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

Designation : Bisolvon®, liquid (Bulk), <= 1 %

Synonyms : Active ingredient: Bromhexine hydrochloride
Bisolvon® syrup, Bisolvon® solution, Bisolvon® ampoules,
Bisolvon® CHESTY 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:
Chronic hazards to the aquatic environment, Aquatic Chronic 2

Classification (67/548/EWG,1999/45/EG):
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Labelling according Regulation (EC) No 1272/2008 [CLP]:

Pictogram(s)

Hazard Statement(s): H411 Toxic to aquatic life with long lasting effects.

Safety precaution(s): P273 Avoid release to the environment.
P391 Collect spillage.
Labelling according to EEC Directive (67/548/EWG,1999/45/EG):

Symbol(s): N

Dangerous for the environment

R phrase(s) : R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S phrase(s) : S61 Avoid release to the environment. Refer to special instructions/Safety data sheets.

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>Aquatic Chronic 1, H410</td>
<td>&lt;= 1%</td>
</tr>
</tbody>
</table>

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

Non-hazardous galenic excipients

Chemical name | Classification | GHS classification | Concentration |
---------------|----------------|--------------------|---------------|
Non-hazardous galenic excipients | | | >= 99% |

4. First-aid Measures

General advice: Remove affected person from danger area. 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 extinguishing media, 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 feeding stuffs. Advice on Segregation

Storage class according to VCI: 12.00 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available.</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available.</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available.</td>
</tr>
<tr>
<td>pH value</td>
<td>No data available.</td>
</tr>
<tr>
<td>Melting point/ -range</td>
<td>No data available.</td>
</tr>
<tr>
<td>Boiling point/Boiling range</td>
<td>No data available.</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Ignition temperature</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available.</td>
</tr>
<tr>
<td>Flammability</td>
<td>does not ignite</td>
</tr>
<tr>
<td>Lower explosion limit</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available.</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available.</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available.</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>No data available.</td>
</tr>
<tr>
<td>Partitioning coefficient n- octanol/water (log Pow)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Thermal decomposition</td>
<td>No data available.</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available.</td>
</tr>
<tr>
<td>Explosiveness</td>
<td>No data available.</td>
</tr>
</tbody>
</table>
Peroxides : No data available.

Further information

Density : No data available.

10. Stability and Reactivity

Hazardous reactions : No data available.

Conditions 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.

Acute inhalation toxicity : No data available.

Acute dermal toxicity : No data available.

Skin irritation : Non-irritant (rabbit) Method: OECD Guideline 404
The values mentioned are those of the active ingredient.

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.

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

Carcinogenicity : No data available.

Reproductive toxicity : Experiments have shown no reproductive toxicity effects on laboratory animals., The values mentioned are those of the active ingredient.

Teratogenicity : Did not show carcinogenic, teratogenic or mutagenic effects in animal experiments., The values mentioned are those of the active ingredient.
12. Ecological information

Ecotoxicity
Toxicity to fish: No data available.
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.
Toxicity to algae: EC50 (Growth rate) = 0,25 mg/l (green algae) Exposition time: 72 h
Method: OECD Guideline 201
The values mentioned are those of the active ingredient.
EC50 (yield) = 0,07 mg/l (green algae) Exposition time: 72 h
Method: OECD Guideline 201
The values mentioned are those of the active ingredient.
Chronic toxicity to aquatic invertebrates: No data available.

Persistence 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.
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.
PBT and vPvB assessment: No data available.

13. Disposal Considerations

Product: Dispose of in accordance with local authority regulations. Must not be disposed off together with household garbage. Do not allow product to reach sewage system.
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

Land transport
UN-No: 3082
15. Regulatory information

National legislation/regulations
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.