

Erythromycin

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 03/09/2012 Revision date: 03/02/2017

504963

Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Erythromycin
IUPAC name : Erythromycin A: (3R,4S,5S,6R,7R,9R,11R,12R,13S,14R)-4-[(2,6-dideoxy-3-C-methyl-3-O-methyl- α -L-ribo-hexapyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[(3,4,6-trideoxy-3-dimethylamino- β -D-xylo-hexapyranosyl)-oxy]oxacyclotetradecane-2,10-dione
EC-No. : 204-040-1
CAS-No. : 114-07-8
Product code : 504963
Formula : Erythromycin A: C₃₇H₆₇NO₁₃
Product group : Raw material
Other means of identification : Mixture of macrolide antibiotics produced by a strain of Streptomyces erythreus, the main component being erythromycin A.

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Industrial/Professional use spec : For professional use only
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - The Netherlands
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Respiratory sensitisation, Category 1

H334

Skin sensitisation, Category 1

H317

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard pictograms (CLP)

:



GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements (CLP)

: P261 - Avoid breathing dust
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician**2.3. Other hazards**

No additional information available

SECTION 3: Composition/information on ingredients**3.1. Substances**

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Erythromycin	(CAS-No.) 114-07-8 (EC-No.) 204-040-1	100	Resp. Sens. 1, H334 Skin Sens. 1, H317

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures**4.1. Description of first aid measures**

First-aid measures after inhalation : Remove victim to fresh air. Seek medical attention immediately.

- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical attention if ill effect or irritation develops.
- First-aid measures after eye contact : Rinse immediately with plenty of water. If eye irritation persists, take medical advice.
- First-aid measures after ingestion : Rinse mouth. Drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical advice.

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

- Symptoms/effects : Exposure may produce an allergic reaction. This material or its emissions may induce blood disorders and/or aggravate pre-existing blood disorders. Gastrointestinal complaints.

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

No additional information available

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

- Suitable extinguishing media : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon dioxide. Carbon monoxide. Nitrogen oxides.
- Explosion hazard : Product is not explosive.

5.3. Advice for firefighters

- Precautionary measures fire : Exercise caution when fighting any chemical fire.
- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Ensure adequate air ventilation. Avoid raising dust.

6.1.2. For emergency responders

- Protective equipment : Wear proper protective equipment. Wear respiratory protection.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Sodium hypochlorite solution.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Protect from light.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Hand protection:**

Chemical resistant PVC gloves (to European standard EN 374 or equivalent)

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck). The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace

Respiratory protection:

Respiratory protection according to European standard EN 14387 or equivalent. Dust production: dust mask with filter type P2

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Powder. Crystalline solid.
Molecular mass	: 734 g/mol erythromycin A
Colour	: White. Slightly yellow.
Odour	: odourless.
Odour threshold	: No data available
pH	: 8 - 10.5 saturated solution
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 135 - 140 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available

Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Material nearly insoluble in water. Soluble in : Ethanol. Methanol. Water: 2 g/l
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

heat. High temperature. Light (daylight).

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Erythromycin (114-07-8)	
LD50 oral rat	4600 mg/kg

Skin corrosion/irritation	: Not classified pH: 8 - 10.5 saturated solution
Serious eye damage/irritation	: Not classified pH: 8 - 10.5 saturated solution
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Erythromycin (114-07-8)	
LC50 fish 1	349 mg/l

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

- Overland transport

No data available

- Air transport

No data available

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

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Erythromycin is not on the REACH Candidate List

Erythromycin is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Skin and body protection	Modified	Added additional information (type of clothing related to concentration levels)

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

Data sources : EP. Supplier.

Full text of H- and EUH-statements:

Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Sens. 1	Skin sensitisation, Category 1
H317	May cause an allergic skin reaction
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

SDS EU (REACH Annex II) Version 2017

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product