamide

Formula

C₆₂H₈₆N₁₂O₁₆

Chemical Name	CAS No	Weight %	EC No	Classification (1272/2008)	REACH Registration Number
dactinomycin	50-76-0	100	200-063-6	Acute Tox. 2 (H300) Skin Corr. 1B (H314) Carc. 1B (H350) Repr. 2 (H361)	no data available

For the full text of the R-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.
Skin contact	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Ingestion	Clean mouth with water and afterwards drink plenty of water.

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

Toxic effects (excepting nausea and vomiting) usually do not become apparent until two to four days after exposure and may not peak until one to two weeks. Manifestations of overdose in patients have included nausea, vomiting, diarrhea, mucositis including stomatitis, gastrointestinal ulceration, severe skin disorders including skin exfoliation, exanthema, desquamation and epidermolysis, severe hematopoietic depression, veno-occlusive disease, acute renal failure, sepsis (including neutropenic sepsis) with fatal outcome and death.

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

Notes to physician	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable Extinguishing Media	No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

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	Evacuate personnel to safe areas. Ensure adequate ventilation.
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	Take up mechanically, placing in appropriate containers for disposal.

15021 Actinomycin D

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)

Use as a laboratory reagent.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls

Showers, eyewash stations, and ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Safety glasses with side-shields.

Skin protection

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
Appearance	Crystalline Powder
Color	Red Orange
Odor	No information available
Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH		No information available
Melting point/freezing point	241.5 - 243 °C	(with decomposition)
Initial boiling point and boiling range		No information available
Flash point		No information available.
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

15021 Actinomycin D

Relative density	No information available
Solubility	No information available
Partition coefficient: n-octanol/water	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available.
Viscosity	No information available
Explosive properties	No information available
Oxidizing properties	No information available

9.2. Other information

Softening point	No information available
Molecular Weight	1255.4 g/mol
Solubility in other solvents	Soluble in dimethyl sulfoxide (DMSO) @ 50 mg/mL, Ethanol, propylene glycol
VOC content	No information available
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

None known based on information supplied.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

None under normal use conditions.

SECTION 11: Toxicological information

11.1. 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
dactinomycin	7.2 mg/kg (Rat)	-	-

Information on likely routes of exposure

Inhalation	There is no data available for this product.
Eye contact	Corrosive to the eyes and may cause severe damage including blindness.
Skin contact	May cause burns. May be harmful in contact with skin.
Ingestion	May be fatal if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May cause adverse liver effects.

Symptoms	Toxic effects (excepting nausea and vomiting) usually do not become apparent until two to four days after exposure and may not peak until one to two weeks. Manifestations of overdose in patients have included nausea, vomiting, diarrhea, mucositis including stomatitis, gastrointestinal ulceration, severe skin disorders including skin exfoliation, exanthema, desquamation and epidermolysis, severe hematopoietic depression, veno-occlusive disease, acute renal failure, sepsis (including neutropenic sepsis) with fatal outcome and death.
Skin corrosion/irritation	Causes burns.
Serious eye damage/eye irritation	Risk of serious damage to eyes.
Sensitization	No information available.
Mutagenic effects	Dactinomycin has been shown to be mutagenic in a number of test systems in vitro and in vivo including human fibroblasts and leukocytes, and HeLa cells. DNA damage and cytogenetic effects have been demonstrated in the mouse and the rat.
Carcinogenic effects	The International Agency on Research on Cancer (IARC) has judged that dactinomycin is a positive carcinogen in animals. Local sarcomas were produced in mice and rats after repeated subcutaneous or intraperitoneal injection. Mesenchymal tumors occurred in male F344 rats given intraperitoneal injections of 0.05 mg/kg, 2 to 5 times per week for 18 weeks. The first tumor appeared at 23 weeks. Two groups of 25 male and 25 female Charles River CD rats were given i.p. injections of 0.022 or 0.045 mg/kg bw thrice weekly for 6 months, followed by observation for a further 12 months, at which time the animals were killed. Peritoneal sarcomas developed in 32/38 males and 25/36 females.
Reproductive toxicity	This material is classified as a Pregnancy Category D: Positive evidence of risk. Has been shown to cause malformations and embryotoxicity in rats, rabbits, and hamsters when given in doses of 0.05-0.1 mg/kg.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Target Organ Effects	Liver, Reproductive system, Hematopoietic System, Eyes, Skin.
Aspiration Hazard	No information available.
Other information	No information available.

SECTION 12: Ecological information

12.1. Toxicity

No information available.

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. 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

IMDG/IMO

14.1 UN number	UN2928
14.2 UN proper shipping name	Toxic solid, corrosive, organic, n.o.s. (dactinomycin)
14.3 Transport hazard class(es)	6.1,(8)
14.4 Packing group	II
14.5 Environmental hazards	None
14.6 Special precautions for user	None
EmS No.	F-A, S-B
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not regulated

ADR/RID

14.1 UN number	UN2928
14.2 UN proper shipping name	Toxic solid, corrosive, organic, n.o.s. (dactinomycin)
14.3 Transport hazard class(es)	6.1,(8)
14.4 Packing group	II
14.5 Environmental hazards	None
14.6 Special precautions for user	None
Classification Code	TC2
Tunnel Restriction Code	(D/E)

IATA

14.1 UN number	UN2928
14.2 UN proper shipping name	Toxic solid, corrosive, organic, n.o.s. (dactinomycin)
14.3 Transport hazard class(es)	6.1,(8)
14.4 Packing group	II
14.5 Environmental hazards	None
14.6 Special precautions for user	None
Special provisions	A5

SECTION 15: Regulatory information

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

Candidate List of Substances of Very High Concern for Authorization Information

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

SEVESO Directive Information

H2 - Acute Toxic [50 tonnes (Lower-tier) 200 tonnes (Upper-tier)]

International inventories

TSCA 8(b)	-
DSL/NDSL	-
EINECS/ELINCS	Complies
ENCS	-

15021 Actinomycin D

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

H300 - Fatal if swallowed
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H350 - May cause cancer
H361 - Suspected of damaging fertility or the unborn child

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.