

Version 3.0      Revision Date: 08.08.2018      SDS Number: 20724      Date of last issue: -  
Date of first issue: 08.08.2018

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## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

#### BRICANYL SOLUTION

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD      Emergency Telephone  
PO Box 131      +44 (0) 1235 239 670  
66 Talavera Rd, North Ryde  
NSW 2113  
AUSTRALIA  
+61 2 9978 3500  
  
SafetyDataSheets.AlderleyPark@astrazeneca.com

#### Alternative Names

Terbutaline Solution  
Bricanyl solution for injection  
Bricanyl solution for nebulisation  
CAS No. : Not applicable

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : bronchodilator

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## SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Not a hazardous substance or mixture.

#### GHS label elements

Not a hazardous substance or mixture.

#### Other hazards which do not result in classification

May cause trembling and increased heart rate.  
Rare cases of cardiac arrhythmias have been reported.

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## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Hazardous components

| Chemical name        | CAS-No.    | Concentration (% w/w) |
|----------------------|------------|-----------------------|
| Terbutaline sulphate | 23031-32-5 | 0.05 -1               |

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## SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure.  
Obtain medical attention if ill effects occur.

In case of skin contact : Wash skin with soap and water.

In case of eye contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes.  
Obtain medical attention if ill effects remain.

# SAFETY DATA SHEET



Version 3.0      Revision Date: 08.08.2018      SDS Number: 20724      Date of last issue: -  
Date of first issue: 08.08.2018

---

- If swallowed : Wash out mouth with water and give 200-300ml of water to drink.  
Obtain medical attention if ill effects occur.  
Do NOT induce vomiting as a First-Aid measure.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11
- Notes to physician : Symptomatic treatment and supportive therapy as indicated.  
For further information consult the prescribing information.
- 

## SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : water spray, foam, dry powder or CO<sub>2</sub>.
- Unsuitable extinguishing media : -
- Specific hazards during firefighting : If involved in a fire, it may emit noxious and toxic fumes.
- Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
- 

## SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages.  
See Section 8.
- Environmental precautions : Prevent entry into drains.
- Methods and materials for containment and cleaning up : Clear up spillages.  
Transfer to a container for disposal.  
Wash the spillage area with water.
- 

## SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Avoid contact with skin and eyes.
- Conditions for safe storage : Keep container tightly closed.  
Protect from light.
- Recommended storage temperature : < 25 °C
- 

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

| Components | CAS-No. | Value type | Control | Basis |
|------------|---------|------------|---------|-------|
|------------|---------|------------|---------|-------|

---

# SAFETY DATA SHEET



Version  
3.0

Revision Date:  
08.08.2018

SDS Number:  
20724

Date of last issue: -  
Date of first issue: 08.08.2018

|                      |            | (Form of exposure) | parameters / Permissible concentration |          |
|----------------------|------------|--------------------|--|----------|
| Terbutaline sulphate | 23031-32-5 | TWA                | 0.003 mg/m <sup>3</sup>                | COM; HYG |

**Engineering measures** : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains.

## Personal protective equipment

Respiratory protection : Use a negative pressure air purifying respirator (half face mask) with filter class A if the risk assessment does not support the selection of other protection.

Eye protection : Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

Skin and body protection : Avoid contact with skin. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : No data available

# SAFETY DATA SHEET



Version 3.0      Revision Date: 08.08.2018      SDS Number: 20724      Date of last issue: -  
Date of first issue: 08.08.2018

---

Odour : No data available

Odour Threshold : No data available

pH : 3 - 3.5

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

    Water solubility : No data available

    Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

    Viscosity, dynamic : No data available

    Viscosity, kinematic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

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## SECTION 10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.

Version 3.0      Revision Date: 08.08.2018      SDS Number: 20724      Date of last issue: -  
Date of first issue: 08.08.2018

---

Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : None known.  
Conditions to avoid : No conditions producing hazardous situations known.  
Incompatible materials : None known.  
Hazardous decomposition products : No hazardous decomposition products are known.

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## SECTION 11. TOXICOLOGICAL INFORMATION

### 11.1 Acute toxicity

Not classified based on available information.

#### **Product:**

Acute oral toxicity : Remarks: Low acute oral toxicity.

Acute inhalation toxicity : Remarks: Low acute toxicity.

#### **Components:**

##### **Terbutaline sulphate:**

Acute oral toxicity : LD50 Oral (Rat): 1,800 mg/kg

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : Remarks: No information available.

### 11.2 Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

##### **Terbutaline sulphate:**

Remarks: No information available.

### 11.3 Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

##### **Terbutaline sulphate:**

Remarks: No information available.

