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

Designation : Berotec® metered aerosol with CFC (Bulk), <= 1 %

Synonyms : Active ingredient: Fenoterol hydrobromide
Berotec® metered aerosol

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:
Hazardous to the ozone layer, Category 1,

Classification (67/548/EWG,1999/45/EG):
R59 Dangerous for the ozone layer.

Labelling according to Regulation (EC) No 1272/2008 [CLP]:

<table>
<thead>
<tr>
<th>Pictogram(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>! Warning</td>
</tr>
</tbody>
</table>

Hazard Statement(s): H420 Harms public health and the environment by destroying ozone in the upper atmosphere

Safety precaution(s): P502 Refer to manufacturer/ supplier for information on recovery/ recycling.

Labelling according to EEC Directive (67/548/EWG,1999/45/EG):
### 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>1-(3,5-Dihydroxyphenyl)-2-((1-(4-hydroxybenzyl)ethyl)amino)ethanol Hydrobromide</td>
<td>R51/53</td>
<td>Category 2, H411</td>
<td>&lt;= 0,2%</td>
</tr>
<tr>
<td>Molecular formula: C17-H21-N-O4 X HBR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular weight: 384.27</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-No.: 1944-12-3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC-No.: 217-742-8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1,2-Dichloro-1,1,2,2-tetrafluoroethane</td>
<td>N; R59</td>
<td>EUH059</td>
<td>&gt;= 22 - &lt;= 22%</td>
</tr>
<tr>
<td>Molecular formula: C2-Cl2-F4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular weight: 170.920</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-No.: 76-14-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC-No.: 200-937-7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trichlorofluoromethane</td>
<td>N; R59</td>
<td>EUH059</td>
<td>&gt;= 52 - &lt;= 53%</td>
</tr>
<tr>
<td>Molecular formula: C-Cl3-F</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular weight: 137.370</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-No.: 75-69-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC-No.: 200-892-3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dichlorodifluoromethane</td>
<td>N; R59</td>
<td>EUH059</td>
<td>&gt;= 24 - &lt;= 25%</td>
</tr>
<tr>
<td>Molecular formula: C-Cl2-F2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular weight: 120.910</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-No.: 75-71-8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC-No.: 200-893-9</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Non-hazardous galenic excipients | <= 0,2% 
---|---

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, Hydrogen bromide (HBr), Hydrogen fluoride, nitrogen oxides (NOx)

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

**Further information**
Cool endangered containers with water spray jet. Fire or intense heat may cause violent rupture of packages. Product itself is non-combustible. 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 : Pack in tightly closed containers for disposal.

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.
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. Keep in a well-ventilated place. Protect from heat and direct sunlight. Jointless smooth floor
Advice on storage compatibility : Keep away from food, drink and animal feeding stuffs. Advice on Segregation
Storage class according to VCI : 2B Compressed Gas (Aerosol cans)

8. Exposure controls/personal protections

Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>Basis</th>
<th>Factor</th>
<th>BIEL-Group</th>
<th>Values</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2-Dichloro-1,1,2,2-tetrafluoroethane 76-14-2</td>
<td>AGW</td>
<td>8(II)</td>
<td>1.000 ppm 1.000 ml/m3 7.100 mg/m3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trichlorofluoromethane 75-69-4</td>
<td>AGW</td>
<td>2(II)</td>
<td>1.000 ppm 1.000 ml/m3 5.700 mg/m3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dichlorodifluoromethane 75-71-8</td>
<td>AGW</td>
<td>2(II)</td>
<td>1.000 ppm 1.000 ml/m3 5.000 mg/m3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Factor = Ceiling limit/Exceeding factor

Exposure controls
Personal protective equipment
Respiratory protection : Not required; except in case of aerosol formation.
Hand protection : Handglove made of PVAC, plastics, synthetic gum or natural caoutchouc.
Eye protection : Safety glasses with side-shields conforming to EN166
Body protection : Protective work clothing
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 : Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice.

