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

Designation : Sputolysin®, solid (Bulk), <= 1%

Synonyms : Active ingredient: Dembrexine hydrochloride
Sputolysin® powder

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>Hazardous ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
</tr>
<tr>
<td>N-(trans-4-Hydroxycyclohexyl)-3,5-dibromo-2-hydroxybenzylamine Hydrochloride</td>
</tr>
<tr>
<td>Molecular formula: C13-H17-Br2-N-O2 x HCl</td>
</tr>
<tr>
<td>Molecular weight: 415.55</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>Non-hazardous galenic excipients</td>
<td></td>
<td></td>
<td>&gt;= 99%</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: Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.

Skin contact: Wash off immediately with plenty of water. Cover wound with sterile dressing. Call a physician immediately.

Inhalation: Move to fresh air. Call a physician immediately.

Ingestion: Rinse mouth. Drink plenty of water. Call a physician immediately.

Notes to physician
Treatment: Observe the summary of product characteristics of proprietary medicinal products

5. Fire-fighting Measures

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water, Dry chemical, Foam, Carbon dioxide (CO2)

Hazards during fire-fighting: In case of fire and/or explosion do not breathe fumes. Can be released in case of fire.; hydrogen chloride, Hydrogen bromide (HBr), nitrogen oxides (NOx), Carbon oxides

Protective equipment for fire-fighting: Self-contained breathing apparatus (EN 133) complete suit protecting against chemicals

Further information: Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

6. Accidental Release Measures

Personal precautions: Wear personal protective equipment. Ensure adequate ventilation. Refer to protective measures listed in sections 7 and 8. Keep people away from and upwind of spill/leak.

Environmental precautions: Do not flush into surface water or sanitary sewer system.

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.

Hints for protection against fire and explosion: Keep away from heat and sources of ignition. Take precautionary measures against static discharges.

Hygienic measures: General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes 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
Advice on system design: Use with local exhaust ventilation.

Personal protective equipment
Respiratory protection: Use breathing apparatus if exposed to vapours/dust/aerosol. No personal respiratory protective equipment normally required. half mask (EN 140) particle filter P2 (EN 143)
Hand protection: Chemical safety glove category III (EN 374). Handglove made of PVAC, plastics, synthetic gum or natural caoutchouc.
Eye protection: Safety glasses with side-shields conforming to EN166
Body protection: Laboratory: laboratory coat; factory: chemical protection overall if dust is formed.
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: powder
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.
Self-ignition temperature : No data available.
Thermal decomposition : No data available.
Explosiveness : No data available.
Fire promoting properties : 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 > 5.000 mg/kg rat
The values mentioned are those of the active ingredient.
LD50 >> 5.000 mg/kg mouse
The values mentioned are those of the active ingredient.
<table>
<thead>
<tr>
<th>Property</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>Non-irritant (rabbit) Method: OECD Test Guideline 404 The values mentioned are those of the active ingredient.</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>Mild eye irritation (rabbit) The values mentioned are those of the active ingredient.</td>
</tr>
<tr>
<td>Sensitization</td>
<td>No data available.</td>
</tr>
<tr>
<td>Genetic toxicity in vitro</td>
<td></td>
</tr>
<tr>
<td>Salmonella typhimurium</td>
<td>Result: negative The values mentioned are those of the active ingredient.</td>
</tr>
<tr>
<td>Escherichia Coli</td>
<td>Result: negative The values mentioned are those of the active ingredient.</td>
</tr>
<tr>
<td>HGPRT assay</td>
<td>V79 cells (Chinese hamster) Result: negative The values mentioned are those of the active ingredient.</td>
</tr>
<tr>
<td>Genetic toxicity in vivo</td>
<td>No data available.</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>No data available.</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Study for Effects on Embryo-Fetal Development rat Dose: 5, 50, 500 mg/kg/day Did not show teratogenic effects in animal experiments, The values mentioned are those of the active ingredient.</td>
</tr>
<tr>
<td>Teratogenicity</td>
<td>No data available.</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>No data available.</td>
</tr>
</tbody>
</table>

### 12. Ecological information

**Ecotoxicity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>No data available.</td>
</tr>
<tr>
<td>Toxicity to daphnia</td>
<td>EC50 &gt; 100 mg/l (‘Daphnia magna’) Exposition time: 48 h Method: OECD Test Guideline 202 The values mentioned are those of the active ingredient.</td>
</tr>
<tr>
<td>Toxicity to algae</td>
<td>No data available.</td>
</tr>
<tr>
<td>Toxicity to bacteria</td>
<td>No data available.</td>
</tr>
<tr>
<td>Chronic toxicity to fish</td>
<td>No data available.</td>
</tr>
<tr>
<td>Chronic toxicity to aquatic invertebrates</td>
<td>No data available.</td>
</tr>
</tbody>
</table>
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.