



# CHEMO

## SAFETY DATA SHEET TERBINAFINA TABLET

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### 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Trade name : TERBINAFINA TABLET  
Product code : LC009

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

Use : Pharmaceutical.

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

Company identification : Laboratorios Liconsa, S.A.  
Poligono Industrial Miralcampo. Avda. Miralcampo, 7  
Tfo: +34 94 93 49700  
19200 Azuqueca de Henares - Guadalajara SPAIN  
ana.pizarro@chemogroup.net

#### 1.4. Emergency telephone number

Phone nr : Tfo: +34 94 93 49700 [ Office hours ]

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### 2. Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification EC 67/548 or EC 1999/45

Classification : Xi; R36/37/38  
N; R50-53

##### Hazard Class and Category Code(s), Regulation (EC) No 1272/2008 (CLP)

Health hazards : Skin irritation - Category 2 - Warning (CLP : Skin Corr. 2) H315  
Eye irritation - Category 2 - Warning (CLP : Eye Irrit. 2) H319  
Specific Target Organ Toxicity - Single exposure - Respiratory tract irritation -  
Category 3 - Warning (CLP : STOT SE 3) H335

Environmental hazards : Hazardous to the aquatic environment - Chronic hazard - Category 1 - Warning ( CLP : Aquatic Chronic 1) H410

#### 2.2. Label elements

##### Labelling EC 67/548 or EC 1999/45

Symbol(s)



: Xi : Irritant  
N : Dangerous for the environment

R Phrase(s)

: R36/37/38 : Irritating to eyes, respiratory system and skin.  
R50/53 : Very toxic to aquatic organisms, may cause long-term adverse effects in

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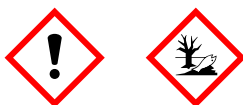
### TERBINAFINA TABLET

#### 2. Hazards identification (continued)

|                        |   |
|------------------------|---|
| <b>S Phrase(s)</b>     | the aquatic environment.<br>: S2 : Keep out of the reach of children.<br>S18 : Handle and open container with care.<br>S22 : Do not breathe dust.<br>S24/25 : Avoid contact with skin and eyes.<br>S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.<br>S29/35 : Do not empty into drains ; dispose of this material and its container in a safe way.<br>S29/56 : Do not empty into drains, dispose of this material and its container to hazardous or special waste collection point.<br>S37 : Wear suitable gloves.<br>S46 : If swallowed seek medical advice immediately and show this container or label.<br>S51 : Use only in well-ventilated areas.<br>S61 : Avoid release to the environment. Refer to special instructions/Safety data sheets.<br>S64 : If swallowed, rinse mouth with water (only if the person is conscious). |
| <b>Further Phrases</b> | : Contains : COLLOIDAL SILICON DIOXIDE. May produce an allergic reaction.   |
| <b>Contains</b>        | : TERBINAFINE HCL - MAGNESIUM STEARATE - COLLOIDAL SILICON DIOXIDE  |

#### Labelling Regulation EC 1272/2008 (CLP)

#### Hazard pictograms



#### Signal words

: Warning

#### Hazard statements

: H319 : Causes serious eye irritation.  
H315 : Causes skin irritation.  
H335 : May cause respiratory irritation.  
H410 : Very toxic to aquatic life with long lasting effects.

#### Precautionary statements

##### • Prevention

: P271: Use only outdoors or in a well-ventilated area.  
P261: Avoid breathing dust, fume, gas, mist, vapours, spray.  
P273: Avoid release to the environment.  
P280: Wear eye protection, face protection.  
P280: Wear protective gloves.  
P264: Wash thoroughly after handling.

##### • Response

: P302+P352: IF ON SKIN : Wash with plenty of soap and water.  
P332+P313: If skin irritation occurs : Get medical advice.  
P391: Collect spillage.  
P305+P351+P338: IF IN EYES : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P304+P340: IF INHALED : Remove to fresh air and keep at rest in a position comfortable for breathing.  
P363: Wash contaminated clothing before reuse.  
P312: Call a POISON CENTER or doctor if you feel unwell.  
P321: Specific treatment (see on this label).

