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

1.1 Product identifier

Product name: Glyceryl trinitrate solution Assay Standard

Part number: Cat 652

1.2 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

1.3 Details of the supplier of the safety data sheet

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

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

GHS02 flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

GHS06 skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed.
Acute Tox. 3 H311 Toxic in contact with skin.
Acute Tox. 3 H331 Toxic if inhaled.

2.2 Label elements

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

Hazard pictograms

GHS02 GHS06

Signal word Danger

Hazard-determining components of labelling:
Glycerol trinitrate

Hazard statements
H225 Highly flammable liquid and vapour.
H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.

Precautionary statements
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
Product name: Glyceryl trinitrate solution Assay Standard

(Contd. from page 1)

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
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

· 3.2 Chemical characterisation: Mixtures
· Description: Mixture: consisting of the following components.

- Dangerous components:

| CAS: 64-17-5 | Ethanol | Flam. Liq. 2, H225 | > 99% |
| EINECS: 200-578-6 | RTECS: KQ6300000 |
| CAS: 55-63-0 | Glycerol trinitrate | Unst. Expl., H200; Acute Tox. 2, H300; Acute Tox. 1, H310; Acute Tox. 2, H330; STOT RE 2, H373; Aquatic Chronic 2, H411 | < 1.0% |
| EINECS: 200-240-8 | RTECS: QX 2100000 |

- 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
· General information:
  Immediately remove any clothing soiled by the product.
  Remove breathing equipment only after contaminated clothing has been completely removed.
  In case of irregular breathing or respiratory arrest provide artificial respiration.
· After inhalation:
  Supply fresh air or oxygen; call for doctor.
  In case of unconsciousness place patient in recovery position for transport.
  Seek immediate medical advice.
· After skin contact:
  Immediately wash with water and soap and rinse thoroughly.
  Seek immediate medical advice.
· After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
· After swallowing:
  Rinse mouth. Do not induce vomiting.
  Call a doctor immediately.
  Call for a doctor immediately.
· 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:
  CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Product name: Glyceryl trinitrate solution Assay Standard

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:
   - Mouth respiratory protective device.
   - Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
   Wear protective equipment. Keep unprotected persons away.
6.2 Environmental precautions:
   Dilute with plenty of water.
   Do not allow to enter sewers/surface or ground water.
6.3 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.
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
   Ensure good ventilation/extraction at the workplace.
   Store in cool, dry place in tightly closed receptacles.
   Open and handle receptacle with care.
   Information about fire - and explosion protection:
   Keep ignition sources away - Do not smoke.
   Protect against electrostatic charges.
   Keep respiratory protective device available.
7.2 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.
   - 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:

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Substance</th>
<th>WEL</th>
<th>Long-term value</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5</td>
<td>Ethanol</td>
<td></td>
<td>1920 mg/m³, 1000 ppm</td>
</tr>
</tbody>
</table>

#### Ingredients with biological limit values:

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Substance</th>
<th>BMGV</th>
<th>Medium</th>
<th>Sampling time</th>
<th>Parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>55-63-0</td>
<td>Glycerol trinitrate</td>
<td>15 µmol/mol creatinine</td>
<td>urine</td>
<td>at the end of the period of exposure</td>
<td>total nitroglycerols</td>
</tr>
</tbody>
</table>

#### 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.
- Store protective clothing separately.
- 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.
- Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149.
- Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

