

COSMEGEN® / COSMEGEN LYOVAC® / LYOVAC COSMEGEN® (dactinomycin)



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : COSMEGEN® (DACTINOMYCINE)

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

Drug.

1.3. Details of the supplier of the safety data sheet

Registered company name : ORPHAN EUROPE.

Address : Immeuble Le Wilson - 70, avenue du Général de Gaulle.92800.PUTEAUX.France.

Telephone : +33 (0)1 47 73 97 58. Fax : +33 (0)1 49 00 18 00.

Email: ynarcisse@orphan-europe.com

<http://www.orphan-europe.com>

1.4. Emergency telephone number : +33 (0)1 45 42 59 59.

Association/Organisation : INRS / ORFILA <http://www.centres-antipoison.net>.

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Acute oral toxicity, Category 3 (Acute Tox. 3, H301).

Skin irritation, Category 2 (Skin Irrit. 2, H315).

Eye irritation, Category 2 (Eye Irrit. 2, H319).

Carcinogenicity, Category 1A (Carc. 1A, H350).

Reproductive toxicity, Category 1A (Repr. 1A, H360).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS08



GHS06

Signal Word :

DANGER

Product identifiers :

EC 200-063-6

DACTINOMYCIN

Additional labeling :

For professional use only.

Hazard statements :

H301

Toxic if swallowed.

H315

Causes skin irritation.

H319

Causes serious eye irritation.

H350

May cause cancer (if swallowed).

H360FD

May damage fertility. May damage the unborn child.

Precautionary statements - Prevention :

P201

Obtain special instructions before use.

P202

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

P264

Wash hands thoroughly after handling.

P280

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

Precautionary statements - Response :

P301 + P310

IF SWALLOWED: Immediately call a POISON CENTER/doctor.

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P302 + P352	IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P330	Rinse mouth.
P332 + P313	If skin irritation occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.
Precautionary statements - Disposal :	
P501	Dispose of contents/container at a disposal facility in accordance with local regulations.

2.3. Other hazards

In use, may form flammable/explosive dust-air mixture.

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	Note	%
CAS: 69-65-8 EC: 200-711-8 MANNITOL			97,60 %
CAS: 50-76-0 EC: 200-063-6 DACTINOMYCIN	GHS08, GHS06, GHS05 Dgr Acute Tox. 2, H300 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335 Carc. 1A, H350 Repr. 1A, H360FD	[2]	2,40 %

Information on ingredients :

[2] Carcinogenic, mutagenic or reprotoxic (CMR) substance.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of exposure by inhalation :

If inhaled, move the patient into the fresh air and keep warm and at rest.

If breathing is irregular or has stopped, proceed with artificial respiration and seek medical attention.

In the event of splashes or contact with eyes :

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of splashes or contact with skin :

Remove contaminated clothing and wash the skin thoroughly with soap and water or a recognised cleaner.

Watch out for any remaining product between skin and clothing, watches, shoes, etc.

If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.

In the event of swallowing :

Do not give the patient anything orally.

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water, administer activated medical charcoal and consult a doctor.

Seek medical attention immediately, showing the label.

If swallowed accidentally, do not allow to drink, do not induce vomiting and transfer to hospital immediately by ambulance. Show the label to the doctor.

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

No data available.

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

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

No data available.

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)
- carbon dioxide (CO₂)
- nitrogen oxide (NO)
- nitrogen dioxide (NO₂)

5.3. Advice for firefighters

Due to the toxicity of the gas emitted on thermal decomposition of the products, fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Avoid any contact with the skin and eyes.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Retrieve the product by mechanical means (sweeping/vacuuming) : do not generate dust.

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

Avoid exposure to pregnant women and warn women of child-bearing age of the possible risks

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid skin and eye contact with this mixture.

Avoid exposure - obtain special instructions before use.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Storage

Keep away from food and drink, including those for animals.

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Packaging

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No data available.