##### • Storage

: P403+P233: Store in well-ventilated place. Keep container tightly closed.  
P405: Store locked up.

##### • Disposal considerations

: P501: Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.



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**2. Hazards identification (continued)**

**Contains** : TERBINAFINE HCL - MAGNESIUM STEARATE - COLLOIDAL SILICON DIOXIDE

**2.3. Other hazards**

**Other hazards** : The substance does not fulfil the criteria to be identified as PBT substance or vPvB substance according to Annex XIII of Regulation REACH.

**3. Composition/information on ingredients**

**Substance / Preparation** : Preparation.  
**Hazardous component(s)** : This product is hazardous.

| Substance name            | Contents | CAS No     | EC No     | Annex No | REACH Ref. | Classification  |
|---------------------------|----------|------------|-----------|----------|------------|---|
| TERBINAFINE HCL           | :        | 78628-80-5 | ----      | ----     | ----       | Xi; R36/37/38<br>N; R50-53<br>-----<br>Eye irrit 2<br>Skin Irrit. 2<br>STOT SE 3<br>Aquatic Acute 2<br>Aquatic Chronic 1  |
| COLLOIDAL SILICON DIOXIDE | :        | ----       | ----      | ----     | ----       | Carc. Cat. 3; R40<br>Xn; R20/21/22<br>Xi; R36/37/38<br>R43<br>-----<br>Acute Tox. 4 (skin)<br>Acute Tox. 4 (inhal)<br>Acute Tox. 4 (oral)<br>Carc. 2<br>Eye irrit 2<br>Skin Irrit. 2<br>STOT SE 3<br>Skin Sens. 1 |
| MAGNESIUM STEARATE        | :        | 557-04-0   | 209-150-3 | ----     | ----       | Xi; R36<br>-----<br>Eye irrit 2<br>Skin Irrit. 2<br>STOT SE 3   |

**4. First aid measures**

**4.1. Description of first aid measures**

**Inhalation** : Call a POISON CENTER or doctor if you feel unwell. Remove to fresh air and keep at rest in a position comfortable for breathing. Assure fresh air breathing. Allow the victim to rest.

**Skin contact** : If skin irritation occurs : Wash with plenty of soap and water. Specific treatment ( see on this label). Get medical advice. Wash contaminated clothing before reuse. Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

**Eye contact** : Rinse immediately with plenty of water. 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. Obtain medical attention if pain, blinking or redness persist.

**Ingestion** : Do NOT induce vomiting. Rinse mouth. Obtain emergency medical attention.

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



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**4. First aid measures (continued)**

**Symptoms relating to use** : Causes serious eye irritation.  
Causes skin irritation. May cause respiratory irritation.

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

**General information** : Never give anything by mouth to an unconscious person.  
If you feel unwell, seek medical advice (show the label where possible).

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**5. Fire-fighting measures**

**5.1. Extinguishing media**

**Suitable extinguishing media** : Foam. Dry powder. Carbon dioxide. Water spray. Sand.  
**Unsuitable extinguishing media** : Do not use a heavy water stream.  
**Surrounding fires** : Use water spray or fog for cooling exposed containers.

**5.2. Special hazards arising from the substance or mixture**

**Hazardous combustion products** : Under fire conditions, hazardous fumes will be present.

**5.3. Advice for fire-fighters**

**Protection against fire** : Do not enter fire area without proper protective equipment, including respiratory protection.  
**Special procedures** : Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.

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**6. Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

**For emergency responders** : Equip cleanup crew with proper protection.  
Ventilate area.  
**For non-emergency personnel** : Evacuate unnecessary personnel.

**6.2. Environmental precautions**

**Environmental precautions** : Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

**6.3. Methods and material for containment and cleaning up**

**Clean up methods** : Store away from other materials. On land, sweep or shovel into suitable containers.  
Minimize generation of dust.

