

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

BRICANYL SOLUTION

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
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Alternative Names

Terbutaline Solution
 Bricanyl solution for injection
 Bricanyl solution for nebulisation

CAS No. : Not applicable
 Use : bronchodilator

2. HAZARDS IDENTIFICATION

This mixture is not classified as hazardous for supply/use according to GHS v 4.0. May cause trembling and increased heart rate. Rare cases of cardiac arrhythmias have been reported.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

Component	%	CAS No.		
Terbutaline sulphate	0,05 - 1	23031-32-5		
		Hazard class #	Category	Hazard statements #
		Acute toxicity	4	H302
		Acute toxicity	4	H332
Specific target organ toxicity - repeated exposure	2	H373		

Refer to Section 16 'Other Information'

4. FIRST-AID MEASURES

Description of first aid measures

Inhalation : Remove patient from exposure. Obtain medical attention if ill effects occur.
 Skin Contact : Wash skin with soap and water.
 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.
 Ingestion : 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

Indication of any immediate medical attention and special treatment needed

Symptomatic treatment and supportive therapy as indicated. For further information consult the prescribing information.

5. FIRE-FIGHTING MEASURES

- Extinguishing Media (suitable) : water spray, foam, dry powder or CO₂.
Extinguishing Media (unsuitable) : -
- Special hazards arising from the substance or mixture : If involved in a fire, it may emit noxious and toxic fumes.
- Special protective actions for fire-fighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

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 material for containment and cleaning up : Clear up spillages. Transfer to a container for disposal. Wash the spillage area with water.

7. HANDLING AND STORAGE

- Precautions for safe handling : Avoid contact with skin and eyes.
- Conditions for safe storage, including any incompatibilities : Keep container tightly closed. Protect from light.
- Specific end use(s) : Storage temperature : < 25 °C
Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Components	Value	Control parameters	Comments
Terbutaline sulphate	0,003 mg/m ³	LTEL 8hr TWA	COM, HYG

Exposure Controls

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.

Occupational exposure controls

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.

The information below 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.

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.

Skin 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form : Aqueous solution
pH : 3 - 3,5

Other information

No other data available

10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.
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.

11. TOXICOLOGICAL INFORMATION

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

Inhalation	:	Low acute toxicity.
Skin Contact	:	No information available.
Eye Contact	:	No information available.
Ingestion	:	Low acute oral toxicity.
Specific Target Organ Toxicity (STOT)	:	<p>Single exposure Exposure routes: Inhalation, Oral 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.</p> <p>Repeated exposure Exposure routes: Oral Target Organs: Heart Repeated exposure may produce adverse effects., These effects are derived from studies in animals.</p>
Sensitisation	:	No information available.
Carcinogenicity	:	The substance is not considered to be carcinogenic.
Mutagenicity	:	No information available.
Reproductive toxicity	:	There is no evidence of reprotoxicity in animal tests.

12. ECOLOGICAL INFORMATION

No information on this formulation. The following information refers to active ingredient:

Toxicity	:	ErC50 green algae 72 H > 500 mg/l (OECD 201) EC50 Daphnia magna (Water flea) 48 H 240 mg/l (OECD 202) LOEC Daphnia magna (Water flea) 48 H 100 mg/l (OECD 202) NOEC Danio rerio (zebra fish) 96 H 1 000 mg/l (OECD 203)
Effect on Effluent Treatment	:	No information available.
Persistence and degradability	:	Not rapidly degradable.
Bioaccumulative potential	:	The substance has low potential for bioaccumulation.
Mobility in soil	:	Water solubility >= 1 mg/l.

Other adverse effects : No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods : Disposal should be in accordance with local, state or national legislation.

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

14. TRANSPORT INFORMATION

NOT RESTRICTED FOR TRANSPORT

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Hazard statements H302 : Harmful if swallowed.
H332 : Harmful if inhaled.
H373 : May cause damage to organs through prolonged or repeated exposure.

The following sections contain revisions or new statements :

New significant SHE information:

1. Alternative names
8. New Occupational Exposure Limit Value

Minor changes: 3, 9

GLOSSARY

COM	:	In-house occupational exposure limit
LEL	:	Long-term exposure limit (8 hour TWA (time-weighted average))
STEL	:	Short-term exposure limit (15-minute TWA (time-weighted average))
TLV	:	Threshold Limit Value (ACGIH)
TLV-C	:	Threshold Limit Value - Ceiling limit (ACGIH)
HYG	:	An in-house analytical method for occupational exposure monitoring is available
Sk	:	Can be absorbed through skin, thus contributing to systemic effects
Sen	:	Capable of causing respiratory sensitisation

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.