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

- **Product identifier**
  - Trade name: homatropine hydrobromide
    Homatropini hydrobromidum
  - Article number:
    156391
    100537
  - CAS Number:
    51-56-9
  - EC number:
    200-105-3
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Pharma Active ingredients

- **Details of the supplier of the safety data sheet**
  - Manufacturer/Supplier: Fagron UK Ltd
    First Floor, 1 Pink Lane
    Newcastle upon Tyne
    England NE1 5DW
  - Further information obtainable from: Tel.: +44 (0) 845 652 2525
  - Emergency telephone number:
    Emergency response telephone number:
    +44 (0) 845 652 2525

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**

  GHS06 skull and crossbones

  Acute Tox. 3  H301  Toxic if swallowed.
  Acute Tox. 1  H310  Fatal in contact with skin.
  Acute Tox. 1  H330  Fatal if inhaled.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**

  T+; Very toxic

  R26/27/28:  Very toxic by inhalation, in contact with skin and if swallowed.

- **Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**
    The substance is classified and labelled according to the CLP regulation.
  - **Hazard pictograms** GHS06

(Contd. on page 2)
Safety data sheet
According to 1907/2006/ EEC/ Article 31

Trade name: homatropine hydrobromide
Homatropini hydrobromidum

· Signal word Danger

· Hazard statements
  H301 Toxic if swallowed.
  H310 Fatal in contact with skin.
  H330 Fatal if inhaled.

· Precautionary statements
  P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
  P310 Immediately call a POISON CENTER or doctor/physician.
  P320 Specific treatment is urgent (see on this label).
  P322 Specific measures (see on this label).
  P361 Remove/Take off immediately all contaminated clothing.
  P405 Store locked up.
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Other hazards
  · Results of PBT and vPvB assessment
    · PBT: Not applicable.
    · vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Substances formula: C16H22BrNO3  m: 356.3
· CAS No. Description
  51-56-9 homatropine hydrobromide
  Homatropini hydrobromidum
· Identification number(s)
  EC number: 200-105-3

4 First aid measures

· Description of first aid measures
  · General information:
    Immediately remove any clothing soiled by the product.
    Remove breathing equipment only after contaminated clothing have been completely removed.
    In case of irregular breathing or respiratory arrest provide artificial respiration.

  · After inhalation:
    Supply fresh air or oxygen; call for doctor.
    In case of unconsciousness place patient stably in side position for transportation.

  · After skin contact:
    Immediately wash with water and soap and rinse thoroughly.
    Seek medical treatment.

  · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

  · After swallowing: Call a doctor immediately.
Trade name: homatropine hydrobromide
Homatropini hydrobromidum

5 Firefighting measures

· Extinguishing media
  · Suitable extinguishing agents: CO2, powder or water spray. Fight larger fires with water spray.
· Special hazards arising from the substance or mixture
  Formation of toxic gases is possible during heating or in case of fire.
· Advice for firefighters
  · Protective equipment:
    Wear self-contained respiratory protective device.
    Wear fully protective suit.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures
  Wear protective equipment. Keep unprotected persons away.
· Environmental precautions: Do not allow to enter sewers/ surface or ground water.
· Methods and material for containment and cleaning up: Ensure adequate ventilation.
· Reference to other sections
  See Section 7 for information on safe handling.
  See Section 8 for information on personal protection equipment.
  See Section 13 for disposal information.

7 Handling and storage

· Handling:
  · Precautions for safe handling
    Prevent formation of dust.
    Ensure good ventilation/exhaustion at the workplace.
    Open and handle receptacle with care.
· Information about fire - and explosion protection:
  Protect against electrostatic charges.
  Keep ignition sources away - Do not smoke.
· Conditions for safe storage, including any incompatibilities
· Storage:
  · Requirements to be met by storerooms and receptacles: No special requirements.
  · Information about storage in one common storage facility: Not required.
Trade name: homatropine hydrobromide
Homatropini hydrobromidum

- Further information about storage conditions:
  Store in cool, dry conditions in well sealed receptacles.
  Protect from exposure to the light.
  Store under lock and key and with access restricted to technical experts or their assistants only.
- Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- Control parameters
- Ingredients with limit values that require monitoring at the workplace: Not required.
- Additional information: The lists valid during the making were used as basis.
- Exposure controls
- Personal protective equipment:
  - General protective and hygienic measures:
    The usual precautionary measures are to be adhered to when handling chemicals.
    Keep away from foodstuffs, beverages and feed.
    Immediately remove all soiled and contaminated clothing
  - Protection of hands:
    Protective gloves
    - Material of gloves
      PVA gloves
      Plastic gloves
      Synthetic rubber gloves
      Natural rubber, NR
    - Penetration time of glove material
      The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
  - Eye protection:
    Tightly sealed goggles