**6.4. Reference to other sections**

See section 8. Exposure controls/personal protection

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#### 7. Handling and storage

##### 7.1. Precautions for safe handling

**Technical protective measures** : Provide good ventilation in process area to prevent formation of vapour.  
**Handling** : Wash thoroughly after handling.  
Wash thoroughly after handling. Use only outdoors or in a well-ventilated area.  
Wash thoroughly after handling.

**Special precautions** : Avoid breathing dust, fume, gas, mist, vapours, spray.

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

**Storage** : Keep container tightly closed. Keep only in the original container in a cool, well ventilated place.

**Storage - away from** : Strong bases. Strong acids. Sources of ignition. Direct sunlight.

##### 7.3. Specific end use(s)

**Specific end use(s)** : See section 1.

#### 8. Exposure controls/personal protection

##### 8.1. Exposure controls

###### Personal protection



**Personal protection** : Avoid all unnecessary exposure.  
• **Respiratory protection** : Wear approved mask.  
• **Hand protection** : Wear protective gloves.  
• **Skin protection** : Wear suitable protective clothing.  
• **Eye protection** : Chemical goggles or safety glasses.  
• **Others** : When using, do not eat, drink or smoke.

##### 8.2. Control parameters

**Occupational Exposure Limits** : No data available.

#### 9. Physical and chemical properties

##### 9.1. Information on basic physical and chemical properties

**Physical state at 20 °C** : Solid.  
**Colour** : Colourless.  
**Odour** : Characteristic.  
**Odour threshold** : No data available.  
**pH value** : Not applicable.  
**Melting point [°C]** : No data available.  
**Decomposition point [°C]** : No data available.



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**9. Physical and chemical properties (continued)**

|  |                        |
|--|------------------------|
| Critical temperature [°C]              | : Not applicable.      |
| Auto-ignition temperature [°C]         | : No data available.   |
| Flammability (solid, gas)              | : Non flammable.       |
| Flash point [°C]                       | : Not applicable.      |
| Final boiling point [°C]               | : No data available.   |
| Initial boiling point [°C]             | : No data available.   |
| Evaporation rate                       | : Not applicable.      |
| Vapour pressure [20°C]                 | : No data available.   |
| Explosion limits - lower [%]           | : 0 No data available. |
| Vapour density                         | : No data available.   |
| Explosion limits - upper [%]           | : No data available.   |
| Relative density, liquid (water=1)     | : Not applicable.      |
| Density [g/cm <sup>3</sup> ]           | : No data available.   |
| Solubility in water                    | : No data available.   |
| Log Pow octanol / water at 20°C        | : No data available.   |
| Viscosity at 40°C [mm <sup>2</sup> /s] | : No data available.   |

**9.2. Other information**

|                      |                      |
|----------------------|----------------------|
| Explosive properties | : No data available. |
| Oxidising properties | : No data available. |

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**10. Stability and reactivity**

**10.1. Reactivity**

|            |                    |
|------------|--------------------|
| Reactivity | : Not established. |
|------------|--------------------|

**10.2. Chemical stability**

|                    |  |
|--------------------|--|
| Chemical stability | : Stable under recommended storage conditions. |
|--------------------|--|

**10.3. Possibility of hazardous reactions**

|                     |                    |
|---------------------|--------------------|
| Hazardous reactions | : Not established. |
|---------------------|--------------------|

**10.4. Conditions to avoid**

|                     |  |
|---------------------|--|
| Conditions to avoid | : Direct sunlight. Extremely high or low temperatures. |
|---------------------|--|

**10.5. Incompatible materials**

|                    |                               |
|--------------------|-------------------------------|
| Materials to avoid | : Strong acids. Strong bases. |
|--------------------|-------------------------------|

**10.6. Hazardous decomposition products**

|                                  |   |
|----------------------------------|---|
| Hazardous decomposition products | : Fumes. Carbon monoxide. Carbon dioxide. |
|----------------------------------|---|



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**11. Toxicological information**

