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

Designation: **Buscopan® Compositum, solid (Bulk)**

Synonyms: Active ingredient: Hyoscine butylbromide + Metamizole sodium
Buscopan® Compositum tablets; Buscopan® Compositum sugar-coated tablets; Buscopan® Compositum dragees; Buscopan® Compositum suppositorien; Buscopan® Compositum suppositories; Buscapina® Compositum tablets; Buscapina® Compositum sugar-coated tablets; Buscapina® Compositum; Buscopan® Compositum; Buscapina® Compositum gargeas; Buscopan® Composto; Bipasmin® Compuesto N

Identified uses: Mixture 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 mixture of single components and need not be labelled according to EC-Directive 1999/45/EC, as amended.

3. Composition/Information on 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

<table>
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</tbody>
</table>

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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.

Ihalation: 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, Sulphur oxides, Hydrogen bromide (HBr), Carbon oxides

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: Dampen, pick up mechanically and dispose of. Avoid raising dust. For residues: Use approved industrial vacuum cleaner for removal. Pack in tightly closed containers for disposal.

Additional information: Never return spills in original containers for re-use.

7. Handling and Storage

Handling
Advice on safe handling: Do not open until use. Provide good ventilation of working area (local exhaust ventilation if necessary). Keep away from sources of ignition - No smoking. Protect from moisture.

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: Store in original container. Protect from heat and direct sunlight. Jointless smooth floor. Keep container tightly closed.

Advice on storage compatibility: Keep away from food, drink and animal feedingstuffs. Storage class according to VCI Advice on Segregation

8. Exposure controls/personal protections

Exposure controls

Personal protective equipment
Respiratory protection: Use breathing apparatus if exposed to vapours/dust/aerosol. half mask (EN 140) particle filter P2 (EN 143)
Hand protection: Chemical resistant protective gloves (EN 374)
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. Do not breathe dust. Avoid contact with skin, eyes and clothing.

9. Physical and Chemical Properties

Form: solid
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 : not applicable
Flash point : not applicable
Ignition temperature : No data available.
Evaporation rate : No data available.
Flammability : No data available.
Lower explosion limit : No data available.
Upper explosion limit : No data available.
Vapour pressure : not applicable
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.
Explosiveness : No data available.
Peroxides : No data available.

Further information
Minimum ignition energy : No data available.

10. Stability and Reactivity
Conditions to avoid : No data available.
Substances to avoid : No data available.
Hazardous decomposition products : 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.
(Hyoscine Butylbromide)
LD50 = 3,000 mg/kg rat
The values mentioned are those of the active ingredient.
(Metamizol Sodium Monohydrate)

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.
(Hyoscine Butylbromide)
Chromosomal aberration test
Result: negative

Genetic toxicity in vivo : No data available.
Carcinogenicity : No data available.
Reproductive toxicity : No data available.
Teratogenicity : No data available.
Asspiration 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. (Hyoscine Butylbromide)

Assessment of carcinogenicity : Did not show carcinogenic effects in animal experiments., The values mentioned are those of the active ingredient. (Hyoscine Butylbromide)

Assessment of teratogenicity : Did not show teratogenic effects in animal experiments., The values mentioned are those of the active ingredient. (Hyoscine Butylbromide)

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. (Hyoscine Butylbromide)

LC50 > 500,0 mg/l (golden orfe) Exposition time: 48 h Method: Fish, Acute Toxicity Test
The values mentioned are those of the active ingredient. (Metamizol Sodium Monohydrate)
LC50 > 500,0 mg/l (golden orfe) Exposition time: 96 h Method: Fish, Acute Toxicity Test
The values mentioned are those of the active ingredient. (Metamizol Sodium Monohydrate)

Toxicity to daphnia : NOEC = 32,0 mg/l (Daphnia magna) Exposition time: 21 d (Hyoscine Butylbromide)

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. (Hyoscine Butylbromide)

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. (Hyoscine Butylbromide)

EC50 > 1.000,0 mg/l (activated sludge) Method: OECD Guideline 209
The values mentioned are those of the active ingredient. (Hyoscine Butylbromide)

EC50 > 1.000,0 mg/l (Pseudomonas putida)
The values mentioned are those of the active ingredient. (Metamizol Sodium Monohydrate)

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. (Hyoscine Butylbromide)

Biological degradation : 20 - 50 % Exposition time: 11 d The values mentioned are those of the active ingredient. (Metamizol Sodium Monohydrate)

Transport between environmental compartments : No data available.
Bioaccumulation : No bioaccumulation is to be expected (log P(o/w)<1). (Metamizol Sodium Monohydrate)
PBT and vPvB assessment : No data available.

13. Disposal Considerations
Product : Buscopan® Compositum, solid (Bulk)

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 3 highly 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.