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

- Product identifier
- Trade name: Bisoprolol Fumarate

- Reference number: Cat 1058
- CAS Number: 104344-23-2
- Relevant identified uses of the substance or mixture and uses advised against
  No further relevant information available.
- Application of the substance / the mixture
  Reference material for laboratory use only
- Manufacturer/Supplier:
  British Pharmacopoeia Commission
  MHRA
  151 Buckingham Palace Road
  London SW1W 9SZ
  United Kingdom

- Further information obtainable from: eMail: bpcrs@mhra.gsi.gov.uk
- Emergency telephone number: +44 (0) 20 3080 6561 (Monday - Friday: 8am - 5pm)

SECTION 2: Hazards identification

- Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008
  GHS07
  Acute Tox. 4  H302  Harmful if swallowed.
  Aquatic Chronic 3  H412  Harmful to aquatic life with long lasting effects.

- Classification according to Directive 67/548/EEC or Directive 1999/45/EC
  Xn; Harmful
  R22:  Harmful if swallowed.
  R52/53:  Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- 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
    GHS07

- Signal word Warning
- Hazard statements
  H302 Harmful if swallowed.
  H412 Harmful to aquatic life with long lasting effects.
- Precautionary statements
  P273  Avoid release to the environment.
  P264  Wash thoroughly after handling.
  P270  Do not eat, drink or smoke when using this product.
  P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

(Contd. on page 2)
SECTION 3: Composition/information on ingredients

- Chemical characterization: Substances
- CAS No. Description
  104344-23-2 Bisoprolol Fumarate
- Identification number(s) -

SECTION 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; consult doctor in case of complaints.
- After skin contact: Immediately wash with water and soap and rinse thoroughly.
- After eye contact: Rinse opened eye for several minutes under running water.
- 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.

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

SECTION 6: Accidental release measures

- Personal precautions, protective equipment and emergency procedures
  Wear protective clothing.
- 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.
- Methods and material for containment and cleaning up:
  Dispose of contaminated material as waste according to item 13.
- Reference to other sections
  See Section 7 for information on safe handling.
SECTION 7: Handling and storage

- Handling:
- Precautions for safe handling: 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: None.
- 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.
- 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.
    - Wash hands before breaks and at the end of work.
  - Respiratory protection: Not required.
  - Protection of hands:
    - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
    - Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
    - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
  - Material of gloves
    - The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
  - Penetration time of glove material
    - The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
  - Eye protection: Safety glasses

SECTION 9: Physical and chemical properties

- Information on basic physical and chemical properties
- General Information
- Appearance:
  - Form: Solid

(Contd. on page 4)
### Safety data sheet according to 1907/2006/EC, Article 31

**Trade name:** Bisoprolol Fumarate

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>White</td>
</tr>
<tr>
<td>Odour</td>
<td>Odourless</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not determined.</td>
</tr>
<tr>
<td>pH-value</td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

- **Change in condition**
  - Melting point/Melting range: 95 - 105 °C
  - Boiling point/Boiling range: Not determined.

- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not determined.
- **Ignition temperature:**
  - Decomposition temperature: Not determined.
  - Self-igniting: Not determined.
  - Danger of explosion: Not determined.

- **Explosion limits:**
  - Lower: Not determined.
  - Upper: 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: Easily soluble.
  - Partition coefficient (n-octanol/water): Not determined.

- **Viscosity:**
  - Dynamic: Not applicable.
  - Kinematic: Not applicable.
- **Other information**
  - No further relevant information available.

### SECTION 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.
  - Moisture.
  - Air.
- **Incompatible materials:** Strong oxidizing agents.
- **Hazardous decomposition products:** Formation of toxic gases is possible during heating or in case of fire.

(Contd. on page 5)
**SECTION 11: Toxicological information**

- **Information on toxicological effects**
  - **Acute toxicity:**
    - **LD/LC50 values relevant for classification:**
      | Oral | LD50 678 mg/kg (mouse)  |
      |      | 940 mg/kg (rat)         |
  - **Primary irritant effect:**
    - **on the skin:** No irritating effect.
    - **on the eye:** No irritating effect.
    - **Sensitization:** No sensitizing effects known.

**SECTION 12: Ecological information**

- **Toxicity**
  - **Aquatic toxicity:**
    - EC50/48 h: 90 mg/l (daphnia)
    - LC50/96 h: >100 mg/l (fish)
  - **Persistence and degradability**
    - Biodegradation: 4 %/28d
  - **Behaviour in environmental systems:**
    - Bioaccumulative potential: No further relevant information available.
    - Mobility in soil: No further relevant information available.
  - **Ecotoxicological effects:**
    - **Remark:** Harmful to fish
  - **Additional ecological information:**
    - **General notes:**
      - Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
      - Do not allow undiluted product to reach ground water, water course or sewage system.
      - Harmful to aquatic organisms
    - **Results of PBT and vPvB assessment**
      - PBT: Not applicable.
      - vPvB: Not applicable.
      - Other adverse effects: No further relevant information available.

**SECTION 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.
    - **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

**SECTION 14: Transport information**

- **UN-Number**
  - **ADR, ADN, IMDG, IATA**
    - Not applicable
Safety data sheet
according to 1907/2006/EC, Article 31

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(Contd. from page 5)

- **ADR, ADN, IMDG, IATA**
  Not applicable

- **Transport hazard class(es)**
  - **ADR, ADN, IMDG, IATA**
    Not applicable

- **Packing group**
  - **ADR, ADN, IMDG, IATA**
    Not applicable

- **Environmental hazards:**
  - **Marine pollutant:**
    No

- **Special precautions for user**
  Not applicable.

- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**
  Not applicable.

- **UN "Model Regulation":**
  -

SECTION 15: Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Philippines Inventory of Chemicals and Chemical Substances Substance is not listed.
  - Australian Inventory of Chemical Substances Substance is not listed.
  - Standard for the Uniform Scheduling of Drugs and Poisons Substance is not listed.
  - 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 InternationalCarriage 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
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent

- **Sources**