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

- **Designation:** Bisolvon® FLU, liquid (Bulk)
- **Synonyms:** Active ingredient: Bromhexine hydrochloride (<= 1 %), Chlorphenamine maleate (<= 0.1 %), Phenylephrine hydrochloride (<= 1 %) and Paracetamol (<= 5 %) Bisolvon® FLU 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:**
- Specific target organ toxicity - single exposure, Category 2,
- Chronic aquatic toxicity, Category 3,

**Classification (67/548/EWG,1999/45/EG):**
- R39/25 Toxic: danger of very serious irreversible effects if swallowed.
- R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Labelling according Regulation (EC) No 1272/2008 [CLP]:**
- Hazard Statement(s):
  - H371 May cause damage to organs.
  - H412 Harmful to aquatic life with long lasting effects.
- Safety precaution(s):
  - P273 Avoid release to the environment.
  - P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
  - P309 + P311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/ physician.
P405 Store locked up.  
P501 Dispose of contents/container to an approved incineration plant.

**Labelling according to EEC Directive (67/548/EWG,1999/45/EG):**

**R phrase(s):**
- R39/25: Toxic: danger of very serious irreversible effects if swallowed.
- R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**S phrase(s):**
- S22: Do not breathe dust.
- S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
- 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>Category 1, H410</td>
<td>&lt;= 1%</td>
</tr>
<tr>
<td><strong>Molecular formula:</strong> C14-H20-Br2-N2 x HCl</td>
<td><strong>CAS-No.:</strong> 611-75-6</td>
<td><strong>EC-No.:</strong> 210-280-8</td>
<td></td>
</tr>
<tr>
<td><strong>Molecular weight:</strong> 412.64</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>2-Pyridinepropanamine,gamma-(4-cholorophenyl)-N,N-dimethyl-(Z)-2-butenedioate(1:1)</td>
<td>T; R25, R43</td>
<td>Category 3, H301</td>
<td></td>
</tr>
<tr>
<td><strong>Molecular formula:</strong> C20-H23-Cl-N2-O4</td>
<td><strong>CAS-No.:</strong> 113-92-8</td>
<td><strong>EC-No.:</strong> 204-037-5</td>
<td></td>
</tr>
<tr>
<td><strong>Molecular weight:</strong> 390.90</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Classification</th>
<th>GHS classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>(R)-1-{(3-Hydroxyphenyl)-2-methylaminoethanol Hydrochloride</td>
<td>Xn; R21/22</td>
<td>Category 4, H302</td>
<td></td>
</tr>
<tr>
<td><strong>Molecular formula:</strong> C9-H13-N-O2 x HCl</td>
<td><strong>CAS-No.:</strong> 61-76-7</td>
<td><strong>EC-No.:</strong> 200-517-3</td>
<td></td>
</tr>
<tr>
<td><strong>Molecular weight:</strong> 203.69</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
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<th>GHS classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
N-Acetyl-4-aminophenole  |  T; R22, R39/25, R52/53  |  Category 4, H302, Category 1, H370, Category 3, H412  |  <= 5%  

Molecular formula: C8-H9-N-O2  |  CAS-No.: 103-90-2  |  EC-No.: 203-157-5  
Molecular weight: 151,16

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Classification</th>
<th>GHS classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-hazardous galenic excipients</td>
<td></td>
<td></td>
<td>&gt;= 92,9%</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:, 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

**Personal precautions:** Wear protective equipment. Keep unprotected persons away. Avoid creating dust. Remove all sources of ignition. 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.

**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 = 2,400 mg/kg rat
The values mentioned are those of the active ingredient.
(Paracetamol)

LD50 = 350 mg/kg rat
The values mentioned are those of the active ingredient.
((−)-Phenylephrine hydrochloride)

LD50 = 306 mg/kg rat
The values mentioned are those of the active ingredient.
(Chlorphenamine maleate)

Acute inhalation toxicity: No data available.

Acute dermal toxicity: No data available.

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

Non-irritant (rabbit)
The values mentioned are those of the active ingredient.
(Paracetamol)

Non-irritant (rabbit)
The values mentioned are those of the active ingredient.
((−)-Phenylephrine hydrochloride)

Eye irritation: No eye irritation (rabbit)
Product dust may be irritating to eyes, skin and respiratory system., The values mentioned are those of the active ingredient.
(Paracetamol)

Sensitization: May cause sensitization by skin contact., The values mentioned are those of the active ingredient.
(Paracetamol)

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)
Ames-test  
Result: negative  
The values mentioned are those of the active ingredient.  ((-)-Phenylephrine 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. (Bromhexine Hydrochloride)

Carcinogenicity  
: No data available.

Reproductive toxicity  
: No data available.

Teratogenicity  
: 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 mutagenicity  
: Test in human lymphocytes: negative, The values mentioned are those of the active ingredient.  (Paracetamol)

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 daphnia  
:  
EC50  > 100,0 mg/l  ("Daphnia magna")  Exposition time: 48 h  
Method: Daphnia sp., Acute Immobilisation Test.  
The values mentioned are those of the active ingredient.  (Bromhexine Hydrochloride)

EC50  = 250,0 mg/l  (Daphnia magna)  Exposition time: 24 h  
The values mentioned are those of the active ingredient.  (Paracetamol)
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)

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). 0 % Exposition time: 28 d Method: OECD 301 F Guideline
The values mentioned are those of the active ingredient. (Bromhexine Hydrochloride)

Biological degradation: biodegradable 57 % Exposition time: 28 d The values mentioned are those of the active ingredient. (Paracetamol)

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. (Paracetamol)

PBT and vPvB assessment: No data available.

**13. Disposal Considerations**

Product: Dispose of in accordance with local 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
- Class: 9
- Classification Code: M6
- Packaging group: III
- TRC: (E)
- Hazard ID-No.: 90
- Label(s): 9
- Designation of goods: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Bromhexine Hydrochloride)

**Air transport - Passenger Aircraft**

- UN-No: 3082
- Class: 9
- Packaging group: III
- ICAO-Label(s): 9
- Correct technical name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Bromhexine Hydrochloride)

**Air transport - Cargo Aircraft**

- UN-No: 3082
- Class: 9
- Packaging group: III
- ICAO-Label(s): 9
- Correct technical name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Bromhexine Hydrochloride)

**Sea transport**

- UN-No: 3082
- Class: 9
- Packaging group: III
- ICAO-Label(s): 9
- EmS: F-AS-F
- Correct technical name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Bromhexine Hydrochloride)

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.