9. Physical and Chemical Properties

Form : aerosol
Colour : colourless
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 : 8.440 hPa at 50 °C
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 : Keep away from sources of ignition - No smoking.
Viscosity, dynamic : No data available.
Explosiveness : No data available.
Peroxides : No data available.
Further information

Density : not applicable

10. Stability and Reactivity

Conditions to avoid : No data available.
Substances to avoid : No data available.
Hazardous decomposition products : hydrogen halides, Carbonyl halides

11. Toxicological Information

<table>
<thead>
<tr>
<th>Toxicological Parameter</th>
<th>Rat</th>
<th>Mouse</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 = 2.200 mg/kg</td>
<td>LD50 = 3.750 mg/kg</td>
<td>The values mentioned are those of the active ingredient.</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 &gt; 5 µg/l</td>
<td>LD50 = 3.750 mg/kg</td>
<td>The values mentioned are those of the active ingredient.</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>No data available.</td>
<td>LD50 = 3.750 mg/kg</td>
<td>The values mentioned are those of the active ingredient.</td>
</tr>
<tr>
<td>Repeated dose toxicity</td>
<td>NOAEL: 0,136 mg/kg</td>
<td>NOAEL: 2 mg/kg</td>
<td>Exposition time: 26 weeks (oral)</td>
</tr>
<tr>
<td></td>
<td>NOAEL: 0,3 mg/kg</td>
<td>NOAEL: 0,136 mg/kg</td>
<td>Exposition time: 26 weeks (Inhalation)</td>
</tr>
<tr>
<td></td>
<td>NOAEL: 0,5 mg/kg</td>
<td>NOAEL: 0,5 mg/kg</td>
<td>Exposition time: 26 weeks (Inhalation)</td>
</tr>
<tr>
<td></td>
<td>NOAEL: 20 mg/kg</td>
<td>NOAEL: 2 mg/kg</td>
<td>Exposition time: 26 weeks (oral)</td>
</tr>
<tr>
<td></td>
<td>NOAEL: 20 mg/kg</td>
<td>NOAEL: 20 mg/kg</td>
<td>Exposition time: 26 weeks (Inhalation)</td>
</tr>
</tbody>
</table>
Exposition time: 13 weeks (Inhalation)
The values mentioned are those of the active ingredient.

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

Eye irritation : No eye irritation (rabbit)
The values mentioned are those of the active ingredient.

Sensitization : Did not cause sensitisation on laboratory animals.
The values mentioned are those of the active ingredient.

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

HGPRT assay
V79 cells (Chinese hamster)
Result: negative
The values mentioned are those of the active ingredient.

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

Carcinogenicity : Did not show carcinogenic effects in animal experiments.

Reproductive toxicity : rat
Dose: 2.5; 25; 100 mg/kg/day
Did not show teratogenic effects in animal experiments, The values mentioned are those of the active ingredient.

Teratogenicity : No data available.

12. Ecological information

Ecotoxicity
Toxicity to fish : No data available.

Toxicity to daphnia : EC50 > 100 mg/l (Daphnia) Exposition time: 48 h Method: OECD Test Guideline 202
The values mentioned are those of the active ingredient.

Toxicity to algae : EC50 (yield) = 7 mg/l (Algae) Method: Algae, Growth Inhibition Test
The values mentioned are those of the active ingredient.

EC50 (Growth rate) = 54 mg/l (Algae)
The details of the toxic effect relate to the nominal concentration., The values mentioned are those of the active ingredient.

Toxicity to bacteria : EC50 = 700.5 mg/l (activated sludge) Method: OECD 209
The values mentioned are those of the active ingredient.
Chronic toxicity to fish : No data available.
Chronic toxicity to aquatic invertebrates : No data available.
Further information : Dangerous for the ozone layer. Contributes to the greenhouse effect.

**Persistence and degradability**

Biological degradation : Not readily biodegradable. 2 % Exposition time: 28 d Method: OECD 301 D Guideline  
The values mentioned are those of the active ingredient.

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.

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.