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

**Designation:** Buscopan®, liquid (Bulk), <= 2 %

**Synonyms:**
- Active ingredient: Hyoscine Butylbromide
- Buscopan® ampoules, Buscapina® ampoules, Butilhioscina ampoules, Buscopan® drops, Bipsamin® N drops, Buscapina® drops, Buscopan® solution for injection, Buscopan ® Mono solution for injection Buscopan® syrup

**Identified uses:** Solution for production of finished medicinal products.

**Company:** Boehringer Ing. Pharma GmbH & Co.KG
Binger Str. 173
55216 Ingelheim am Rhein

**Telephone:** +49800/7790900
**Telefax number:** +496132/729999
**E-mail address:** gefahr@boehringer-ingelheim.com

**Information providing division:** Quality & Environmental Health & Safety

**Emergency information:** (+49) (0)61 32 / 77 23 22 (24 h)

2. Hazards Identification

**Classification according to Regulation (EC) No. 1272/2008:**

This product is a non-hazardous solution of single components and need not be labelled according to EC-Directive 1999/45/EC, as amended.

3. Composition/Information on Ingredients

**Hazardous ingredients**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Classification</th>
<th>GHS classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>[7(S)-(1alpha,2ß,4ß,5alpha,7ß)-3-Oxa-9-azoniatricyclo[3.3.1.02,4]nonane-9-butyl-7-(3-hydroxy-1-oxo-2-phenylpropoxy)-9-methylbromide</td>
<td>Xn; R22</td>
<td>Category 4, H302</td>
<td>&lt;= 2%</td>
</tr>
</tbody>
</table>

Molecular formula: C21-H30-N-O4-BR
Molecular weight: 440,39

**Non-hazardous galenic excipients**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Classification</th>
<th>GHS classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt;= 98%</td>
</tr>
</tbody>
</table>
4. First-aid Measures

General advice: Remove from exposure, lie down. Immediately remove contaminated clothing. If danger of loss of consciousness, place patient in recovery position and transport accordingly. Apply artificial respiration if necessary. First aid personnel should pay attention to their own safety.

Eye contact: Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.

Skin contact: Wash off thoroughly with ample water. Seek medical attention.

Inhalation: Keep patient calm, remove to fresh air, seek medical attention.

Ingestion: Rinse mouth immediately and then drink plenty of water, seek medical attention.

Notes to physician

Treatment: Observe the summary of product characteristics of proprietary medicinal products.

5. Fire-fighting Measures

Suitable extinguishing media: Use extinguishing measures to suit surroundings., Water, Dry chemical, Foam, carbon dioxide.

Hazards during fire-fighting: In case of fire and/or explosion do not breathe fumes. Can be released in case of fire: nitrogen oxides, Hydrogen bromide (HBr), Carbon oxides.

Protective equipment for fire-fighting: Wear self-contained breathing apparatus and chemical-protective clothing.

Further information: Collect separately contaminated extinguishing water, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

6. Accidental Release Measures

Personal precautions: Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation.

Environmental precautions: Do not discharge into drains/surface waters/groundwater.

Methods for cleaning-up or taking-up: For large amounts: Pump off product. For residues: Contain with absorbent material (e.g. sand, silica gel, acid binder, general purpose binder, sawdust). Pack in tightly closed containers for disposal.

Additional information: High risk of slipping due to leakage/spillage of product.

7. Handling and Storage

Handling
Advice on safe handling: Ensure thorough ventilation of stores and work areas. Do not open until use.

Hints for protection against fire and explosion: No hazards which require special first aid measures.

Hygienic measures: General safety and hygiene measures. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately.

Storage

Requirements for storage rooms and vessels: Protect from heat and direct sunlight. Keep container tightly closed. Jointless smooth floor.

Advice on storage compatibility: Keep away from food, drink and animal feedingstuffs. Advice on Segregation.

Storage class according to VCI: 12 Non Combustible Liquids

8. Exposure controls/personal protections

Exposure controls

Personal protective equipment

Respiratory protection: Not required; except in case of aerosol formation.

Hand protection: Chemical safety glove category III (EN 374). Glove material: Nitrile rubber, Layer thickness: 0.43 mm (f.e. Camatril® green, Article No.732, Company KCL). Resistance (permeability): Level 6 (480 min).

