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

- **Product identifier**
- **Trade name**: Atropine sulfate Assay Standard
- **Reference number**: Cat 023
- **CAS Number**: 5908-99-6
- **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
  
  10 South Colonnade, Canary Wharf
  
  London E14 4PU
  
  United Kingdom
- **Further information obtainable from**: eMail: bpcrs@mhra.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**

  ![GHS07]

  Acute Tox. 4  H302  Harmful if swallowed.
  
  Skin Sens. 1  H317  May cause an allergic skin reaction.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**

  ![Xn: Harmful]

  R22:  Harmful if swallowed.

  ![Xi: Sensitising]

  R43:  May cause sensitisation by skin contact.

- **Information concerning particular hazards for human and environment**: Not applicable.

- **Label elements**

  ![GHS07]

- **Signal word** Warning
- **Hazard statements**

  H302 Harmful if swallowed.
  
  H317 May cause an allergic skin reaction.

- **Precautionary statements**

  P261  Avoid breathing dust/fume/gas/mist/vapours/spray.

  P280  Wear protective gloves/protective clothing/eye protection/face protection.

  P321  Specific treatment (see on this label).
Trade name: Atropine sulfate Assay Standard

(Contd. from page 1)

- P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
- P363 Wash contaminated clothing before reuse.
- 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: Substances
· CAS No. Description
  5908-99-6 Atropine Sulphate monohydrate
· Identification number(s) -

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 and to be sure call for a doctor.
  In case of unconsciousness place patient in recovery position for transport.
· 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.
· 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.

(Contd. on page 3)
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.

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.
    - Respiratory protection: Not required.
    - 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
dergradation
  - 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.

(Contd. from page 2)
### 9 Physical and chemical properties

**General Information**

- **Appearance:**
  - Form: Solid
  - Colour: White
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value (20 g/l) at 20 °C:** 5.2

**Change in condition**

- **Melting point/Melting range:** 188 - 194 °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**
  - Glycerol, Alcohol: 2000 g/l

**Partition coefficient (n-octanol/water):** 1.83 logP

**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.
- **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.
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- **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 | 468 mg/kg (mouse) |
      | 600 mg/kg (rat) |
  - **Primary irritant effect:**
    - **on the skin:** No irritating effect.
    - **on the eye:** No irritating effect.
    - **Sensitization:** Sensitization possible through skin contact.

### 12 Ecological information

- **Toxicity**
  - **Aquatic toxicity:**
    - **LC50/96 h** 468 mg/l (fish)
  - **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.
  - **Uncleaned packaging:**
    - **Recommendation:** Dispose of in accordance with national regulations.

### 14 Transport information

- **UN-Number**
  - UN1544
- **ADR, IMDG, IATA**
  - Not applicable
- **ADR**
  - 1544 ALKALOIDS, SOLID, N.O.S. (Atropine Sulphate monohydrate)
### Trade name: Atropine sulfate Assay Standard

(Contd. from page 5)

| · ADN       | Not applicable |
| · IMDG, IATA | ALKALOIDS, SOLID, N.O.S. (Atropine Sulphate monohydrate) |

**Transport hazard class(es)**
- ADR, IMDG, IATA
  - Class: 6.1 Toxic substances.
  - Label: 6.1
  - ADN/R Class: Not applicable

**Packing group**
- ADR, IMDG, IATA
  - Packing group: III

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

**Special precautions for user**
- Warning: Toxic substances.
- EMS Number: F-A,S-A

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

**Transport/Additional information:**
- ADR
  - Limited quantities (LQ): 5 kg

**UN "Model Regulation":**
- UN1544, ALKALOIDS, SOLID, N.O.S. (Atropine Sulphate monohydrate), 6.1, III

### 15 Regulatory information

- **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 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 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**