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

Designation: Spasmo-Mucosolvan®, liquid (Bulk)

Synonyms: Active ingredient: Ambroxol hydrochloride, Clenbuterol hydrochloride
Spasmo-Mucosolvan® syrup, Mucospas® syrup, Mucosolvon® Compositum syrup, Sekretovit Ex syrup<br> Vaksan compositum® syrup, Sekretovit Ex drops, Mucosolvon® Compositum drops

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

<table>
<thead>
<tr>
<th>Hazardous ingredients</th>
<th>Chemical name</th>
<th>Classification</th>
<th>GHS classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>trans-4-(2-Amino-3,5, dibrombenzyl)amino)cyclohexanol Hydrochloride</td>
<td>N; R51/53</td>
<td>Category 2, H411</td>
<td>&lt; 1%</td>
<td></td>
</tr>
<tr>
<td>Molecular formula: C13-H18-Br2-N2-O x HCl</td>
<td>CAS-No.: 23828-92-4</td>
<td>EC-No.: 245-899-2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>4-Amino-(tert-butylamino)methyl-3,5-dichlorobenzylalcohol Hydrochloride</td>
<td>T; R23/25, R48</td>
<td>Category 3, H301, Category 3, H331, Category 1, H372</td>
<td>&lt; 1%</td>
<td></td>
</tr>
<tr>
<td>Molecular formula: C12-H18-CI2-N2-O x HCl</td>
<td>CAS-No.: 21898-19-1</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: 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: Carbon oxides, hydrogen chloride, nitrogen oxides (NOx), Hydrogen bromide (HBr)

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. Refer to protective measures listed in sections 7 and 8. Keep people away from and upwind of spill/leak. Ensure adequate ventilation.

Environmental precautions: Do not flush into surface water or sanitary sewer system.
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: Provide sufficient air exchange and/or exhaust in work rooms. Breathing must be protected when large quantities are decanted without local exhaust ventilation. Keep container closed when not in use.

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

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: Keep tightly closed in a dry and cool place. Protect from heat and direct sunlight. Keep in a well-ventilated place. 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
Advice on system design: Local exhaust

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 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 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. 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.
Self-ignition temperature: No data available.
Thermal decomposition: No data available.
Viscosity, dynamic: No data available.
Explosiveness: No data available.
Fire promoting properties: No data available.
Peroxides: No data available.

Further information

Density: No data available.

10. Stability and Reactivity
Hazardous reactions : No data available.
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 = 4.203 mg/kg rat (male)
The values mentioned are those of the active ingredient.
(Ambroxol hydrochloride)
LD50 = 4.495 mg/kg rat (female)
The values mentioned are those of the active ingredient.
(Ambroxol hydrochloride)
LD50 = 170 mg/kg rat (male)
The values mentioned are those of the active ingredient.
(Clenbuterol hydrochloride)
LD50 = 180 mg/kg rat (female)
The values mentioned are those of the active ingredient.
(Clenbuterol hydrochloride)
ALD (ATE) = 500 - 600 mg/kg dog
The values mentioned are those of the active ingredient.
(Clenbuterol hydrochloride)

Acute inhalation toxicity : No data available.

Acute dermal toxicity : No data available.

Repeated dose toxicity : rat
NOAEL: 150 mg/kg
Exposition time: 26 weeks (oral)
The values mentioned are those of the active ingredient.
(Ambroxol hydrochloride)

rabbit
NOAEL: 40 mg/kg
Exposition time: 26 weeks The values mentioned are those of
the active ingredient.
(Ambroxol hydrochloride)

dog
NOAEL: 10 mg/kg
Exposition time: 26 weeks The values mentioned are those of
the active ingredient.
(Ambroxol hydrochloride)

rat
NOAEL: 5 mg/kg
Exposition time: 13 weeks (oral)
The values mentioned are those of the active ingredient. 
(Clenbuterol hydrochloride)

rat
NOAEL: 0,16 mg/kg
Exposition time: 13 weeks (Inhalation)
The values mentioned are those of the active ingredient. 
(Clenbuterol hydrochloride)

rat
NOAEL: 25 mg/kg
Exposition time: 26 weeks (oral)
The values mentioned are those of the active ingredient. 
(Clenbuterol hydrochloride)

Dog
NOAEL: 0,1 mg/kg
Exposition time: 52 weeks (oral)
The values mentioned are those of the active ingredient. 
(Clenbuterol hydrochloride)

Monkey
NOAEL: 0,15 mg/kg
Exposition time: 26 weeks (Inhalation)
The values mentioned are those of the active ingredient. 
(Clenbuterol hydrochloride)

Skin irritation: Non-irritant
The values mentioned are those of the active ingredient. 
(Ambroxol hydrochloride)

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

Eye irritation: No data available.