- Body protection: Protective work clothing

(Contd. on page 5)
Trade name: homatropine hydrobromide  
Homatropini hydrobromidum

### 9 Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information on basic physical and chemical properties</strong></td>
<td></td>
</tr>
<tr>
<td><strong>General Information</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Appearance:</strong></td>
<td></td>
</tr>
<tr>
<td>Form:</td>
<td>Solid</td>
</tr>
<tr>
<td>Colour:</td>
<td>White</td>
</tr>
<tr>
<td>Odour:</td>
<td>Odourless</td>
</tr>
<tr>
<td><strong>pH-value (20 g/l) at 20°C:</strong></td>
<td>~ 6</td>
</tr>
<tr>
<td><strong>Change in condition</strong></td>
<td></td>
</tr>
<tr>
<td>Melting point/Melting range:</td>
<td>212-214, Zers.°C</td>
</tr>
<tr>
<td>Boiling point/Boiling range:</td>
<td>Undetermined.</td>
</tr>
<tr>
<td><strong>Flash point:</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Ignition temperature:</strong></td>
<td></td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>215°C</td>
</tr>
<tr>
<td><strong>Danger of explosion:</strong></td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td><strong>Density:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Solubility in / Miscibility with water at 20°C:</strong></td>
<td>100 g/l</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

### 10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** To avoid thermal decomposition do not overheat.
- **Possibility of hazardous reactions** Risk of dust explosion.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide  
  Nitrogen oxides (NOx)  
  Hydrogen bromide

(Contd. on page 6)
11 Toxicological information

- Information on toxicological effects
  - Acute toxicity:
    - LD/LC50 values relevant for classification:
      - Oral LD50 154 mg/kg (rat)

- Primary irritant effect:
  - on the skin: Irritant to skin and mucous membranes.
  - Sensitization: No sensitizing effects known.

- Additional toxicological information: Danger through skin adsorption.

12 Ecological information

- Toxicity
  - Aquatic toxicity: No further relevant information available.
  - Persistence and degradability: No further relevant information available.

- Behaviour in environmental systems:
  - Bioaccumulative potential: No further relevant information available.
  - Mobility in soil: No further relevant information available.

- Additional ecological information:
  - General notes:
    Water hazard class 3 (German Regulation) (Assessment by list): extremely hazardous for water
    Do not allow product to reach ground water, water course or sewage system, even in small quantities.

- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

- Other adverse effects: No further relevant information available.

13 Disposal considerations

- Waste treatment methods
  - Recommendation: Must be specially treated adhering to official regulations.

- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.
**14 Transport information**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UN-Number</strong></td>
<td>ADR, IMDG, IATA: 1544 (2)</td>
</tr>
<tr>
<td><strong>UN proper shipping name</strong></td>
<td>ADR: Alkaloide, fest, n.a.g. (Homatropinhdrobromid, Homatropini hydrobromidum)</td>
</tr>
<tr>
<td></td>
<td>IMDG, IATA: Alkaloid salts, solid, n.o.s. (Homatropine hydrobromide, Homatropini hydrobromidum)</td>
</tr>
<tr>
<td><strong>Transport hazard class(es)</strong></td>
<td>ADR: Class 6.1 ADR-Code T2 Toxic substances. Label 6.1</td>
</tr>
<tr>
<td></td>
<td>IMDG, IATA: Class 6.1 Toxic substances.</td>
</tr>
<tr>
<td><strong>Packing group</strong></td>
<td>IMDG, IATA: III</td>
</tr>
<tr>
<td><strong>Special precautions for user</strong></td>
<td>Warning: Toxic substances. EMS Number: F-A,S-A</td>
</tr>
<tr>
<td><strong>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>UN &quot;Model Regulation&quot;:</strong></td>
<td>UN1544, ALKALOID SALTS, SOLID, N.O.S., 6.1, III</td>
</tr>
</tbody>
</table>

**15 Regulatory information**

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.
Trade name: homatropine hydrobromide
Homatropini hydrobromidum

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing MSDS:**
  Fagron UK
  Quality Assurance
- **Contact:** kathryn.mason@fagron.co.uk
- **Abbreviations and acronyms:**
  RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
  ICAO: International Civil Aviation Organization
  ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  IMDG: International Maritime Code for Dangerous Goods
  IATA: International Air Transport Association
  GHS: Globally Harmonized System of Classification and Labelling of Chemicals
  EINECS: European Inventory of Existing Commercial Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent

* Data compared to the previous version altered.