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

**Designation:** Bisolvon® COUGH, liquid (Bulk)

**Synonyms:**
- Active ingredient: Bromhexine hydrochloride, Dihydrocodeine phosphate, Methylephedrine hydrochloride, Chlorphenamine maleate + Caffeine
- Bisolvon® COUGH 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>N-Cyclohexyl-N-methyl-(2-amino-3,5-dibromobenzyl)amine Hydrochloride</td>
<td>N; R50/53</td>
<td>Category 1, H410</td>
<td>&lt;= 0,2%</td>
</tr>
</tbody>
</table>

  **Molecular formula:** C14-H20-Br2-N2 X HCl
  **Molecular weight:** 412,64
  **CAS-No.:** 611-75-6
  **EC-No.:** 210-280-8

<table>
<thead>
<tr>
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<th>GHS classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3,7-Trimethylxanthine</td>
<td>Xn; R22</td>
<td>Category 3, H301</td>
<td>&lt;= 0,1%</td>
</tr>
</tbody>
</table>

  **Molecular formula:** C8-H10-N4-O2
  **Molecular weight:** 194,22
  **CAS-No.:** 58-08-2
  **EC-No.:** 200-362-1
  **INDEX-No.:** 613-086-00-5
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: 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.; Carbon oxides, nitrogen oxides, hydrogen chloride, Hydrogen bromide (HBr)

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


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.

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.
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

Conditions to avoid : No data available.
Substances to avoid : No data available.

11. Toxicological Information

Acute oral toxicity : LD50 > 5,000 mg/kg rat
The values mentioned are those of the active ingredient.
(Bromhexine Hydrochloride)
LD50 261 - 383 mg/kg rat
The values mentioned are those of the active ingredient.
(Caffeine)
LD50 = 306 mg/kg rat
The values mentioned are those of the active ingredient.
(Chlorphenamine maleate)

Acute inhalation toxicity : LC50 4,940 mg/l Method: Acute Inhalation Toxicity
Exposition time: 4 h, rat
The values mentioned are those of the active ingredient.
(Caffeine)

Acute dermal toxicity : LD50 > 2,000 mg/kg rat The values mentioned are those of the active ingredient.
(Caffeine)

Skin irritation : Non-irritant (rabbit) Method: Acute Dermal Irritation/Corrosion.
The values mentioned are those of the active ingredient.
(Bromhexine Hydrochloride)
Non-irritant (rabbit) Method: Acute Dermal Irritation/Corrosion.
The values mentioned are those of the active ingredient.
(Caffeine)

Eye irritation : No eye irritation (rabbit) Method: OECD Guideline 405
The values mentioned are those of the active ingredient.
(Caffeine)

Sensitization : May cause sensitization by inhalation and skin contact.
The values mentioned are those of the active ingredient.
(Chlorphenamine maleate)

Genetic toxicity in vitro : Ames-test
Salmonella typhimurium
Result: negative Method: OECD Guideline 471
The values mentioned are those of the active ingredient.
(Bromhexine Hydrochloride)
Salmonella typhimurium Result: negative The values mentioned are those of the active ingredient. (Chlorphenamine maleate)

mouse lymphoma cells Result: negative The values mentioned are those of the active ingredient. (Chlorphenamine maleate)

Chromosomal aberration test
Concentration: 500µg/ml Metabolic activation: S9-Mix
The values mentioned are those of the active ingredient. (Chlorphenamine maleate)

Genetic toxicity in vivo
: Micronucleus assay
rat
Result: negative
The values mentioned are those of the active ingredient. (Chlorphenamine maleate)

Carcinogenicity : 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. (Bromhexine Hydrochloride)

Assessment of teratogenicity : Did not show carcinogenic, teratogenic or mutagenic effects in animal experiments., The values mentioned are those of the active ingredient. (Bromhexine Hydrochloride)

Further information : May cause harm to breastfed babies., The values mentioned are those of the active ingredient. (Chlorphenamine maleate)

12. Ecological information

Ecotoxicity

Toxicity to fish : LC50 87,0 mg/l (golden orfe) Exposition time: 96 h Method: DIN 38412
The details of the toxic effect relate to the nominal concentration., The values mentioned are those of the active ingredient. (Caffeine)

Toxicity to daphnia : EC50 > 100,0 mg/l ('Daphnia magna') Exposition time: 48 h Method: OECD Guideline 202, part 1
The values mentioned are those of the active ingredient. (Bromhexine Hydrochloride)
EC50 182,0 mg/l (Daphnia magna) Exposition time: 48 h Method: Annex V of Directive 67/548/EEC
The details of the toxic effect relate to the nominal concentration., The values mentioned are those of the active ingredient. (Caffeine)

Toxicity to algae : EC50 (Growth rate) = 0,25 mg/l (green algae) Exposition time: 72 h Method: Algae, Growth Inhibition Test
The values mentioned are those of the active ingredient. (Bromhexine Hydrochloride)
EC50 (yield) = 0.07 mg/l (green algae) Exposition time: 72 h Method: Algae, Growth Inhibition Test The values mentioned are those of the active ingredient. (Bromhexine Hydrochloride)

> 100.0 mg/l (Desmodesmus subspicatus (green algae)) Exposition time: 72 h Method: Algae, Growth Inhibition Test The values mentioned are those of the active ingredient. (Caffeine)

Toxicity to bacteria

Toxicity to bacteria

Toxicity to fish: No data available.

Chronic toxicity to aquatic invertebrates: No data available.

Persistency and degradability

Biological degradation: Not easily biodegradable (by OECD criteria). 0 % Exposition time: 28 d Method: OECD 301 F Guideline The values mentioned are those of the active ingredient. (Bromhexine Hydrochloride)

Transport between environmental compartments: No data available.

Bioaccumulation: No bioaccumulation is to be expected (log P(o/w)<1), The values mentioned are those of the active ingredient. (Bromhexine Hydrochloride)

Bioaccumulation: No bioaccumulation is to be expected (log P(o/w)<1), The values mentioned are those of the active ingredient. (Caffeine)

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 hazardous under transport regulations. For the internal transport: Use only released containers. Use only tightly closed containers. The container must be correctly labelled. Protect container against fall down.

15. Regulatory information

National legislation/regulations
Water hazard class : VWVWS
WGK 2 water endangering
Annex 4 VwVwS (Germany) dated Mai, 17 th 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.