SAFETY DATA SHEET

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

Product identifier

TERBUTALINE SULPHATE

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
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Alternative Names
1-(3,5-Dihydroxyphenyl)-2-t-butylaminoethanol sulphate
Also valid for:
Bricanyl turbohaler

CAS No. : 23031-32-5
Use : Pharmaceutical active: bronchodilator (Beta-2-adrenoceptor agonist)

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification UN GHS

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'

Label elements

Signal word
Warning

Hazard statements

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

Precautionary statements

P261		Avoid breathing dust.
P264		Wash hands thoroughly after handling.
P301 + P312	:	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P304 + P340	:	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P314	:	Get medical advice/ attention if you feel unwell.
P501	:	Dispose of contents/ container to an approved incineration plant.

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance:

Components	%	CAS No.
Terbutaline sulphate		23031-32-5

4. FIRST-AID MEASURES

Description of first aid measures

Inhalation	:	Remove patient from exposure, keep warm and at rest. Obtain medical attention.
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.
Eye Contact	:	Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
Ingestion	:	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

Indication of any immediate medical attention and special treatment needed
Symptomatic treatment and supportive therapy as indicated.For further detail consult the prescribing information.

5. FIRE-FIGHTING MEASURES

Extinguishing Media (suitable)	:	water spray, foam, dry powder or CO2.
Extinguishing Media (unsuitable)	:	Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

Special hazards arising from the substance or mixture	:	If involved in a fire, it may burn and 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. Avoid dispersal of dust in the air.
Environmental Precautions	:	Prevent entry into drains, sewers or watercourses.
Methods and material for containment and cleaning up	:	Moisten spillages with water. Transfer to a container for disposal. Wash the spillage area with water.

7. HANDLING AND STORAGE

Precautions for 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, including any incompatibilities	:	Keep container tightly closed. Store at room temperature. Protect from light.
Specific end use(s)	:	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/m3	LTEL 8hr TWA	COM, HYG

Exposure Controls
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.

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.

Respiratory protection
Use an air fed hood if the risk assessment does not support the selection of other protection.

Skin 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form	:	Crystalline powder
Colour	:	white to almost white
Molecular Weight	:	548,60 g/mol
Molecular Formula	:	(C12H19NO3)2.H2SO4
Melting Point	:	250 °C with decomposition
Minimum Ignition Energy	:	10 - 30 mJ
Solubility (Water)	:	Freely soluble
Solubility (Other)	:	slightly soluble in:, Ethanol
Partition Coefficient (Log Pow)	:	-1,29

Other information

Minimum ignition temperature	:	500 - 550 °C
Dissociation constant (pKa):	:	8,8
	:	10,1
	:	11,2

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

Inhalation	:	Harmful if inhaled.
Skin Contact	:	No information available.
Eye Contact	:	No information available.
Ingestion	:	Harmful if swallowed. LD50 Oral Rat 1.800 mg/kg
Specific Target Organ Toxicity (STOT)	:	**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. **Repeated exposure** Exposure routes: Oral Target Organs: Heart May cause damage to organs through prolonged or repeated exposure. These effects are derived from studies in animals.
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

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. 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.

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:
8. New Occupational Exposure Limit Value

Minor changes:, 13

GLOSSARY

COM	:	In-house occupational exposure limit
LTEL	:	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.