

According to Regulation (EC) No 1907/2006/EC and Commission Regulation (UE) No 453/2011

## 1. Identification of the Substance/ Mixture and of the company/undertaking

### 1.1 Product identifier:

#### MINOCYCLINE HYDROCHLORIDE

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

Antibiotic (active pharmaceutical ingredient) - industrial use

### 1.3 Details of the supplier of the safety data sheet:

CIPAN - Companhia Industrial Produtora de Antibióticos, S.A

Rua da Estação, 42 Vala do Carregado

2600-726 Castanheira do Ribatejo, Portugal

+351 263 856 800 (tel) +351 263 855 086 (Fax)

info@atralcipan.pt

www.atralcipan.pt

### 1.4 Emergency telephone number:

(POR) CENTRO INFORMAÇÃO ANTI-VENENOS – 808 250 143

(USA) POISON CONTROL NUMBER – 1-800-222-1222

## 2. Hazards Identification

### 2.1 Classification of the substance or mixture

#### According to Regulation (EC) No1272/2008 and amendments

Skin irritation (category 2), H315

Eye irritation (category 2), H319

Specific target organ toxicity – single exposure (category 3), H335

Specific target organ toxicity – repeated exposure (category 2), H373

Reproductive toxicity (category 2), H361d

Effect on or via lactation (lact.), H362

For the full text of the Hazard Statements, see Section 16.

#### According to European Directive 67/548/EEC or 1999/45/EC and amendments

Danger of cumulative effects. Irritating to eyes, respiratory system and skin. Possible risk of harm to the unborn child.

May cause harm to breastfed babies.

Xn - Harmful

R33

R36/37/38

R64 / 63

For the full text, see Section 16.

## 2.2 Label Elements

*Regulation (EC) No 1272/2008 and amendments*

### Hazard Pictograms



### Signal-Word

Warning


### Hazard statement(s)

H315 Causes skin irritation  
H319 Causes serious eye irritation  
H335 May cause respiratory irritation  
H373 May cause damage to organs through prolonged or repeated exposure  
H361d Suspected of damaging the unborn child  
H362 May cause harm to breast-fed children

### Precautionary statement(s)

P202 Do not handle until all safety precautions have been read and understood.  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P263 Avoid contact during pregnancy/while nursing.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P403+P233 Store in a well-ventilation place. Keep container tightly closed.  
P410 Protect from sunlight  
P411 Store at temperatures not exceeding 25°C/77°F.  
P501 Dispose of contents/containers to licensed operator of hazardous waste.

### DL N° 98/2010

|                      |                                |  |
|----------------------|--------------------------------|--|
| <b>Symbol(s)</b>     | Xn                             |   |
| <b>R – Phrase(s)</b> | R33<br>R63<br>R36/37/38<br>R64 | Danger of cumulative effects.<br>Possible risk of harm to the unborn child.<br>Irritating to eyes, respiratory system and skin.<br>May cause harm to breastfed babies. |
| <b>S – Phrase(s)</b> | S36-26                         | Wear suitable protective clothing. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.                                       |

**Toxic for reproduction:** unborn child : Category 3 : Substances which cause concern for humans owing to possible developmental toxic effects.

### 2.3 Other Hazards:

No data available

## 3. Composition/ Information on Ingredients

### 3.1 Substances:

| Chemical Name   | CAS n°     | EINECS n° | Chemical Formula   | Molecular Weight | Concentration | Classification   |
|---|------------|-----------|--|------------------|---------------|--|
| [4S-(4 $\alpha$ ,4a $\alpha$ ,5a $\alpha$ ,12a $\alpha$ )]-4,7-bis(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydroxy-1,11-dioxonaphthacene-2-carboxamide monohydrochloride | 13614-98-7 | 237-099-7 | C <sub>23</sub> H <sub>27</sub> N <sub>3</sub> O <sub>7</sub> .HCl | 493.94 g/mol     | -             | Skin Irrit. 2; Eye Irrit. 2; STOT SE 3; STOT RE 2; Repr. 2; Lact.; H315, H319, H335, H373, H361d, H362<br><br>Xn; R33; R64; R36/37/38; Repr. Cat. 3, R63 |

For the full text of the H-Statements and R-phrases mentioned in this Section, see Section 16.

## 4. First aids measures

### 4.1 Description of first aid measures:

|                     |  |
|---------------------|--|
| <b>Skin Contact</b> | IF ON SKIN: Wash with plenty of soap and water( P302+P352).  |
| <b>Eyes Contact</b> | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. (P305 + P351 + P338). |
| <b>Inhalation</b>   | IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. (P304+P340).  |
| <b>Ingestion</b>    | Call a POISON CENTER or doctor/physician if you feel unwell. (P312).   |

### 4.2 Most important symptoms and effects, both acute and delayed:

May be harmful if inhaled. Causes respiratory tract irritation. May be harmful if swallowed. May be harmful if absorbed through skin. Causes skin irritation. Causes eye irritation.

### 4.3 Indication of any immediate medical attention and special treatment needed:

No data available.

## 5. Firefighting measures

### 5.1 Extinguishing media:

|                                       |  |
|---------------------------------------|--|
| <b>Suitable Extinguishing Media</b>   | Water spray, dry powder, carbon dioxide or foam. |
| <b>Unsuitable Extinguishing Media</b> | No data available.                               |

### 5.2 Special hazards arising from the substance or mixture:

Emits toxic fumes under fire conditions.

### 5.3 Advice for firefighters:

Firefighters should wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.



## 6. Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures:

#### For non-emergency personnel

Avoid contact with skin and eyes. Avoid breathing dust.

#### For emergency responders

Use personal protective equipment. Avoid dust formation. Ensure adequate ventilation.

