

Oxytetracycline hydrochloride

Safety Data Sheet

according to Regulation (EU) 2015/830

Date of issue: 06/01/2012 Revision date 18/12/2017

O0140

Version: 2.0

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

1.1. Product identifier

Product form : Substance
 Trade name : Oxytetracycline hydrochloride
 EC-No. : 218-161-2
 CAS-No. : 2058-46-0
 Product code : O0140
 Formula : C₂₂H₂₄N₂O₉ · HCl
 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
 Industrial/Professional use spec : For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Biochemie B.V.
 A. Hofmanweg 71
 2031 BH Haarlem - The Netherlands
 T +31(0)23-5319093 - F +31(0)23-5318027
info@duchefa.nl

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
World Health Organization world directory of poison centres	http://apps.who.int/poisoncentres/	Consult website for a local poison centre

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Acute toxicity (oral), Category 4 H302
 Acute toxicity (dermal), Category 4 H312
 Acute toxicity (inhal.), Category 4 H332
 Reproductive toxicity, Category 2 H361

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) :

H302+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled
H361 - Suspected of damaging fertility or the unborn child.

Precautionary statements (CLP) :

P201 - Obtain special instructions before use.
P280 - Wear Protective clothing, protective gloves, face shield, eye protection.
P308+P313 - IF exposed or concerned: Get medical advice/attention.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name : Oxytetracycline hydrochloride

CAS-No. : 2058-46-0

EC-No. : 218-161-2

Name	Product identifier	%
Oxytetracycline hydrochloride	(CAS-No.) 2058-46-0 (EC-No.) 218-161-2	> 95

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 person to fresh air and keep comfortable for breathing.
Seek medical advice.First-aid measures after skin contact : Flush with plenty of water
Seek medical advice.First-aid measures after eye contact : Rinse with plenty of water
Seek medical advice.First-aid measures after ingestion : Rinse mouth out with water
Seek medical advice.

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

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

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 : Alcohol resistant foam.
Dry chemical powder.
Carbon dioxide (CO₂).
Water spray.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : When heated to decomposition, emits toxic fumes:
- CO_x
- NO_x.

5.3. Advice for firefighters

Firefighting instructions : Avoid (reject) fire-fighting water to enter 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

Measures in case of dust release : Avoid dust formation.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Do not allow to enter drains or water courses.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly.

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
Store at ambient temperature
Keep container tightly closed and dry
Moisture sensitive.

7.3. Specific end use(s)

For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

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:

Long sleeved protective clothing. Chemical resistant apron

Respiratory protection:

Wear appropriate mask. Filter type P3 (EN 143)

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Molecular mass	: 496,9 g/mol
Colour	: Yellow.
Odour	: Odourless.
Odour threshold	: No data available
pH	: 2,3 - 2,9 (Source: Pharmacopoeia)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
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 ethanol Soluble in water.
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

Stable under normal conditions of storage, handling and use.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Direct sunlight

- Moisture.

10.5. Incompatible materials

Strong bases.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed. Dermal: Harmful in contact with skin. Inhalation: Harmful if inhaled.

Oxytetracycline hydrochloride (2058-46-0)	
LD50 oral rat	4800 mg/kg
LD50 oral	6696 mg/kg (mouse)

Skin corrosion/irritation	: Not classified pH: 2,3 - 2,9 (Source: Pharmacopoeia)
Serious eye damage/irritation	: Not classified pH: 2,3 - 2,9 (Source: Pharmacopoeia)
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Other information	: See actual entry in RTECS for complete information: Q18225000.

SECTION 12: Ecological information

12.1. Toxicity

Oxytetracycline hydrochloride (2058-46-0)	
LC50 fish 1	< 200 mg/l (Salvelinus namaycush)

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Oxytetracycline hydrochloride (2058-46-0)	
EC50 Daphnia 1	46,2 mg/l (Daphnia magna)

12.2. Persistence and degradability

Oxytetracycline hydrochloride (2058-46-0)	
Persistence and degradability	Minimally biodegradable.

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

Additional information : Prevent entry to sewers and public waters. Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment.

SECTION 14: Transport information

In accordance with IMDG / ADR / IATA

ADR	IMDG	IATA
14.1. UN number		
Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name		
Not regulated	Not regulated	Not regulated
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
Not regulated	Not regulated	Not regulated
No supplementary information available		

14.6. Special precautions for user

· Overland transport

Not regulated

- Transport by sea

Not regulated

- Air transport

Not regulated

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

Oxytetracycline hydrochloride is not on the REACH Candidate List

Oxytetracycline hydrochloride is not on the REACH Annex XIV List

15.1.2. National regulations

Ensure all national/local regulations are observed.

Germany

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV

: Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen

: The substance is not listed

SZW-lijst van mutagene stoffen

: The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding

: The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid

: The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling

: The substance is not listed

Denmark

Recommendations Danish Regulation

: Young people below the age of 18 years are not allowed to use the product
Pregnant/breastfeeding women working with the product must not be in direct contact with the product
The requirements from the Danish Working Environment Authorities regarding work with carcinogens must be followed during use and disposal

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

1.4	Emergency number	Modified	
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

ATE	Acute Toxicity Estimate
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ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet

Data sources : Manufacturer. ECHA (European Chemicals Agency).

Full text of H- and EUH-statements:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Repr. 2	Reproductive toxicity, Category 2
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H332	Harmful if inhaled.
H361	Suspected of damaging fertility or the unborn child.

SDS Biochemicals version 2017

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