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

1.1 Product identifier
- **Product name:** 5-[1-Hydroxy-2-(1-methyl-3-phenylpropylamino)ethyl]salicylic acid hydrochloride

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

1.3 Details of the supplier of the safety data sheet
- **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

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
- **Classification according to Regulation (EC) No 1272/2008**

  - GHS08 health hazard
    - **Repr. 2** H361d Suspected of damaging the unborn child.

  - GHS09 environment
    - **Aquatic Chronic 2** H411 Toxic to aquatic life with long lasting effects.

  - GHS07
    - **Skin Irrit. 2** H315 Causes skin irritation.
    - **Eye Irrit. 2** H319 Causes serious eye irritation.
    - **STOT SE 3** H335 May cause respiratory irritation.

2.2 Label elements
- **Labelling according to Regulation (EC) No 1272/2008**
  - The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**
  - GHS07
  - GHS08
  - GHS09
Product name: 5-[1-Hydroxy-2-(1-methyl-3-phenylpropylamino)ethyl]salicylic acid hydrochloride

- Signal word Warning
- Hazard statements
  H315 Causes skin irritation.
  H319 Causes serious eye irritation.
  H361d Suspected of damaging the unborn child.
  H335 May cause respiratory irritation.
  H411 Toxic to aquatic life with long lasting effects.
- 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.
  P321 Specific treatment (see on this label).
  P405 Store locked up.
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- 3.1 Chemical characterisation: Substances
  - CAS No. Description
    5-[1-Hydroxy-2-(1-methyl-3-phenylpropylamino)ethyl]salicylic acid hydrochloride
  - Identification number(s) None
  - RTECS: -
  - Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- 4.1 Description of first aid measures
  - After inhalation: Supply fresh air; consult doctor in case of complaints.
  - 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.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed
  No further relevant information available.

SECTION 5: Firefighting measures

- 5.1 Extinguishing media
  - Suitable extinguishing agents: Use fire extinguishing methods suitable for surrounding conditions.
Product name: 5-[1-Hydroxy-2-(1-methyl-3-phenylpropylamino)ethyl]salicylic acid hydrochloride

- 5.2 Special hazards arising from the substance or mixture
  Formation of toxic gases is possible during heating or in case of fire.

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

SECTION 6: Accidental release measures

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

- 6.2 Environmental precautions:
  Inform respective authorities in case of seepage into water course or sewage system.
  Do not allow to enter sewers/surface or ground water.

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

- 6.4 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.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling
  Store in cool, dry place in tightly closed receptacles.

- 7.2 Conditions for safe storage, including any incompatibilities
  - Storage:
    - Requirements to be met by storerooms and receptacles:
      Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
      Store only in the original receptacle unless other advice is given on the CoA.
      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.

- 7.3 Specific end use(s)
  No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

- 8.1 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.

- 8.2 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 and skin.
Product name: 5-[1-Hydroxy-2-(1-methyl-3-phenylpropylamino)ethyl]salicylic acid hydrochloride

- **Respiratory protection:**
  In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Protection of hands:**
  The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

- **Eye protection:**
  Tightly sealed goggles

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - Form: Solid
      - Colour: Off white
      - Odour: Odourless
      - Odour threshold: Not determined.
    - **pH-value:** Not applicable.
  - **Change in condition**
    - Melting point/freezing point: Not determined. Not determined.
    - Initial boiling point and boiling range: Not determined.
  - **Flash point:** Not applicable.
  - **Flammability (solid, gas):** Not determined.
  - **Ignition temperature:** Not determined
  - **Decomposition temperature:** Not determined.
  - **Auto-ignition temperature:** Not determined.
  - **Explosive properties:** Not determined.
Safety data sheet  
according to 1907/2006/EC, Article 31

Product name: 5-[1-Hydroxy-2-(1-methyl-3-phenylpropylamino)ethyl]salicylic acid hydrochloride

| · Explosion limits: | · Not determined. |
| · Vapour pressure: | · Not applicable. |
| · Density: | · Not determined. |
| · Relative density | · Not determined. |
| · Vapour density | · Not applicable. |
| · Evaporation rate | · Not applicable. |
| · Solubility in / Miscibility with water: | · Not determined. |
| · Partition coefficient: n-octanol/water: | · Not determined. |
| · Viscosity: | · Dynamic: Not applicable. |
| · Kinematic: | · Not applicable. |
| · 9.2 Other information | · No further relevant information available. |

SECTION 10: Stability and reactivity

· 10.1 Reactivity
Stable under normal conditions.
No further relevant information available.

