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

- **Product identifier**
- **Trade name:** Melatonin Assay Standard
- **Reference number:** Cat 1077
- **CAS Number:** 73-31-4
- **EC number:** 200-797-7

- **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
  - 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)

2 Hazards identification

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

- **GHS08 health hazard**
  - Repr. 1B  H360  May damage fertility or the unborn child.

- **GHS07**
  - Eye Irrit. 2  H319  Causes serious eye irritation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
  - **T:** Toxic
  - Repr. Cat. 2
  - R60-61:  May impair fertility. May cause harm to the unborn child.

- **Xi; Irritant**
  - 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**
  - GHS07  GHS08

- **Signal word** Danger

(Contd. on page 2)
· Hazard statements
  H319 Causes serious eye irritation.
  H360 May damage fertility or the unborn child.

· Precautionary statements
  P280 Wear protective gloves/protective clothing/eye protection/face protection.
  P281 Use personal protective equipment as required.
  P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P308+P313 IF exposed or concerned: Get medical advice/attention.
  P405 Store locked up.
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Additional information:
  Restricted to professional users.

· 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
    73-31-4 Melatonin
  · Identification number(s) -
    · EC number: 200-797-7
    · RTECS: AC5955000

4 First aid measures

· 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.
  · 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.
    If symptoms persist consult doctor.

· 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: Melatonin Assay Standard

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

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- 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.
- 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 Store in cool, dry place in tightly closed receptacles.
  - Information about fire - and explosion protection: The product is not flammable.
- 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.
    - 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

(Contd. from page 2)
### 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:

Tightly sealed goggles

### 9 Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information on basic physical and chemical properties</strong></td>
<td></td>
</tr>
<tr>
<td><strong>General Information</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Appearance</strong></td>
<td></td>
</tr>
<tr>
<td>Form</td>
<td>Solid</td>
</tr>
<tr>
<td>Colour</td>
<td>Off 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>
<tr>
<td><strong>Change in condition</strong></td>
<td></td>
</tr>
<tr>
<td>Melting point/Melting range</td>
<td>115-121 °C</td>
</tr>
<tr>
<td>Boiling point/Boiling range</td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flammability (solid, gaseous)</strong></td>
<td>Product is not flammable</td>
</tr>
<tr>
<td><strong>Ignition temperature</strong></td>
<td></td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Self-igniting</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Danger of explosion</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Explosion limits</strong></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>Not determined</td>
</tr>
<tr>
<td>Upper</td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Vapour pressure</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Vapour density</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Solubility in / Miscibility with water</strong></td>
<td></td>
</tr>
<tr>
<td>Chloroform, Methanol</td>
<td>Negligible</td>
</tr>
<tr>
<td><strong>Partition coefficient (n-octanol/water)</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td></td>
</tr>
<tr>
<td>Dynamic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Kinematic</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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 >3200 mg/kg (rat)**
- **Primary irritant effect**:
  - **on the skin**: No irritating effect.
  - **on the eye**: Irritating effect.
- **Sensitization**: No sensitizing effects known.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
  - Oral **Reproductive 27 mg/kg (rat)**
  - Repr. 1B

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
  - 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.
Trade name: Melatonin Assay Standard

(Contd. from page 5)

- 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 MARPOL73/78 and the IBC Code
  - Not applicable.

- UN "Model Regulation": -

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Philippines Inventory of Chemicals and Chemical Substances Substance is listed.
  - Australian Inventory of Chemical Substances Substance is 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.

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:
  RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
  ICAO: International Civil Aviation Organization
  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

(Contd. on page 7)
### Trade name: Melatonin Assay Standard

<table>
<thead>
<tr>
<th>EINECS: European Inventory of Existing Commercial Chemical Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: Chemical Abstracts Service (division of the American Chemical Society)</td>
</tr>
<tr>
<td>LC50: Lethal concentration, 50 percent</td>
</tr>
<tr>
<td>LD50: Lethal dose, 50 percent</td>
</tr>
</tbody>
</table>

### Sources