### 11.4 Respiratory or skin sensitisation

#### **Skin sensitisation**

Not classified based on available information.

Version 3.0      Revision Date: 08.08.2018      SDS Number: 20724      Date of last issue: -  
Date of first issue: 08.08.2018

---

## **Respiratory sensitisation**

Not classified based on available information.

### **Components:**

#### **Terbutaline sulphate:**

Remarks: No information available.

## **Chronic toxicity**

### **11.5 Germ cell mutagenicity**

Not classified based on available information.

#### **Components:**

##### **Terbutaline sulphate:**

Germ cell mutagenicity - Assessment : No information available.

### **11.6 Carcinogenicity**

Not classified based on available information.

#### **Components:**

##### **Terbutaline sulphate:**

Carcinogenicity - Assessment : The substance is not considered to be carcinogenic.

### **11.7 Reproductive toxicity**

Not classified based on available information.

#### **Components:**

##### **Terbutaline sulphate:**

Reproductive toxicity - Assessment : There is no evidence of reprotoxicity in animal tests.

### **11.8 STOT - single exposure**

Not classified based on available information.

#### **Components:**

##### **Terbutaline sulphate:**

Exposure routes: Inhalation, Oral

Remarks: May cause trembling and increased heart rate.

Rare cases of cardiac arrhythmias have been reported.

Nausea, headache, restlessness and cramps in hands and feet can occur.

### **11.9 STOT - repeated exposure**

Not classified based on available information.

#### **Components:**

##### **Terbutaline sulphate:**

Exposure routes: Oral

Version 3.0      Revision Date: 08.08.2018      SDS Number: 20724      Date of last issue: -  
Date of first issue: 08.08.2018

---

Target Organs: Heart  
Assessment: The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 2.  
Remarks: These effects are derived from studies in animals.

#### 11.10 Aspiration toxicity

Not classified based on available information.

##### Components:

##### **Terbutaline sulphate:**

No information available.

##### **Further information**

##### Product:

Remarks: This health hazard assessment is based on a consideration of the composition of this product.

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## SECTION 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### Components:

##### **Terbutaline sulphate:**

Toxicity to fish : NOEC (Danio rerio (zebra fish)): 1,000 mg/l  
Exposure time: 96 H  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 240 mg/l  
Exposure time: 48 H  
Method: OECD Test Guideline 202

LOEC (Daphnia magna (Water flea)): 100 mg/l  
Exposure time: 48 H  
Method: OECD Test Guideline 202

Toxicity to algae : ErC50 (green algae): > 500 mg/l  
Exposure time: 72 H  
Method: OECD Test Guideline 201

### **Persistence and degradability**

#### Components:

##### **Terbutaline sulphate:**

Biodegradability : Remarks: Not rapidly degradable.

### **Bioaccumulative potential**

#### Components:

##### **Terbutaline sulphate:**

# SAFETY DATA SHEET



Version 3.0      Revision Date: 08.08.2018      SDS Number: 20724      Date of last issue: -  
Date of first issue: 08.08.2018

---

Bioaccumulation : Remarks: The substance has low potential for bioaccumulation.

## Mobility in soil

### Components:

#### **Terbutaline sulphate:**

Mobility : Remarks: Water solubility  $\geq 1$  mg/l.

Distribution among environmental compartments : Remarks: No information available.

#### **Other adverse effects**

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : Disposal should be in accordance with local, state or national legislation.

Contaminated packaging : Empty container will retain product residue. Observe all hazard precautions.

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## SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

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## SECTION 15. REGULATORY INFORMATION

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

In order to comply with legal duties it is necessary to consult local and national legislation.

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory

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|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: -           |
| 3.0     | 08.08.2018     | 20724       | Date of first issue: 08.08.2018 |

---

legislation.

**The components of this product are reported in the following inventories:**

|                      |   |   |
|----------------------|---|---|
| REACH                | : | Not listed  |
| DSL                  | : | This product contains the following components that are not on the Canadian DSL nor NDSL. |
| Terbutaline sulphate | : | 23031-32-5  |
| AICS                 | : | Not listed  |
| ENCS                 | : | Not listed  |
| ISHL                 | : | Not listed  |
| IECSC                | : | Not listed  |
| TCSI                 | : | Not listed  |
| TSCA                 | : | Not On TSCA Inventory   |

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## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations

# SAFETY DATA SHEET



|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: -           |
| 3.0     | 08.08.2018     | 20724       | Date of first issue: 08.08.2018 |

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Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

## Further information

Revision Date : 08.08.2018

Other information : The Safety Data Sheet has been updated to the SAP EH&S Standard template., This update affects all Sections of the Safety Data Sheet.

Date format : dd.mm.yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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