Eye protection: Safety glasses with side-shields (frame goggles) (EN 166)

Body protection: Protective work clothing

Additional information: Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

General protective measures: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing.

9. Physical and Chemical Properties

Form: liquid
Colour: No data available.
Odour: No data available.
Odour threshold: No data available.
pH value: No data available.
Melting point/ -range: No data available.
Boiling point/boiling range: No data available.
Flash point : not applicable
Ignition temperature : not applicable
Evaporation rate : No data available.
Flammability : does not ignite
Lower explosion limit : not applicable
Upper explosion limit : not applicable
Vapour pressure : No data available.
Relative vapour density : No data available.
Relative density : No data available.
Solubility in water : No data available.
Miscibility with water : miscible in all proportions
Partitioning coefficient n-octanol/water (log Pow) : No data available.
Thermal decomposition : No data available.
Viscosity, dynamic : No data available.
Explosiveness : No data available.
Peroxides : No data available.

Further information
Density : No data available.

10. Stability and Reactivity
Hazardous reactions :
Conditions to avoid : No data available.
Substances to avoid : No data available.

11. Toxicological Information
Acute oral toxicity : LD50 = 1.640 mg/kg rat (male/female)
The values mentioned are those of the active ingredient.
Acute inhalation toxicity : No data available.
Acute dermal toxicity : No data available.
Skin irritation : No data available.
Eye irritation : No data available.
Sensitization : No data available.
Genetic toxicity in vitro: Ames-test
   Salmonella typhimurium
   Result: negative  Method: OECD Guideline 471
   The values mentioned are those of the active ingredient.

Chromosomal aberration test
   Result: negative
   The values mentioned are those of the active ingredient.

Genetic toxicity in vivo: No data available.
Carcinogenicity: No data available.
Reproductive toxicity: No data available.
Teratogenicity: No data available.
Aspiration hazard: No data available.
Assessment of reproduction toxicity: Experiments have shown no reproductive toxicity effects on laboratory animals., The values mentioned are those of the active ingredient.
Assessment of carcinogenicity: Did not show carcinogenic effects in animal experiments., The values mentioned are those of the active ingredient.
Assessment of teratogenicity: Did not show teratogenic effects in animal experiments., The values mentioned are those of the active ingredient.

12. Ecological information

Ecotoxicity
Toxicity to fish: LC50 = 2.000,0 mg/l (golden orfe) Exposition time: 48 h Method: Fish, Acute Toxicity Test
   The values mentioned are those of the active ingredient.

Toxicity to daphnia: NOEC = 32,0 mg/l (Daphnia magna) Exposition time: 21 d
   The values mentioned are those of the active ingredient.

Toxicity to algae: NOEC = 80,0 mg/l (green algae) Exposition time: 72 h Method: Algae, Growth Inhibition Test
   The statement of the toxic effect relates to the analytically determined concentration., The values mentioned are those of the active ingredient.

Toxicity to bacteria: EC50 = 21,0 g/L (Pseudomonas putida) Exposition time: 16 h Method: DIN 38412 Part 8
   The values mentioned are those of the active ingredient.
   EC50 > 1.000,0 mg/l (activated sludge) Method: OECD Guideline 209
   The values mentioned are those of the active ingredient.

Chronic toxicity to fish: No data available.
Chronic toxicity to aquatic invertebrates : No data available.

**Persistence and degradability**

Biological degradation : Not easily biodegradable (by OECD criteria). 20 % Exposition time: 28 d Method: OECD 301 E Guideline The values mentioned are those of the active ingredient.

Transport between environmental compartments : No data available.

Bioaccumulation : No data available.

PBT and vPvB assessment : No data available.

**13. Disposal Considerations**

Product : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents. Uncontaminated packaging can be recycled.

**14. Transport Information**

**Further information** : Not classified as dangerous in the meaning of transport regulations. For the internal transport: Use only released containers. Use only tightly closed containers. Protect container against fall down. The container must be correctly labelled.

**15. Regulatory information**

**National legislation/regulations**

Water hazard class : VWWVS

WGK 1 slightly water endangering

Annex 4 VwVwS (Germany) dated Mai, 17th 1999
16. Other particulars

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.