

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 : 00140

Formula : C22H24N2O9 · HCI

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 | http://apps.who.int/poisoncentres/ | Consult website for a local poison centre |
| directory of poison centres     |                                    |   |

### **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

Safety Data Sheet

according to Regulation (EU) 2015/830

#### 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 | > 95 |
|                               | (EC-No.) 218-161-2  |      |

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.

Safety Data Sheet

according to Regulation (EU) 2015/830

### 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 : When heated to decomposition, emits toxic fumes:

- COx

case of fire

- NOx.

### 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.

Safety Data Sheet

according to Regulation (EU) 2015/830

### SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

### Hand protection:

| Туре   | 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 : No data available

(butylacetate=1)

Melting point : No data available Freezing point : No data available **Boiling point** : No data available Flash point : No data available : No data available Auto-ignition temperature Decomposition temperature : No data available : No data available Flammability (solid, gas) : No data available Vapour pressure Relative vapour density at 20 °C : No data available : No data available Relative density 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

 18/12/2017 Duchefa Biochemie B.V.
 EN (English)
 SDS Ref.: 00140
 4/8

Safety Data Sheet

according to Regulation (EU) 2015/830

#### 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: QI8225000.

## **SECTION 12:** Ecological information

### 12.1. Toxicity

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

Safety Data Sheet

according to Regulation (EU) 2015/830

| 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                  | 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

SDS Ref.: 00140

Safety Data Sheet

according to Regulation (EU) 2015/830

### - 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 - : Is not subject of the 12. BlmSchV (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 – : The substance is not listed Vruchtbaarheid

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               |  |

18/12/2017 Duchefa Biochemie B.V. EN (English) SDS Ref.: 00140 7/8

## Safety Data Sheet

according to Regulation (EU) 2015/830

| 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

18/12/2017 Duchefa Biochemie B.V. EN (English) SDS Ref.: 00140 8/8