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

- **Product identifier**
  - **Trade name:** Benzydamine hydrochloride Assay Standard

- **Reference number:** Cat 610
- **CAS Number:** 132-69-4
- **EC number:** 205-076-0

- **Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **Application of the substance / the preparation**
  - Reference material for laboratory use only

- **Manufacturer/Supplier:**
  - British Pharmacopoeia Commission
  - MHRA
  - 10 South Colonnade, Canary Wharf
  - London E14 4PU
  - United Kingdom

- **Further information obtainable from:**
  - eMail: bpcrs@mhra.gov.uk

- **Emergency telephone number:** +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

2 Hazards identification

- **Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**
  - ![GHS07](image)

  - Acute Tox. 4 H302 Harmful if swallowed.
  - Acute Tox. 4 H312 Harmful in contact with skin.
  - Acute Tox. 4 H332 Harmful if inhaled.
  - Eye Irrit. 2 H319 Causes serious eye irritation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
  - ![Xi; Irritant](image)

  - R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.
  - R36: Irritating to eyes.

- **Information concerning particular hazards for human and environment:** Not applicable.

- **Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**
  - The substance is classified and labelled according to the CLP regulation.

- **Hazard pictograms**

- **Signal word** Warning

- **Hazard statements**
  - H302+H312+H332 Harmful if swallowed, in contact with skin or if inhaled.
  - H319 Causes serious eye irritation.
Trade name: Benzydamine hydrochloride Assay Standard

- **Precautionary statements**
  - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
  - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P322 Specific measures (see on this label).
  - P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
  - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Other hazards**

- **Results of PBT and vPvB assessment**
  - PBT: Not applicable.
  - vPvB: Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization: Substances**
  - CAS No. Description: 132-69-4 Benzydamine hydrochloride
  - Identification number(s): EC number: 205-076-0, RTECS: NK7875000

### 4 First aid measures

- **Description of first aid measures**
  - **General information:**
    Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.
  - **After inhalation:**
    Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
    In case of unconsciousness place patient in recovery position for transport.
  - **After skin contact:**
    Immediately wash with water and soap and rinse thoroughly.
    If skin irritation continues, consult a doctor.
  - **After eye contact:**
    Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
  - **After swallowing:**
    Rinse mouth. Do not induce vomiting.
    Call for a doctor immediately.
  - **Information for doctor:**
    Most important symptoms and effects, both acute and delayed: No further relevant information available.
    Indication of any immediate medical attention and special treatment needed: No further relevant information available.

### 5 Firefighting measures

- **Extinguishing media**
  - **Suitable extinguishing agents:**
    CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - **Special hazards arising from the substance or mixture**
    Formation of toxic gases is possible during heating or in case of fire.
Trade name: Benzydamine hydrochloride Assay Standard

6 Accidental release measures

- Advice for firefighters
- Protective equipment:
  - Mouth respiratory protective device.
  - Wear self-contained respiratory protective device.

- Personal precautions, protective equipment and emergency procedures
  Avoid formation of dust.

- Environmental precautions:
  Do not allow to enter sewers/surface or ground water.

- Methods and material for containment and cleaning up:
  Dispose of contaminated material as waste according to item 13.
  Ensure adequate ventilation.

- Reference to other sections
  See Section 7 for information on safe handling.
  See Section 8 for information on personal protection equipment.
  See Section 13 for disposal information.

7 Handling and storage

- Handling:
  - Precautions for safe handling
    Ensure good ventilation/extraction at the workplace.
    Remove dust thoroughly.
    Store in cool, dry place in tightly closed receptacles.
  - Information about fire - and explosion protection: No special measures required.

- Conditions for safe storage, including any incompatibilities
  - Storage:
    - Requirements to be met by storerooms and receptacles:
      Store in a cool location.
      Please refer to the manufacturer’s certificate for specific storage and transport temperature conditions.
      Store only in the original receptacle.
      Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
    - Information about storage in one common storage facility: Store away from foodstuffs.
    - Further information about storage conditions: Keep container tightly sealed.
    - Specific end use(s): No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.

- Control parameters

- Ingredients with limit values that require monitoring at the workplace: Not required.

- Additional information: Lists used were valid at the time of SDS preparation.

