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

Designation : **Combivent® Respimat®, liquid (Bulk)**

Synonyms : Active ingredient: Ipratropium bromide monohydrate and Salbutamol sulphate
Combivent® solution for inhalation for Respimat® (liquids)

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>3-(3-hydroxy-1-oxo-2-phenylpropoxy)-8-methyl-8-(1-methylethyl)-8-azoniabicyclo(3.2.1)octane bromide monohydrate</td>
<td>Xn; R22</td>
<td>Category 4, H302</td>
<td>&lt;= 1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular formula: C20-H30-N-O3-BR x H2O</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-No.: 66985-17-9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular weight: 430,38</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>2-(tert-Butylamino)-1-[4-hydroxy-3-(hydroxymethyl)phenyl]ethanol hemisulphate</td>
<td></td>
<td></td>
<td>&lt;= 3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular formula: C26-H42-N2-O6 X H2SO4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-No.: 51022-70-9</td>
<td></td>
<td></td>
<td></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, Sulphur oxides, 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. 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.
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: Laboratory: laboratory coat; factory: disposable Overall.
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

Conditions to avoid : No data available.

Substances to avoid : No data available.

11. Toxicological Information

Acute oral toxicity : LD50 = 1.722 mg/kg rat (male/female)
The values mentioned are those of the active ingredient.
(Ipratropium Bromide Monohydrate)
**LD50**  = 1.038 mg/kg mouse (male/female)  
The values mentioned are those of the active ingredient.  
(Ipratropium Bromide Monohydrate)  

**LD50**  > 2,000,000 mg/kg rat  
The values mentioned are those of the active ingredient.  
(Salbutamol Sulphat)  

**LD50**  = 3,800,000 mg/kg mouse  
The values mentioned are those of the active ingredient.  
(Salbutamol Sulphat)  

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Skin irritation</td>
<td>No data available</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>No data available</td>
</tr>
<tr>
<td>Sensitization</td>
<td>Non-sensitizing. (guinea pig)</td>
</tr>
</tbody>
</table>
|                                      | The values mentioned are those of the active ingredient.  
|                                      | (Ipratropium Bromide Monohydrate)          |
|                                      | Did not cause sensitization on laboratory animals. (guinea pig)  
|                                      | The values mentioned are those of the active ingredient.  
|                                      | (Salbutamol Sulphat)                       |
| Genetic toxicity in vitro            | Ames-test                                  |
|                                      | Salmonella typhimurium                      |
|                                      | Result: negative                            |
|                                      | The values mentioned are those of the active ingredient.  
|                                      | (Ipratropium Bromide Monohydrate)          |
| Genetic toxicity in vivo             | Micronucleus assay Result: negative         |
|                                      | The values mentioned are those of the active ingredient.  |
| 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.  
(Ipratropium Bromide Monohydrate) |
| Assessment of carcinogenicity        | Did not show carcinogenic effects in animal experiments. The values mentioned are those of the active ingredient.  
(Ipratropium Bromide Monohydrate) |
| Assessment of mutagenicity          | Micronucleus test: negative, The values mentioned are those of the active ingredient.  
(Salbutamol Sulphat)                |
| Assessment of mutagenicity          | Test in human lymphocytes: negative, The values mentioned are those of the active ingredient.  
(Salbutamol Sulphat)                |
12. Ecological information

Ecotoxicity

Toxicity to fish

No data available.

Toxicity to daphnia

NOEC  = 3,16 mg/l (Daphnia magna) Exposition time: 21 d
The values mentioned are those of the active ingredient.
(Ipratropium Bromide Monohydrate)

Lowest observed effect concentration  = 10,0 mg/l (Daphnia magna) Exposition time: 21 d
The values mentioned are those of the active ingredient.
(Ipratropium Bromide Monohydrate)

EC50  > 100,0 mg/l (Daphnia) Exposition time: 48 h
The values mentioned are those of the active ingredient.
(Salbutamol)

Toxicity to algae

No data available.

Toxicity to bacteria

NOEC  = 200,0 mg/l (activated sludge)
The values mentioned are those of the active ingredient.
(Ipratropium Bromide Monohydrate)

NOEC  = 1.000,0 mg/l (activated sludge, industrial)
The values mentioned are those of the active ingredient.
(Ipratropium Bromide Monohydrate)

Chronic toxicity to fish

No data available.

Chronic toxicity to aquatic invertebrates

No data available.

Persistence and degradability

Biological degradation

Not readily biodegradable. ca. 37 % Exposition time: 47 d
The values mentioned are those of the active ingredient.
(Salbutamol)

Biological degradation

Not readily biodegradable. Method: OECD 301 B Guideline
The values mentioned are those of the active ingredient.
(Salbutamol)

Transport between environmental compartments

No data available.

Bioaccumulation

Accumulation in organisms is not to be expected., The values mentioned are those of the active ingredient.
(Ipratropium Bromide Monohydrate)

Bioaccumulation

No appreciable bioaccumulation potential is to be expected (log P(o/w) 1-3), The values mentioned are those of the active ingredient.
(Salbutamol)
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 : VWVWS
   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.