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

Designation : Buscopan® PLUS, solid (Bulk)

Synonyms : Active ingredient: Hyoscine butylbromide and Paracetamol
Buscopan® PLUS tablets, Buscopan® PLUS suppositories,
Buscapina® Compositum N tablets, Buscopan® Compositum
N suppositories, Buscapina® PLUS tablets, Buscapina®
Compositum N comprimidos, Buscapina® Compositum Nf
comprimidos, Buscopan® Compositum "10 Mg+500Mg
Comresse Rivestite", Buscopan® Compositum "10Mg+800Mg
Supposte"

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

Chemical name | Classification | EC-No.: |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>C21-H30-N-O4-BR</td>
<td>205-744-1</td>
<td>149-64-4</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:, nitrogen 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. Advice on Segregation

Storage class according to VCI: 11 Combustible Solids

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 = 2.400 mg/kg rat
The values mentioned are those of the active ingredient.
(Paracetamol)
LD50 = 1.640 mg/kg rat (male/female)
The values mentioned are those of the active ingredient.
(Hyoscine Butylbromide)

LD50 = 3.225 mg/kg mouse (male/female)
The values mentioned are those of the active ingredient.
(Hyoscine Butylbromide)

Acute inhalation toxicity : No data available.
Acute dermal toxicity : No data available.
Skin irritation : Non-irritant (rabbit)
The values mentioned are those of the active ingredient.
(Paracetamol)
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)
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  (Hyoscine Butylbromide)
Genetic toxicity in vivo : No data available.
Carcinogenicity : No data available.
Reproductive toxicity : No data available.
Teratogenicity : No data available.
Aspiration 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 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)

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

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. The values mentioned are those of the active ingredient. (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)

Chronic toxicity to fish : No data available.

Chronic toxicity to aquatic invertebrates : NOEC = 32,0 mg/l (Daphnia) Exposition time: 21 d
The values mentioned are those of the active ingredient. (Butylscopolaminiumbromide)

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

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)

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. (Paracetamol)

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

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

**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. The container must be correctly labelled. Protect container against fall down.

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.