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## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

## TERBUTALINE SULPHATE

Details of the supplier of the safety data sheet

: ASTRAZENECA PTY LTD  
PO Box 131  
Alma Road, North Ryde  
NSW 2113  
AUSTRALIA  
+61 2 9978 3500

Emergency Telephone  
+44 (0) 1235 239 670

SafetyDataSheets.AlderleyPark@astrazeneca.com

### Alternative Names

1-(3,5-Dihydroxyphenyl)-2-t-butylaminoethanol sulphate

Also valid for:

Bricanyl turbohaler

CAS No. : 23031-32-5

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

Use of the Substance/Mixture : Pharmaceutical active:, bronchodilator, (, Beta-2-adrenoceptor agonist, )

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## SECTION 2. HAZARDS IDENTIFICATION

### GHS Classification

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 4

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Heart)

### GHS label elements

Hazard pictograms :



Signal word : Warning

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

Precautionary statements : **Prevention:**  
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
P264 Wash skin thoroughly after handling.

**Response:**  
P301 + P312 + P330 IF SWALLOWED: Call a POISON

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CENTER or doctor/ physician if you feel unwell. Rinse mouth.  
 P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.  
 P314 Get medical advice/ attention if you feel unwell.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

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

May cause trembling and increased heart rate.  
 Rare cases of cardiac arrhythmias have been reported.  
 May form explosible dust-air mixture if dispersed.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Substance

**Hazardous components**

Chemical name	CAS-No.	Concentration (% w/w)
Terbutaline sulphate	23031-32-5	>= 90 - <= 100

**SECTION 4. FIRST AID MEASURES**

If inhaled : Remove patient from exposure, keep warm and at rest. Obtain medical attention.

In case of skin contact : Take off all contaminated clothing immediately. After contact with skin, wash immediately with plenty of water. Obtain medical attention if ill effects occur.

In case of eye contact : Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.

If swallowed : Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention.

Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11  
 Harmful if swallowed or if inhaled  
 May cause damage to organs through prolonged or repeated exposure if swallowed.

Notes to physician : Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

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## SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : water spray, foam, dry powder or CO<sub>2</sub>.
- Unsuitable extinguishing media : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
- Specific hazards during firefighting : If involved in a fire, it may burn and 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.  
 Avoid dispersal of dust in the air.
- Environmental precautions : Prevent entry into drains, sewers or watercourses.
- Methods and materials for containment and cleaning up : Moisten spillages with water.  
 Transfer to a container for disposal.  
 Wash the spillage area with water.

## SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Do not breathe dust.  
 Avoid contact with skin and eyes.  
 Minimize dust generation and accumulation.  
 The material may form explosible dust-air mixture if dispersed.  
 Dust clouds are extremely sensitive to ignition by electrostatic discharge or other ignition sources. Ensure good earthing of equipment and personnel.
- Conditions for safe storage : Keep container tightly closed.  
 Store at room temperature.  
 Protect from light.

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Terbutaline sulphate	23031-32-5	TWA	0.003 mg/m <sup>3</sup>	COM; HYG

- Engineering measures** : Use appropriate controls (e.g. containment, ventilation) as specified in the workplace risk assessment to ensure that the defined occupational exposure limit is not exceeded.  
 Prevent entry into drains, sewers or watercourses.

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**Personal protective equipment**

- Respiratory protection : Use an air fed hood if the risk assessment does not support the selection of other protection.
- Eye protection : Use safety glasses to protect against direct contact with the substance if the risk assessment does not support the selection of other protection.
- Skin and body protection : Use impervious clothing to protect against direct contact with the substance if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the substance. If the substance is dissolved or wetted use a glove material that is resistant to the solvent/liquid.
- 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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- Appearance : Crystalline powder
- Colour : white to almost white
- Odour : No data available
- Odour Threshold : No data available
- pH : No data available
- Melting point/range : 250 °C  
with decomposition
- Initial boiling point and boiling range : Not applicable
- Flash point : No data available
- Evaporation rate : Not applicable
- Flammability (solid, gas) : No data available
- Upper explosion limit : No data available

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Lower explosion limit : No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Solubility(ies)  
Water solubility : Freely soluble

Solubility in other solvents : slightly soluble in:, Ethanol

Partition coefficient: n-octanol/water : log Pow: -1.29

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : No data available

Oxidizing properties : Not applicable

Molecular weight : 548.60 g/mol

Minimum ignition energy : 10 - 30 mJ  
Minimum Ignition Temperature (MIT): 500 - 550°C

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## SECTION 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.

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## SECTION 11. TOXICOLOGICAL INFORMATION

### 11.1.1 Acute toxicity

Harmful if swallowed or if inhaled



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**Components:**

**Terbutaline sulphate:**

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

**11.1.7 Reproductive toxicity**

Not classified based on available information.

**Components:**

**Terbutaline sulphate:**

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

**11.1.8 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.

**11.1.9 STOT - repeated exposure**

May cause damage to organs (Heart) through prolonged or repeated exposure if swallowed.

**Components:**

**Terbutaline sulphate:**

Exposure routes: Oral

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.

**11.1.10 Aspiration toxicity**

Not classified based on available information.

**Components:**

**Terbutaline sulphate:**

No information available.

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## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Terbutaline sulphate:**

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- 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:

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.  
Waste, even small quantities, should never be poured down drains, sewers or water courses.  
Dispose of contents/ container to an approved incineration plant.



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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.

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

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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 -

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Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; CPR - Controlled Products Regulations; 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; HYG – Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); 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; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (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; Sen – Capable of causing respiratory sensitization; Sk – Can be absorbed through skin, thus contributing to systemic effects; STEL – Short-term exposure limit 15-minutes time-weighted average; TLV – Threshold Limit Value (ACGIH); TLV-C – Threshold Limit Value Ceiling limit (ACGIH); TSCA - Toxic Substances Control Act (United States); TWA – Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

## Further information

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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