

**BRITISH PHARMACOPOEIA CHEMICAL REFERENCE SUBSTANCE**

**MATERIAL SAFETY DATA SHEET**

Last revised: 17<sup>th</sup> June 2008.

The substance to which this Safety Data Sheet relates is supplied exclusively as a British Pharmacopoeia Chemical Reference Substance (BPCRS) for chemical test and assay purposes. It is not intended to be used for any other purpose and **is not for human consumption**.

The BPCRS is supplied in accordance with the Terms of Trade and Supply as set out in the catalogue. The information set out in this sheet is applicable solely to the substance when used as a BPCRS and is not intended to apply to any other use or preparation of the substance (e.g. at different concentrations, in drug dosage form or in bulk quantities).

The information which follows has been assembled from sources considered reliable, in particular from material provided in the ordinary way by the manufacturer or supplier. It has not been independently verified by the British Pharmacopoeia. The accuracy of the information cannot therefore be guaranteed, nor does it constitute any expression of opinion by the British Pharmacopoeia concerning the substance. This information is not to be regarded as a representation or statement concerning the quality or safety of the substance except that of use as a BPCRS by professional persons having technical skill and at their own discretion and risk.

All persons using BPCRS materials must determine the risks associated with the substance depending on the actual conditions of use and should take appropriate measures.

Information given in sections 2, 3, 4, 5, 6, 9, 10, 11, 12 and 13 relates to the bulk substance and is not necessarily relevant to the BPCRS regarding the small quantities contained in vials. Information in sections 1, 7, 8 and 14 applies only to the BPCRS.

**1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY**

1-(3-AZABICYCLO{3.3.0}OCT-3-YL)3-o-TOLYLSULPHONYLUREA BPCRS

Caution! This product is a synthesis by-product and/or a degradation product. Its properties have not been fully investigated. *Information given in this MSDS refers to the parent compound; gliclazide.*

British Pharmacopoeia Commission

Secretariat  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ  
United Kingdom

Laboratory  
Queen's Road  
Teddington  
TW11 0LY  
United Kingdom

Telephone: +44 (0)20 70840 2561 (office hours)

Email: [bpccrs@mhra.gsi.gov.uk](mailto:bpccrs@mhra.gsi.gov.uk)

Emergency telephone: +44 (0)20 70840 2561 (office hours)

**2. HAZARDS IDENTIFICATION**

Irritant to eyes and skin.

Symbol: Xn

Risk phrases: R36/37/38

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

C<sub>15</sub>H<sub>21</sub>N<sub>3</sub>O<sub>3</sub>S

CAS: Not known

EINECS Number: Not known

#### **4. FIRST AID MEASURES**

Inhalation: Remove to fresh air. If not breathing give artificial respiration. If breathing becomes difficult, give oxygen.

Skin contact: Flush with copious amounts of water and soap for at least 15 minutes. Remove contaminated clothing and shoes.

Eyes contact: Immediately flush eyes with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers.

Ingestion: Call a physician. Wash out mouth with water, provided person is conscious.

*In any case seek medical advice and call the nearest poison centre.*

#### **5. FIRE FIGHTING MEASURES**

Extinguishing media: Water spray. Carbon dioxide, dry chemical powder or appropriate foam. Wear suitable protective clothing and respiratory protection to prevent contact with skin and eyes. Emits toxic fumes under fire conditions.

#### **6. ACCIDENTAL RELEASE MEASURES**

Wear suitable protective clothing and respiratory protection. Sweep up, place in a bag and hold for waste disposal. Ventilate and wash area with water/detergent.

#### **7. HANDLING AND STORAGE**

Handling: Wear suitable protective clothing and respiratory protection, chemical-resistant gloves and safety goggles. Mechanical exhaust required.

Storage: Keep unopened in the original container at about 2-10 °C

#### **8. EXPOSURE CONTROL/PERSONAL PROTECTION**

Wear suitable protective clothing and respiratory protection, chemical-resistant gloves and safety goggles. Handle in a chemical fume hood.

#### **9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance: white or almost white powder.

Solubility: Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in acetone, slightly soluble in alcohol.

Melting point: 165°C to 167°C

Log Pow (n-octanol:water): 2.12

#### **10. STABILITY AND REACTIVITY**

Incompatibilities: strong oxidising agents and high temperature.

Hazardous combustion or decomposition products: CO<sub>x</sub>, SO<sub>x</sub>, NO<sub>x</sub>..

#### **11. TOXICOLOGICAL INFORMATION**

RTECS No: YT4500000

LD50 (oral-rat): > 3000 mg/kg.

Irritating to eyes, respiratory system and skin.

*See actual entry in RTECS for complete information.*

#### **12. ECOLOGICAL INFORMATION**

Not available.

**13. DISPOSAL CONSIDERATIONS**

Incinerate in an approved facility.  
*Observe all federal state and local environmental regulations.*

**14. TRANSPORT INFORMATION**

Not applicable.

**15. REGULATORY INFORMATION**

EINECS No: 224-260-5  
Symbol: Xn  
R36/37/38, S26, S36, S36/37/39

**16. OTHER INFORMATION**

R36/37/38: Irritating to eyes, respiratory system and skin

S22 Do not breathe dust.

S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.