

Clindamycin hydrochloride

Safety Data Sheet

545945

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
 Date of issue: 10/08/2012 Revision date 04/03/2020
 Supersedes 14/11/2018

Version: 4.0

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

1.1. Product identifier

Product form : Substance
 Substance name : Clindamycin hydrochloride
 EC-No. : 244-398-6
 CAS-No. : 21462-39-5
 Product code : 545945
 Type of product : Antibiotics
 Formula : C₁₈H₃₄Cl₂N₂O₅S
 Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Professional use
 Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals
 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 - Nederland
 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)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] show CLP information only

Serious eye damage/eye irritation, Category 2 H319

Clindamycin hydrochloride

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Skin sensitisation, category 1B

H317

Reproductive toxicity, Category 2

H361d

Full text of 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] Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP)



Signal word (CLP)

: Warning

Hazard statements (CLP)

: H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H361d - Suspected of damaging the unborn child.

Precautionary statements (CLP)

: P261 - Avoid breathing dust.
P302+P352 - IF ON SKIN: Wash with plenty of water/...
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.
P308+P313 - IF exposed or concerned: Get medical advice.

2.3. Other hazards

Other hazards not contributing to the classification : Exposure may produce an allergic reaction.

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Pharmaceuticals

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Clindamycin hydrochloride	(CAS-No.) 21462-39-5 (EC-No.) 244-398-6	91 - 102	Eye Irrit. 2, H319 Skin Sens. 1B, H317 Repr. 2, H361d

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 | : Allow affected person to breathe fresh air
Get medical advice and attention if you feel unwell. |
| First-aid measures after skin contact | : Seek medical attention if ill effect or irritation develops
Wash skin with mild soap and water. |
| 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.
Never give anything by mouth to an unconscious person. |

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

- | | |
|--|---|
| Explosion hazard | : Product is not explosive. |
| Hazardous decomposition products in case of fire | : Halogenated compounds
Carbon oxides (CO, CO ₂)
Nitrogen oxides
Sulphur oxides. |

5.3. Advice for firefighters

- | | |
|--------------------------------|---|
| 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

- | | |
|----------------------|--|
| Protective equipment | : Use the personal protective equipment as indicated in chapter 8. |
| Emergency procedures | : Avoid raising dust. |

6.1.2. For emergency responders

- | | |
|----------------------|--|
| Protective equipment | : Do not attempt to take action without suitable protective equipment. |
|----------------------|--|

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. Clean contaminated surfaces with an excess of water.

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 moisture.

Incompatible products : Oxidizing agent.

Storage temperature : 15 - 25 °C

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**Appropriate engineering controls:**

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Hand protection:

Wear gloves according to EN374 to protect against skin effects from powders.

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

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 461.5 g/mol
Colour	: White to off-white.
Odour	: No data available
Odour threshold	: No data available
pH	: 3 - 5 (10% in water)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 141 - 143 °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	: Soluble in water.
Log Pow	: 1.015
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

Stable under normal conditions.

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

Moisture.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

release of harmful/irritant gases/vapours.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Not classified

Clindamycin hydrochloride (21462-39-5)	
LD50 oral rat	< 2193 mg/kg

Skin corrosion/irritation : Not classified
pH: 3 - 5 (10% in water)

Serious eye damage/irritation : Causes serious eye irritation.
pH: 3 - 5 (10% in water)

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Suspected of damaging the unborn child.

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information**12.1. Toxicity**

Ecology - general : There are no available data for a classification.

12.2. Persistence and degradability

Clindamycin hydrochloride (21462-39-5)	
Persistence and degradability	Biodegradability in water: no data available.

12.3. Bioaccumulative potential

Clindamycin hydrochloride (21462-39-5)	
Log Pow	1.015
Bioaccumulative potential	Low bioaccumulation potential.

12.4. Mobility in soil

Clindamycin hydrochloride (21462-39-5)	
Ecology - soil	There are no available data for a classification.

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**

- Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.
- Waste treatment methods : Avoid release to the environment.
- Product/Packaging 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

Clindamycin hydrochloride is not on the REACH Candidate List

Clindamycin hydrochloride 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:

1.1	EC Index-No.	Removed	
7.3	Specific end uses	Removed	

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
LD50	Median lethal dose
BCF	Bioconcentration factor
ATE	Acute Toxicity Estimate
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DPD	Dangerous Preparations Directive 1999/45/EC

Data sources : EP. Supplier.

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Repr. 2	Reproductive toxicity, Category 2
Skin Sens. 1B	Skin sensitisation, category 1B
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H361d	Suspected of damaging the unborn child.

SDS EU (REACH Annex II) ducheffa nieuwe logo

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.