### 6.2 Environmental precautions:

Do not let product enter drains.

### 6.3 Methods and material for containment and cleaning up:

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections:

See sections 8 and 13.

## 7. Handling and Storage

### 7.1 Precautions for safe handling:

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Wash hands before breaks and at the end of workday. Provide appropriate exhaust ventilation at places where dust is formed and assure the proximity of safety showers. Keep away from sources of ignition. Normal measures for preventive fire protection.

### 7.2 Conditions for safe storage, including any incompatibilities:

Store at a temperature not exceeding 25°C/77°C and protected from light.

### 7.3 Specific end use(s):

See section 1.2

## 8. Exposure Controls/ Personal Protection

### 8.1 Control parameters:

|                         |                   |
|-------------------------|-------------------|
| Threshold Limits Values | No data available |
|-------------------------|-------------------|

|                          |                   |
|--------------------------|-------------------|
| Biological Limits Values | No data available |
|--------------------------|-------------------|

### 8.2 Exposure controls:

#### Appropriate engineering controls

Provide appropriate exhaust ventilation at places where dust is formed.

#### Individual protection measures, such as personal protective equipment

|                        |   |
|------------------------|---|
| Respiratory Protection | Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator. |
| Hand Protection        | Wear suitable gloves resistant to chemical penetration.   |
| Eye Protection         | Chemical goggles or safety glasses.   |
| Skin Protection        | Choose body protection according to the amount and concentration of the dangerous substance at the work place.                      |

**Environmental exposure controls**

Assure the adequate treatment of atmospheric emissions.

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

|  |                   |
|--|-------------------|
| Appearance                                   | Yellow Powder     |
| Odour:                                       | No data available |
| Odour threshold                              | No data available |
| pH   | 3.5 – 4.5         |
| Melting point/freezing point                 | No data available |
| Initial boiling point and boiling range      | No data available |
| Flash point                                  | No data available |
| Evaporation rate                             | No data available |
| Flammability (solid, gas)                    | No data available |
| Upper/lower flammability or explosive limits | No data available |
| Solubility(ies)                              | No data available |
| Partition coefficient: n-octanol/water       | No data available |
| Auto-ignition temperature                    | No data available |
| Decomposition temperature                    | No data available |
| Viscosity;                                   | No data available |
| Explosive properties                         | No data available |
| Oxidising properties                         | No data available |

**9.2 Other information:**

No data available

**10. Stability and Reactivity**

|   |  |
|---|--|
| 10.1 Reactivity                         | No data available  |
| 10.2 Chemical stability                 | Stable   |
| 10.3 Possibility of hazardous reactions | No data available  |
| 10.3 Conditions to avoid                | Keep away from sources of ignition   |
| 10.5 Incompatible materials             | Strong oxidizing agents  |
| 10.6 Hazardous decomposition products   | When heated to decomposition materials emit toxic fumes. Emits toxic fumes under fire conditions |

## 11. Toxicological Information

### 11.1 Information on toxicological effects

|  |   |
|--|---|
| Acute toxicity                                     | LD <sub>50</sub> Oral - rat - 2,380 mg/kg   |
| Skin corrosion/irritation                          | No data available   |
| Serious damage/eye irritation                      | No data available   |
| Respiratory or skin sensitization                  | Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.   |
| Germ cell mutagenicity                             | No data available   |
| Carcinogenicity                                    | IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. |
| Reproductive toxicity                              | Possible risk of congenital malformation in the fetus.  |
| Specific target organ toxicity - single exposure   | May cause damaged to organs.  |
| Specific target organ toxicity - repeated exposure | No data available   |
| Aspiration hazard                                  | No data available   |
| Potential health effects                           | See Section 4.2   |
| Signs and Symptoms of Exposure                     | To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.                                     |

## 12. Ecological Information

|   |                   |
|---|-------------------|
| 12.1 Toxicity                           | No data available |
| 12.2 Persistence and degradability      | No data available |
| 12.3 Bioaccumulative potential          | No data available |
| 12.4 Mobility in soil                   | No data available |
| 12.5 Results of PBT and vPvB assessment | No data available |
| 12.6 Other adverse effects              | No data available |

## 13. Disposal Considerations

### 13.1 Waste treatment methods:

|                  |   |
|------------------|---|
| Product Disposal | Products must be disposed of in compliance with applicable regulations. |
| Package Disposal | Package must be disposed of in compliance with applicable regulations.  |



**14. Transport Information****14.1 UN number:**

Not applicable

**14.2 UN proper shipping name:**

Not applicable

**14.3 Transport hazard class(es):**

Not applicable

**14.4 Packing group:**

Not applicable

**14.5 Environmental hazards:**

Not applicable

**14.6 Special precautions for user:**

Not applicable

**15. Regulatory Information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006, Commission Regulation (UE) No 453/2011 and Regulation (EC) No.1272/2008

**15.2 Chemical safety assessment**

Not data available

**16. Other Information*****Text of H-code(s)***

H315 Causes skin irritation

H319 Causes serious eye irritation

H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure

H361d Suspected of damaging the unborn child

H362 May cause harm to breast-fed children

Repr. Cat. 3 - Toxic for reproduction Category 3: Substances which cause concern for humans owing to possible developmental toxic effects.

**Glossary**

CAS - Chemical Abstract Service Registry Number  
EINECS - European Inventory of Existing Commercial Chemical Substances  
IARC - International Agency for Research on Cancer

**Responsibilities**

The information contained in this publication is true and accurate to the best of our knowledge, any recommendations or suggestions which may be made are without guarantee, since conditions of use are beyond our control. The product is for commercial processing / use only.