- Exposure controls
  - Personal protective equipment:
    - General protective and hygienic measures:
      Keep away from foodstuffs, beverages and feed.
      Immediately remove all soiled and contaminated clothing
      Wash hands before breaks and at the end of work.
      Avoid contact with the eyes.
      Avoid contact with the eyes and skin.
### 9 Physical and chemical properties

<table>
<thead>
<tr>
<th>Information on basic physical and chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Information</strong></td>
</tr>
<tr>
<td><strong>Appearance:</strong></td>
</tr>
<tr>
<td>- Form: Solid</td>
</tr>
<tr>
<td>- Colour: White</td>
</tr>
<tr>
<td>- Odour: Odourless</td>
</tr>
<tr>
<td>- Odour threshold: Not determined.</td>
</tr>
<tr>
<td><strong>pH-value:</strong></td>
</tr>
<tr>
<td>- Not applicable.</td>
</tr>
<tr>
<td><strong>Change in condition</strong></td>
</tr>
<tr>
<td>- Melting point/Melting range: 158 - 161 °C</td>
</tr>
<tr>
<td>- Boiling point/Boiling range: Not determined.</td>
</tr>
<tr>
<td><strong>Flash point:</strong></td>
</tr>
<tr>
<td>- Not applicable.</td>
</tr>
<tr>
<td><strong>Flammability (solid, gaseous):</strong> Not determined.</td>
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<tr>
<td><strong>Ignition temperature:</strong></td>
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<tr>
<td>- Decomposition temperature: Not determined.</td>
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<tr>
<td>- Self-igniting: Not determined.</td>
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<td>- Danger of explosion: Not determined.</td>
</tr>
<tr>
<td><strong>Explosion limits:</strong></td>
</tr>
<tr>
<td>- Lower: Not determined.</td>
</tr>
<tr>
<td>- Upper: Not determined.</td>
</tr>
</tbody>
</table>
Safety data sheet according to 1907/2006/EC, Article 31

Printing date 01.05.2013 Version number 1 Revision: 01.05.2013

Trade name: Benzydamine hydrochloride Assay Standard

10 Stability and reactivity

- Reactivity: Stable under normal conditions.
- Chemical stability: Stable under normal conditions.
- Thermal decomposition / conditions to be avoided:
  Formation of toxic gases is possible during heating or in case of fire.
- Possibility of hazardous reactions: No dangerous reactions known.
- Conditions to avoid: Heat.
- Incompatible materials: Strong oxidizing agents.
- Hazardous decomposition products: Formation of toxic gases is possible during heating or in case of fire.

11 Toxicological information

- Information on toxicological effects
- Acute toxicity:

  - LD/LC50 values relevant for classification:

    Oral LD50  740 mg/kg (rat)
    LD 50 (Intraperitoneal) 72 mg/kg (rat)
    LD 50 (Intravenous) 43.5 mg/kg (rat)

- Primary irritant effect:
  - on the skin: No irritating effect.
  - on the eye: Irritating effect.
  - Sensitization: No sensitizing effects known.

12 Ecological information

- Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability: No further relevant information available.
- Behaviour in environmental systems:
  - Bioaccumulative potential: No further relevant information available.
  - Mobility in soil: No further relevant information available.
- Additional ecological information:
  - General notes:
    Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Trade name: Benzydamine hydrochloride Assay Standard

Do not allow undiluted product to reach ground water, water course or sewage system.

- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.
- Other adverse effects: No further relevant information available.

13 Disposal considerations

- Waste treatment methods
  - Recommendation: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
  - European waste catalogue: Waste disposal key numbers from EWC have to be assigned depending on origin and processing.
- Uncleaned packaging:
  - Recommendation: Dispose of in accordance with national regulations.

14 Transport information

- UN-Number
  - ADR, ADN, IMDG, IATA: Not applicable
  - ADR, ADN, IMDG, IATA: Not applicable
- Transport hazard class(es)
  - ADR, ADN, IMDG, IATA: Not applicable
  - Class: Not applicable
- Packing group
  - ADR, IMDG, IATA: Not applicable
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user
  - Not applicable.
- Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.
- UN "Model Regulation": -

15 Regulatory information

- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

(Contd. on page 7)
The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user’s intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

**Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

**Sources**