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Before handling powders or dust emission, wear mask goggles in accordance with standard EN166.

Prescription glasses are not considered as protection.

Provide eyewash stations in facilities where the product is handled constantly.

- Hand protection

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

Recommended properties :

- Impervious gloves in accordance with standard EN374

- Body protection

Avoid skin contact.

Wear suitable protective clothing.

These clothes shall be chosen to ensure there is no inflammation or irritation of the skin at the neck and wrist by contact with the powder

Suitable type of protective clothing :

Wear protective clothing against solid chemicals and particles suspended in the air (type 5) in accordance with standard EN13982-1 to prevent skin contact.

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection

Avoid breathing dust.

Type of FFP mask :

Wear a disposable half-mask dust filter in accordance with standard EN149.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state :

Powder or dust.

Colour:

Yellow to orange.

Odour:

Odourless.

Important health, safety and environmental information

pH :

Not relevant.

Flash point interval :

Not relevant.

Vapour pressure (50°C) :

Not relevant.

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Density :	Not stated.
Water solubility :	Soluble.
% VOC :	0

9.2. Other information

No data available.

SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid :

- formation of dusts

Dusts can form an explosive mixture with air.

10.5. Incompatible materials

Keep away from :

- strong oxidising agents
- strong acids
- strong bases

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO₂)
- nitrogen oxide (NO)
- nitrogen dioxide (NO₂)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Toxic if swallowed.

May cause irreversible damage to the skin; namely inflammation of the skin or the formation of erythema and eschar or oedema following exposure up to four hours.

May have reversible effects on the eyes, such as eye irritation which is totally reversible by the end of observation at 21 days.

Known human carcinogen.

Known human reproductive toxicant.

May damage fertility and the unborn child.

11.1.1. Substances

Acute toxicity :

DACTINOMYCIN (CAS: 50-76-0)

Oral route :

LD50 = 7.2 mg/kg

Species : Rat

11.1.2. Mixture

No toxicological data available for the mixture.

SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

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12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

German regulations concerning the classification of hazards for water (WGK) :

WGK 2 (VwVwS vom 27/07/2005, KBwS) : Hazardous for water.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14 : TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2015 - IMDG 2014 - ICAO/IATA 2016).

14.1. UN number

2811

14.2. UN proper shipping name

UN2811=TOXIC SOLID, ORGANIC, N.O.S.
(dactinomycin)

14.3. Transport hazard class(es)

- Classification :



6.1

14.4. Packing group

III

14.5. Environmental hazards

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14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	6.1	T2	III	6.1	60	5 kg	274 614	E1	2	E

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ
	6.1	-	III	5 kg	F-A,S-A	223 274	E1

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	6.1	-	III	670	100 kg	677	200 kg	A3 A5	E1
	6.1	-	III	Y645	10 kg	-	-	A3 A5	E1

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

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14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No data available.

SECTION 15 : REGULATORY INFORMATION

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

- Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 487/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 944/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 605/2014.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 1297/2014.

- Container information:

No data available.

Usage restrictions apply to the product : See annex XVII of EC regulation No. 1907/2006.

For professional users only.

- Particular provisions :

No data available.

- German regulations concerning the classification of hazards for water (WGK) :

WGK 2 (VwVwS vom 27/07/2005, KBws) : Hazardous for water.

- Standardised American system for the identification of hazards presented by the product in view of emergency procedures (NFPA 704) :

NFPA 704, Labelling: Health=2 Inflammability=1 Instability/Reactivity=1 Specific Risk=none



15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Wording of the phrases mentioned in section 3 :

H300	Fatal if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H350	May cause cancer .
H360FD	May damage fertility. May damage the unborn child.

Abbreviations :

CMR: Carcinogenic, mutagenic or reprotoxic.

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

WGK : Wassergefährdungsklasse (Water Hazard Class).

GHS06 : Skull and crossbones

GHS08 : Health hazard

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PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.