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, )

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
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terbutaline sulphate</td>
<td>23031-32-5</td>
<td>&gt;= 90 - &lt;= 100</td>
</tr>
</tbody>
</table>

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.
### SECTION 5. FIREFIGHTING MEASURES

- **Suitable extinguishing media**: water spray, foam, dry powder or CO2.
- **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/PERSOAL PROTECTION

#### Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terbutaline sulphate</td>
<td>23031-32-5</td>
<td>TWA</td>
<td>0.003 mg/m3</td>
<td>COM; HYG</td>
</tr>
</tbody>
</table>

**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.
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.

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
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

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.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1.1 Acute toxicity
Harmful if swallowed or if inhaled
SAFETY DATA SHEET

Components:
Terbutaline sulphate:
  Acute oral toxicity: LD50 Oral (Rat): 1,800 mg/kg
  Remarks: Harmful if swallowed.
  Acute inhalation toxicity: Assessment: The component/mixture is moderately toxic after short term inhalation.
  Acute dermal toxicity: Remarks: No information available.

11.1.2 Skin corrosion/irritation
Not classified based on available information.

Components:
Terbutaline sulphate:
Remarks: No information available.

11.1.3 Serious eye damage/eye irritation
Not classified based on available information.

Components:
Terbutaline sulphate:
Remarks: No information available.

11.1.4 Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Terbutaline sulphate:
Remarks: No information available.

11.1.5 Germ cell mutagenicity
Not classified based on available information.

Components:
Terbutaline sulphate:
Germ cell mutagenicity: No information available.
Assessment

11.1.6 Carcinogenicity
Not classified based on available information.
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.

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

Mobility in soil

Components:

Terbutaline sulphate:
    Mobility: Remarks: Water solubility >= 1 mg/l.
    Distribution among environmental compartments: Remarks: No information available.

Other adverse effects
No data available

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

SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

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.
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

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 -
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.