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

- Product identifier
- Trade name: Ibuprofen impurity B
- Reference number: Cat 880
- 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 SWI W 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
  GHS02 flame
  Flam. Liq. 2 H225 Highly flammable liquid and vapour.

GHS07
  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
  Xn: Harmful
  R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.
  Xi: Irritant
  R36: Irritating to eyes.
  F: Highly flammable
  R11: Highly flammable.

- Information concerning particular hazards for human and environment:
  The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- Classification system:
  The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

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

(Contd. on page 2)
Trade name: Ibuprofen impurity B

- Hazard pictograms
  GHS02  GHS07

- Signal word Danger

- Hazard-determining components of labelling:
  acetonitrile

- Hazard statements
  H225 Highly flammable liquid and vapour.
  H312+H332 Harmful in contact with skin or if inhaled.
  H319 Causes serious eye irritation.

- Precautionary statements
  P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
  P241 Use explosion-proof electrical/ventilating/lighting/equipment.
  P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
  P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  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: Mixtures
- Description: Mixture: consisting of the following components.

- Dangerous components:

<table>
<thead>
<tr>
<th>CAS: 75-05-8</th>
<th>acetonitrile</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 200-835-2</td>
<td>Xn R20/21/22; Xi R36; F R11</td>
</tr>
<tr>
<td>RTECS: AL 7700000</td>
<td>Flam. Liq. 2, H225; Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 3585-49-7</th>
<th>(2RS)-2-(4-Butylphenyl)propanoic Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>RTECS: -</td>
<td>Xn R22</td>
</tr>
</tbody>
</table>

- Additional information: For the wording of the listed risk phrases refer to section 16.

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.
Trade name: Ibuprofen impurity B

- **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. 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, sand, extinguishing powder. Do not use water.
- For safety reasons unsuitable extinguishing agents: Water with full jet
- 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: Mouth respiratory protective device. Wear self-contained respiratory protective device.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
  - Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/surface or ground water.
- **Methods and material for containment and cleaning up:**
  - Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  - Dispose of contaminated material as waste according to item 13.
  - Ensure adequate ventilation.
  - Do not flush with water or aqueous cleansing agents
- **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.
  - Store in cool, dry place in tightly closed receptacles.
  - Prevent formation of aerosols.
- **Information about fire - and explosion protection**
  - Keep ignition sources away - Do not smoke.
  - Protect from heat.
  - Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
  - Store in a cool location.
Trade name: Ibuprofen impurity B

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.
  - Store in cool, dry conditions in well sealed receptacles.
  - Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

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### 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:**
    - 75-05-8 acetonitrile
      - WEL Short-term value: 102 mg/m³, 60 ppm
      - Long-term value: 68 mg/m³, 40 ppm
  - **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:**
  - 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:**
  - **Protective gloves**

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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
**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.

(Contd. on page 5)
9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:** Liquid
    - Colour: Colourless
  - **Odour:** Aromatic
  - **Odour threshold:** Not determined.
  - **pH-value:** Not determined.

- **Change in condition**
  - Melting point/Melting range: -46 °C
  - Boiling point/Boiling range: 81 °C

- **Flash point:** 5 °C

- **Flammability (solid, gaseous):** Not determined.

- **Ignition temperature:** 525 °C

- **Decomposition temperature:** Not determined.

- **Self-igniting:** Product is not self-igniting.

- **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapour mixtures is possible.

- **Explosion limits:**
  - Lower: 4.4 Vol %
  - Upper: 16 Vol %

- **Vapour pressure at 20 °C:** 97 hPa

- **Density at 20 °C:** 0.7822 g/cm³
  - **Relative density** Not determined.
  - **Vapour density** Not determined.
  - **Evaporation rate** Not determined.

- **Solubility in / Miscibility with water at 25 °C:** 74 g/l

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**
  - Dynamic: Not determined.
  - Kinematic: Not determined.

- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** Stable under normal conditions.
- **Chemical stability** Stable under normal conditions.

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Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 17.05.2013
Version number 1
Revision: 17.05.2013

Trade name: Ibuprofen impurity B

· Thermal decomposition / conditions to be avoided:
  Formation of toxic gases is possible during heating or in case of fire.
· Possibility of hazardous reactions Forms explosive gas mixture with air.
· Conditions to avoid
  Sources of ignition.
  Heat.
· Incompatible materials:
  Strong oxidizing agents.
  Strong acids.
· 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:
    | 75-05-8 acetonitrile |
    | Oral LD50 | 2730 mg/kg (rat) |
    | Dermal LD50 | 1250 mg/kg (rabbit) |
  · Primary irritant effect:
    · on the skin: No irritating effect.
    · on the eye: Irritating effect.
    · Sensitization: No sensitizing effects known.
· Additional toxicological information:
  The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
  Harmful
  Irritant

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: Ibuprofen impurity B

- **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.

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### 14 Transport information

<table>
<thead>
<tr>
<th>UN-Number</th>
<th>ADR, IMDG, IATA</th>
<th>UN1648</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>1648 ACETONITRILE, mixture</td>
<td></td>
</tr>
<tr>
<td>IMDG, IATA</td>
<td>ACETONITRILE, mixture</td>
<td></td>
</tr>
</tbody>
</table>

- **Transport hazard class(es)**
  - **ADR, IMDG, IATA**
    - **Class** 3
    - **Label** 3
    - **Packing group** II

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

- **Special precautions for user** Warning: Flammable liquids.
- **Danger code (Kemler):** 33
- **EMS Number:** F-E,S-D

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

- **Transport/Additional information:**
  - **ADR**
    - **Limited quantities (LQ)** 1L
    - **Transport category** 2
    - **Tunnel restriction code** D/E
  - **UN "Model Regulation":** UN1648, ACETONITRILE, mixture, 3, II

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### 15 Regulatory information

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

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### 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... (Contd. on page 8)
Trade name: Ibuprofen impurity B

(Contd. from page 7)

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, however arising, direct or otherwise.

- Relevant phrases
  H225 Highly flammable liquid and vapour.
  H302 Harmful if swallowed.
  H312 Harmful in contact with skin.
  H319 Causes serious eye irritation.
  H332 Harmful if inhaled.
  R11 Highly flammable.
  R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
  R22 Harmful if swallowed.
  R36 Irritating to eyes.

- 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
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent

- Sources