Sensitization: Guinea pig maximization test Did not cause sensitisation on laboratory animals. (guinea pig)
The values mentioned are those of the active ingredient. 
(Clenbuterol hydrochloride)

Buehler test Did not cause sensitisation on laboratory animals. 
(guinea pig)
The values mentioned are those of the active ingredient. 
(Clenbuterol hydrochloride)

Genetic toxicity in vitro: Ames-test
Result: negative
The values mentioned are those of the active ingredient. 
(Ambroxol hydrochloride)

Ames-test
Result: negative
The values mentioned are those of the active ingredient. 
(Ambroxol hydrochloride)
HGPRT assay
V79 cells (Chinese hamster)
Result: negative
The values mentioned are those of the active ingredient.
(Clenbuterol hydrochloride)

Genetic toxicity in vivo
Cytogenetic assay
Chinese hamster
Result: negative
The values mentioned are those of the active ingredient.
(Clenbuterol hydrochloride)

Genetic toxicity in vivo
Micronucleus assay
mouse
Result: negative
The values mentioned are those of the active ingredient.
(Clenbuterol hydrochloride)

Genetic toxicity in vivo
Micronucleus assay
mouse
Result: negative
The values mentioned are those of the active ingredient.
(Ambroxol hydrochloride)

Carcinogenicity
Dose: 1000 mg/kg (rat)
Did not show carcinogenic effects in animal experiments.
(Ambroxol hydrochloride)

Carcinogenicity
Dose: 800 mg/kg (mouse)
Did not show carcinogenic effects in animal experiments.
(Ambroxol hydrochloride)

Carcinogenicity
Dose: 6.25, 12.5, 25 mg/kg/day (rat)
Exposition time: 2 years (Oral)
Did not show carcinogenic effects in animal experiments.
(Clenbuterol hydrochloride)

Reproductive toxicity
Study of Fertility and Early Embryonic Development
rat, oral
Dose: 20, 110, 640 mg/kg
Did not show teratogenic effects in animal experiments,
The values mentioned are those of the active ingredient.
(Ambroxol hydrochloride)

Study for Effects on Embryo-Fetal Development
rabbit
Dose: 2000 mg/kg
Did not show teratogenic effects in animal experiments,
The values mentioned are those of the active ingredient.
(Ambroxol hydrochloride)

Study for Effects on Embryo-Fetal Development
rabbit
Dose: 200 mg/kg
Did not show teratogenic effects in animal experiments,
values mentioned are those of the active ingredient. (Ambroxol hydrochloride)

Pre- and Postnatal development study
rat, oral
Dose: 50, 110 mg/kg
Did not show teratogenic effects in animal experiments, The values mentioned are those of the active ingredient. (Ambroxol hydrochloride)
rat
Dose: 0.03, 0.1, 0.3 mg/kg
Did not show teratogenic effects in animal experiments

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. (Ambroxol hydrochloride)
Assessment of carcinogenicity : Did not show carcinogenic effects in animal experiments., The values mentioned are those of the active ingredient. (Clenbuterol hydrochloride)
Assessment of teratogenicity : Did not show carcinogenic or teratogenic effects in animal experiments., The values mentioned are those of the active ingredient. (Ambroxol hydrochloride)

12. Ecological information

Ecotoxicity
Toxicity to fish : LC50 = 22.8 mg/l (Brachydanio rerio) Exposition time: 96 h Method: Fish, Acute Toxicity Test
The values mentioned are those of the active ingredient. (Ambroxol hydrochloride)
Toxicity to daphnia : EC50 = 25.6 mg/l (Daphnia magna) Exposition time: 48 h Method: OECD Test Guideline 202
The values mentioned are those of the active ingredient. (Ambroxol hydrochloride)
Toxicity to algae : EC50 (Growth rate) = 9.5 mg/l (Desmodesmus subspicatus (green algae)) Exposition time: 72 h Method: OECD Test Guideline 201
The values mentioned are those of the active ingredient. (Ambroxol hydrochloride)
EC50 (Biomass) = 2.6 mg/l (Desmodesmus subspicatus (green algae)) Exposition time: 72 h Method: OECD Test Guideline 201
The values mentioned are those of the active ingredient. (Ambroxol hydrochloride)
NOEC = 0.46 mg/l (Desmodesmus subspicatus (green algae))
Exposition time: 72 h Method: OECD Test Guideline 201
The values mentioned are those of the active ingredient.
(Ambroxol hydrochloride)

Exposition time: 3 h Method: OECD Guideline 209
The values mentioned are those of the active ingredient.
(Ambroxol 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). ca. 0 % Exposition time: 28 d Method: OECD 301 D Guideline
The values mentioned are those of the active ingredient. (Ambroxol hydrochloride)

Transport between environmental compartments: No data available.

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

PBT and vPvB assessment: No data available.

### 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 for conveyance in the meaning of the regulations for the transport of dangerous goods by road and rail. Not classified as dangerous in the meaning of sea and air transport regulations.

15. Regulatory information

National legislation/regulations

Water hazard class: VWVWS

WGK 2 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.