#### 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.

#### Material of gloves:
- Butyl rubber, BR

#### 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:
- Tightly sealed goggles

(Contd. from page 3)
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- General Information
- Appearance:
  - Liquid
- Colour: Colourless
- Odour: Alcohol-like
- Odour threshold: Not determined.
- pH-value at 20 °C: 7
- Change in condition
  - Melting point/freezing point: -114.5 °C
  - Initial boiling point and boiling range: 78 °C
- Flash point: 13 °C
- Flammability (solid, gas): Not determined.
- Ignition temperature: 425 °C
- Decomposition temperature: Not determined.
- Auto-ignition temperature: Product is not self-igniting.
- Explosive properties:
  - Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
- Explosion limits:
  - Lower: 3.5 Vol %
  - Upper: 27.7 Vol %
- Vapour pressure at 20 °C: 59 hPa
- Density at 20 °C: 0.79803 g/cm³
- Relative density: Not determined.
- Vapour density: Not determined.
- Evaporation rate: Not determined.
- Solubility in / Miscibility with water at 20 °C: > 100 g/l
- Partition coefficient: n-octanol/water: Not determined.
- Viscosity:
  - Dynamic: Not determined.
  - Kinematic: Not determined.

9.2 Other information
No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity
Stable under normal conditions.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of thermal decomposition / conditions to be avoided:
Formation of toxic gases is possible during heating or in case of fire.

10.4 Conditions of ignition
Sources of ignition
- Heat.

10.5 Incompatible materials:
Strong oxidizing agents.

(Contd. on page 6)
1.0.6 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**
  Toxic if swallowed, in contact with skin or if inhaled.

#### LD/LC50 values relevant for classification:

<table>
<thead>
<tr>
<th>55-63-0 Glycerol trinitrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD₅₀</td>
</tr>
<tr>
<td>Dermal LD₅₀</td>
</tr>
</tbody>
</table>

**Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
  - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
  - **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **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:**

<table>
<thead>
<tr>
<th>55-63-0 Glycerol trinitrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC₅₀/48</td>
</tr>
<tr>
<td>EC₅₀/48 h</td>
</tr>
<tr>
<td>EC₅₀/96 h</td>
</tr>
<tr>
<td>LC₅₀/96 h</td>
</tr>
</tbody>
</table>

- **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.
- **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.

#### 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.
Product name: Glyceryl trinitrate solution Assay Standard

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

14.1 UN-Number
- ADR, IMDG, IATA: UN3064
- ADR: 3064 NITROGLYCERIN, SOLUTION IN ALCOHOL
- IMDG, IATA: NITROGLYCERIN, SOLUTION IN ALCOHOL

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

- Class: 3 Flammable liquids.
- Label: 3

14.4 Packing group
- ADR, IMDG, IATA: II

14.5 Environmental hazards:
- Marine pollutant: No

14.6 Special precautions for user
- Warning: Flammable liquids.
- EMS Number: F,E,S-D
- Stowage Category: E

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Not applicable.

Transport/Additional information:

- ADR
- Limited quantities (LQ): 0
- Excepted quantities (EQ): Code: E0
- Not permitted as Excepted Quantity
- Transport category: 2
- Tunnel restriction code: B

UN "Model Regulation":
- UN 3064 NITROGLYCERIN, SOLUTION IN ALCOHOL, 3, II

SECTION 15: Regulatory information

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

Philippines Inventory of Chemicals and Chemical Substances
- 55-63-0 Glycerol trinitrate

Australian Inventory of Chemical Substances
- 55-63-0 Glycerol trinitrate

(Contd. on page 8)
Product name: Glyceryl trinitrate solution Assay Standard

<table>
<thead>
<tr>
<th>Standard for the Uniform Scheduling of Medicines and Poisons</th>
</tr>
</thead>
<tbody>
<tr>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>Directive 2012/18/EU</td>
</tr>
<tr>
<td>Named dangerous substances - ANNEX I None of the ingredients is listed.</td>
</tr>
<tr>
<td>Seveso category</td>
</tr>
<tr>
<td>H2 ACUTE TOXIC</td>
</tr>
<tr>
<td>P5c FLAMMABLE LIQUIDS</td>
</tr>
<tr>
<td>Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t</td>
</tr>
<tr>
<td>Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t</td>
</tr>
<tr>
<td>REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3</td>
</tr>
<tr>
<td>15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.</td>
</tr>
</tbody>
</table>

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
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 2: Acute toxicity – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 1: Acute toxicity – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
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.