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

- **Product identifier**
- **Trade name:** Isosorbide dinitrate
- **Reference number:** Cat 206
- **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**
  - GHS02 flame
  - Flam. Sol. 1 H228 Flammable solid.
  - GHS07
  - Acute Tox. 4 H302 Harmful if swallowed.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
  - Xn: Harmful
  - R22: Harmful if swallowed.
  - R5: Heating may cause an explosion.
- **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.
- **Hazard pictograms**
  - GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**
  - Isosorbide dinitrate

(Contd. on page 2)
Trade name: Isosorbide dinitrate

3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: Mixture of substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
<th>CAS: 87-33-2</th>
<th>Isosorbide dinitrate</th>
<th>Xn R22</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 201-740-9</td>
<td></td>
<td>R5</td>
</tr>
<tr>
<td>RTECS: LZ4385000</td>
<td></td>
<td>Acute Tox. 4, H302</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; 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.

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: Isosorbide dinitrate

6 Accidental release measures

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

- 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: Protect from heat.
- 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: Store in cool, dry conditions in well sealed receptacles.
- 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:
  The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- 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. As the product is a preparation of several substances, the
Trade name: **Isosorbide dinitrate**

(Contd. from page 3)

resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**
  The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Safety glasses

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Solid
      - **Colour:** White
    - **Odour:** Odourless
    - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.
  - **Change in condition**
    - **Melting point/Melting range:** Not determined.
    - **Boiling point/Boiling range:** Not determined.
  - **Flash point:** Not applicable.
  - **Flammability (solid, gaseous):** Not determined.
  - **Ignition temperature:**
    - **Decomposition temperature:** Not determined.
    - **Self-igniting:** Product is not self-igniting.
    - **Danger of explosion:** Heating may cause an explosion.
  - **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:** Soluble.
  - **Partition coefficient (n-octanol/water):** Not determined.
  - **Viscosity:**
    - **Dynamic:** Not applicable.
    - **Kinematic:** Not applicable.
  - **Other information**
    - No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** Stable under normal conditions.
- **Chemical stability** Stable under normal conditions.
11 Toxicological information

- Information on toxicological effects
- Acute toxicity:
  - LD/LC50 values relevant for classification:

<table>
<thead>
<tr>
<th></th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>747 mg/kg (rat)</td>
<td>&gt;3000 mg/kg (rat)</td>
</tr>
<tr>
<td>87-33-2 Isosorbide dinitrate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD 50 (Intraperitoneal)</td>
<td>670 mg/kg (rat)</td>
<td></td>
</tr>
<tr>
<td>LD 50 (Intravenous)</td>
<td>&gt;40 mg/kg (rat)</td>
<td></td>
</tr>
</tbody>
</table>

- Primary irritant effect:
  - on the skin: No irritating effect.
  - on the eye: No 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

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.
- European waste catalogue
  Waste disposal key numbers from EWC have to be assigned depending on origin and processing.
Trade name: Isosorbide dinitrate

(Contd. from page 5)

· Uncleaned packaging:
  · Recommendation: Dispose of in accordance with national regulations.

14 Transport information

· UN-Number
  · ADR, IMDG, IATA UN2907
  · ADR 2907 ISOSORBIDE DINITRATE MIXTURE
  · IMDG, IATA ISOSORBIDE DINITRATE MIXTURE

· Transport hazard class(es)
  · ADR, IMDG, IATA

· Class
  · 4.1 Flammable solids, self-reactive substances and solid desensitised explosives.

· Label
  · 4.1

· Packing group
  · ADR, IMDG, IATA II

· Environmental hazards:
  · Marine pollutant: No

· Special precautions for user
  · Warning: Flammable solids, self-reactive substances and solid desensitised explosives.

· EMS Number:
  · F-B,S-J

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

· Transport/Additional information:

  · ADR
    · Excepted quantities (EQ): E0
    · Limited quantities (LQ): 0
    · Transport category: 2
    · Tunnel restriction code: B

  · UN "Model Regulation": UN2907, ISOSORBIDE DINITRATE MIXTURE, 4.1, II

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

  · Philippines Inventory of Chemicals and Chemical Substances
    · 87-33-2 Isosorbide dinitrate

  · Australian Inventory of Chemical Substances
    · All ingredients are listed.

  · Standard for the Uniform Scheduling of Drugs and Poisons
    · 87-33-2 Isosorbide dinitrate
    · S3, S4

(Contd. on page 7)
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.

- Relevant phrases
  H302 Harmful if swallowed.
  R22 Harmful if swallowed.
  R5 Heating may cause an explosion.

- 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