**11.1. Information on toxicological effects**

|                               |  |
|-------------------------------|--|
| <b>Toxicity information</b>   | : The product has been not fully tested. The calculated risk has been done under the requirements of the EU regulations. |
| <b>Acute toxicity</b>         |  |
| • Inhalation                  | : No data available.   |
| • Dermal                      | : No data available.   |
| • Ingestion                   | : No data available.   |
| <b>Corrosion</b>              | : No data available.   |
| <b>Irritation</b>             | : Causes serious eye irritation.<br>Causes skin irritation.<br>May cause respiratory irritation.                         |
| <b>Sensitization</b>          | : No data available.   |
| <b>Mutagenicity</b>           | : No data available.   |
| <b>Carcinogenicity</b>        | : No data available.   |
| <b>Toxic for reproduction</b> | : No data available.   |
| <b>STOT-single exposure</b>   | : No data available.   |
| <b>STOT-repeated exposure</b> | : No data available.   |
| <b>Aspiration hazard</b>      | : No data available.   |

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**12. Ecological information**

**12.1. Toxicity**

|                             |   |
|-----------------------------|---|
| <b>Toxicity information</b> | : The product has been not fully tested. The calculated risk has been done under the requirements of the EU regulations.<br>Very toxic to aquatic life with long lasting effects. |
|-----------------------------|---|

**12.2. Persistence - degradability**

|                                    |   |
|------------------------------------|---|
| <b>Persistence - degradability</b> | : May cause long-term adverse effects in the environment. |
|------------------------------------|---|

**12.3. Bioaccumulative potential**

|                                  |                    |
|----------------------------------|--------------------|
| <b>Bioaccumulative potential</b> | : Not established. |
|----------------------------------|--------------------|

**12.4. Mobility in soil**

|                         |                    |
|-------------------------|--------------------|
| <b>Mobility in soil</b> | : Not established. |
|-------------------------|--------------------|

**12.5. Results of PBT and vPvB assessment**

|   |   |
|---|---|
| <b>Results of PBT and vPvB assessment</b> | : The substance does not fulfil the criteria to be identified as PBT substance or vPvB substance according to Annex XIII of Regulation REACH. |
|---|---|

**12.6. Other adverse effects**

|                                  |                                     |
|----------------------------------|-------------------------------------|
| <b>Environmental precautions</b> | : Avoid release to the environment. |
|----------------------------------|-------------------------------------|



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**13. Disposal considerations**

**13.1. Waste treatment methods**

**General** : Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.

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**14. Transport information**

**14.1. Land transport (ADR-RID)**

**General information** : Not regulated.

**14.2. Sea transport (IMDG) [English only]**

**General information** : Not regulated.

**14.3. Air transport (ICAO-IATA) [English only]**

**General information** : Not regulated.

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**15. Regulatory information**

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

**Safety, health and environmental regulations/legislation specific for the substance or mixture** : Ensure all national/local regulations are observed.

**15.2. Chemical Safety Assessment**

**Chemical Safety Assessment** : It has not been carried out.

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**16. Other information**

**Revision** : Revision - See : \*

**Sources of key data used** : 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

**Abbreviations and acronyms** : PBT: persistent, bioaccumulative and toxic.  
vPvB: very persistent and very bioaccumulative

**List of relevant R phrases (heading 3)** : R20/21/22 : Harmful by inhalation, in contact with skin and if swallowed.  
R36 : Irritating to eyes.  
R36/37/38 : Irritating to eyes, respiratory system and skin.  
R37 : Irritating to respiratory system.  
R38 : Irritating to skin.  
R40 : Limited evidence of a carcinogenic effect.  
R43 : May cause sensitization by skin contact.  
R50/53 : Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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#### 16. Other information (continued)

##### Further information

: This Material Safety Data Sheet contains instructions for the safety manipulation of this substances to allow the labour and environmental risks reduction, making possible to work with this substance in a safety way. This MSDS does not apply to the final consumer but only for workers thar may manipulate it.

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In accordance with REACH Regulation (CE) N° 1907/2006 and N° 453/2010 and with CLP Regulation (CE) N° 1272/2008.

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