· 10.2 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.

· 10.3 Possibility of hazardous reactions
No dangerous reactions known.

· 10.4 Conditions to avoid
Heat.
Sources of ignition

· 10.5 Incompatible materials: Strong oxidizing agents.

· 10.6 Hazardous decomposition products:
Formation of toxic gases is possible during heating or in case of fire.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects
Acute toxicity
Based on available data, the classification criteria are not met.

· Primary irritant effect:
Skin corrosion/irritation
Causes skin irritation.

· Serious eye damage/irritation
Causes serious eye irritation.

· Respiratory or skin sensitisation
Based on available data, the classification criteria are not met.

· CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
Repr. 2

· Germ cell mutagenicity
Based on available data, the classification criteria are not met.
Product name: 5-[1-Hydroxy-2-(1-methyl-3-phenylpropylamino)ethyl]salicylic acid hydrochloride

- Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Suspected of damaging the unborn child.
- STOT-single exposure May cause respiratory irritation.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- Ecotoxicological effects:
  - Remark: Toxic for fish
  - Additional ecological information:
    - General notes:
      Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
      Do not allow product to reach ground water, water course or sewage system.
      Danger to drinking water if even small quantities leak into the ground.
      Also poisonous for fish and plankton in water bodies.
      Toxic for aquatic organisms
    - 12.5 Results of PBT and vPvB assessment
      - PBT: Not applicable.
      - vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- 13.1 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.

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, IMDG, IATA UN3077
Product name: 5-[1-Hydroxy-2-(1-methyl-3-phenylpropylamino)ethyl]salicylic acid hydrochloride

### 14.3 Transport hazard class(es)
- **ADR, IMDG, IATA**

<table>
<thead>
<tr>
<th>Class</th>
<th>9 Miscellaneous dangerous substances and articles.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label</td>
<td>9</td>
</tr>
</tbody>
</table>

### 14.4 Packing group
- **ADR, IMDG, IATA**

<table>
<thead>
<tr>
<th>Class</th>
<th>III</th>
</tr>
</thead>
</table>

### 14.5 Environmental hazards:
- **Marine pollutant:** Symbol (fish and tree)
- **Special marking (ADR):** Symbol (fish and tree)
- **Special marking (IATA):** Symbol (fish and tree)

### 14.6 Special precautions for user
- **Danger code (Kemler):** 336
- **EMS Number:** F-A,S-F
- **Stowage Category** A
- **Stowage Code** SW2.3 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
- **Transport category** 3
- **Tunnel restriction code** E

(Contd. on page 8)
Product name: 5-[1-Hydroxy-2-(1-methyl-3-phenylpropylamino)ethyl]salicylic acid hydrochloride

- UN "Model Regulation":
  UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (5-[1-HYDROXY-2-(1-METHYL-3-PHENYL PROPYLAMINO)ETHYL] SALICYLIC ACID HYDROCHLORIDE), 9, III

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Directive 2012/18/EU
  - Named dangerous substances - ANNEX I Substance is not listed.
  - Seveso category E2: Hazardous to the Aquatic Environment
  - Qualifying quantity (tonnes) for the application of lower-tier requirements: 200 t
  - Qualifying quantity (tonnes) for the application of upper-tier requirements: 500 t

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

SECTION 16: Other information

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 Harmonised System of Classification and Labelling of Chemicals
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- Repr. 2: Reproductive toxicity – Category 2
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

Sources
- Data compared to the previous version altered. All sections have been updated.