

Minocycline hydrochloride dihydrate

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 02/03/2015 Revision date: 24/02/2017

900624

Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Minocycline hydrochloride dihydrate
EC No : 237-099-7
CAS No : 13614-98-7
Product code : 900624
Type of product : Antibiotics
Formula : C₂₃H₂₇N₃O₇ · HCl
Synonyms : 7-dimethylamino-6-demethyl-6-deoxytetracycline hydrochloride
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 : Pharmaceutical industry
Industrial/Professional use spec : Industrial
For professional use only
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

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)

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]

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Reproductive toxicity, Additional category, Effects on or via lactation	H362
Reproductive toxicity, Category 2	H361
Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation	H335

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)



GHS07

GHS08

Signal word (CLP) : Warning

Hazard statements (CLP) : H315 - Causes skin irritation
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation
H361 - Suspected of damaging fertility or the unborn child
H362 - May cause harm to breast-fed children

Precautionary statements (CLP) : P261 - Avoid breathing dust, vapours
P263 - Avoid contact during pregnancy/while nursing
P280 - Wear protective gloves, protective clothing, eye protection, face shield
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Minocycline hydrochloride dihydrate	(CAS No) 13614-98-7 (EC No) 237-099-7	> 95	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Lact., H362 Repr. 2, H361 STOT SE 3, H335

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 general	: Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention. May cause harm to breast-fed children.
First-aid measures after inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
First-aid measures after skin contact	: Wash with plenty of soap and water. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Do not give an unconscious person anything to drink.

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

Symptoms/injuries	: Suspected of damaging fertility or the unborn child.
Symptoms/injuries after inhalation	: May cause respiratory irritation.
Symptoms/injuries after skin contact	: Causes skin irritation.
Symptoms/injuries after eye contact	: Causes serious eye irritation.

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	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic and irritating gases are released.
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5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
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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 : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection. Extra personal protection: P2 filter respirator for harmful particles. Protective gloves.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Take precautionary measures against static discharges. Do not breathe dust. Avoid contact with skin and eyes. Avoid frequent contact with substance.

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy/while nursing. Avoid raising dust. Avoid breathing gas, vapours, mist, fume, spray, dust. Use only outdoors or in a well-ventilated area.

Hygiene measures : Wash hands and other exposed parts thoroughly after handling. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Water, humidity. Keep container tightly closed.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Minocycline hydrochloride dihydrate (13614-98-7)		
EU	IOELV TWA (mg/m³)	0.07 mg/m³ 8h

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8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Facilities: shower, eye shower.

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

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)

Respiratory protection:

Dustmask with filtertype P3

Consumer exposure controls:

Avoid contact during pregnancy/while nursing.

Other information:

Do not eat, drink or smoke during use. Wash hands thoroughly after handling.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 493.95 g/mol
Colour	: Yellow.
Odour	: Characteristic.
Odour threshold	: No data available
pH	: 3.5 - 4.5 (1% w/v sol. in water).
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 228 °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)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 0.55
Solubility	: Poorly soluble in water.

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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

Minimum ignition energy : ≈

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable at normal conditions. zie rubriek 7. Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. UV sources. Carbonizes at 223°C. Extremely high or low temperatures.

10.5. Incompatible materials

Strong oxidizers. Strong acids. Strong bases.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Chlorine gas. fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Minocycline hydrochloride dihydrate (13614-98-7)	
LD50 oral rat	2380 mg/kg
LD50 oral	3600 mg/kg mouse
LD50 intraperitoneal	331 mg/kg (rat)
LD50 intravenous	164 mg/kg (rat)
LD50 intraperitoneal	299 mg/kg (mouse)
LD50 intravenous	154 mg/kg (mouse)

Skin corrosion/irritation : May cause eye, skin and respiratory system irritation
pH: 3.5 - 4.5 (1% w/v sol. in water).

Serious eye damage/irritation : May cause eye-irritation of susceptible persons
pH: 3.5 - 4.5 (1% w/v sol. in water).

Respiratory or skin sensitisation : May cause irritation or asthma-like symptoms. Dust and/or fine particles,
minimize inhalation exposure

Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

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Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: May cause harm to breast-fed children. Suspected of damaging fertility or the unborn child.
Additional information	: May cause harm to breast-fed children Detected: maximal concentrations of 0.8 mg/l in milk after administration of a dose of 200 mg
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

Minocycline hydrochloride dihydrate (13614-98-7)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Minocycline hydrochloride dihydrate (13614-98-7)	
Bioaccumulative potential	Not established.

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

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials : Avoid release to the environment.

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

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ADR	IATA
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

Minocycline hydrochloride dihydrate is not on the REACH Candidate List

Minocycline hydrochloride dihydrate 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:

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.

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

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

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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
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation
Repr. 2	Reproductive toxicity, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children

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