

SAFETY DATA SHEET



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

Product identifier

'SYMBICORT' pMDI

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

'Vannair' pMDI
'Rapihaler' pMDI
'Frévia' pMDI

CAS No. : Not applicable
Use : Treatment of asthma

2. HAZARDS IDENTIFICATION

SUSPENSION IN DELIVERY DEVICE: The risk to health in normal handling of the inhaler is expected to be low. Exposure to the content of crushed container may cause adverse health effects. May produce an allergic reaction.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

Component	%	CAS No.			
Formoterol fumarate dihydrate	0,007	43229-80-7			
		Hazard class #	Category	Hazard statements #	
		Acute toxicity	4	H332	
		Specific target organ toxicity - single exposure	1	H370	
		Specific target organ toxicity - repeated exposure	1	H372	
		Acute aquatic toxicity	3	H402	
		Chronic aquatic toxicity	3	H412	
Component	%	CAS No.			
Budesonide	0,06 - 0,243	51333-22-3			
		Hazard class #	Category	Hazard statements #	
		Acute toxicity	4	H302	
		Skin sensitisation	1	H317	
		Reproductive toxicity	2	H361	
		Specific target organ toxicity - repeated exposure	1	H372	
		Acute aquatic toxicity	3	H402	
	Chronic aquatic toxicity	3	H412		
Component	%	CAS No.			
1,1,1,2,3,3,3-heptafluoropropane (HFC 227)	>98 -	431-89-0			
			Hazard class #	Category	Hazard statements #
			Gases under pressure	Liquefied gas	H280

Refer to Section 16 'Other Information'

4. FIRST-AID MEASURES

Description of first aid measures

- Inhalation : Remove patient from exposure, keep warm and at rest. Obtain medical attention.
- Skin Contact : Remove contaminated clothing. Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention.
- Eye Contact : 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. 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. Water spray should be used to cool containers.
- Extinguishing Media (unsuitable) : -
- Special hazards arising from the substance or mixture : Thermal decomposition will evolve toxic and corrosive vapours. Heating of containers may cause pressure rise with risk of explosion.
- Special protective actions for fire-fighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.

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

7. HANDLING AND STORAGE

- Precautions for safe handling : Avoid contact with skin and eyes. Liquid splashes or spray may cause freeze burns to skin and eyes.
- Conditions for safe storage, including any incompatibilities : Keep in a cool, well ventilated place.
- 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
Formoterol fumarate dihydrate	0,0002 mg/m ³	LTEL 8hr TWA	COM, HYG
Budesonide	0,01 mg/m ³	LTEL 8hr TWA	COM, HYG, Sk

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.

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 a self-contained breathing apparatus if the risk assessment does not support the selection of other protection.

Skin protection

Impervious gloves

Eye protection

Use goggles or visor to protect against direct contact with the liquid 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 : liquid
 Colour : colourless
 Odour : odourless

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 : Stable under normal conditions. Keep away from heat and sources of ignition.
 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 : May cause effects as described under single exposure.(STOT)

Skin Contact : Spray may cause freeze burns.

Eye Contact : Spray may cause freeze burns.

Ingestion : Low acute oral toxicity.

Specific Target Organ Toxicity (STOT) : **Single exposure**
 Exposure routes: Inhalation
 Target Organs: Heart
 May cause palpitation, trembling, headache and widening of the bronchii., Rare cases of hypersensitivity reactions have been reported., May cause Candida infections and mild irritation in the throat, coughing and hoarseness.

Repeated exposure
 Exposure routes: Inhalation, Dermal, Oral
 Prolonged overexposure may cause symptoms such as weakness, muscle aches, nausea and vomiting.
 Exposure routes: Inhalation
 Target Organs: Heart
 Tachycardia and musculoskeletal and connective tissue disorders and muscle cramps have been reported., Common side effects reported from patients include palpitations, headache and tremor.

- Sensitisation : May produce an allergic reaction.
- Carcinogenicity : The substance is not considered to be carcinogenic.
- Mutagenicity : There is no evidence of genotoxic potential in in vitro and in vivo tests.
- Reproductive toxicity : Studies in animals have shown that low doses produce teratogenic effects.

12. ECOLOGICAL INFORMATION

No information on this preparation. The following information refers to active ingredient: Harmful to aquatic life with long lasting effects.

- Toxicity : Budesonide: ErC50 green algae 72 H > 8,6 mg/l
 NOEC green algae 72 H 5,6 mg/l
 Formoterol fumarate dihydrate: EbC50 green algae 72 H 46 mg/l
 ErC50 green algae 72 H 94 mg/l
 NOEC green algae 72 H 15 mg/l
 Budesonide: EC50 Daphnia magna 48 H 14 mg/l
 NOEC Daphnia magna 48 H 3,8 mg/l
 Formoterol fumarate dihydrate: EC50 Daphnia magna 48 H 114 mg/l
 NOEC Daphnia magna 48 H 55 mg/l
 Budesonide: LC50 Rainbow trout 96 H > 13 mg/l
 NOEC Rainbow trout 96 H > 13 mg/l
 Formoterol fumarate dihydrate: LC50 Zebra Fish 96 H > 120 mg/l
 NOEC Rainbow trout 96 H 120 mg/l
- 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 \geq 1 mg/l.
- Other adverse effects : HFC 227:
 Does not deplete ozone.
 The substance has a green house warming potential (GWP) of 0.5 measured against a standard GWP of 1 for CFC11.

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

RESTRICTED FOR TRANSPORT

ICAO/IATA

UN No. : 1950
 Proper Shipping Name : Aerosols, non-flammable
 Class : 2.2

IMO/IMDG

UN No. : 1950
 Proper Shipping Name : AEROSOLS
 Class : 2.2
 Marine pollutant : Not classified as a Marine Pollutant

ADR

UN No. : 1950
 Proper Shipping Name : AEROSOLS
 Class : 2
 Label(s) : 2.2

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Hazard statements : H280 : Contains gas under pressure; may explode if heated.
 H302 : Harmful if swallowed.
 H317 : May cause an allergic skin reaction.
 H332 : Harmful if inhaled.
 H361d : Suspected of damaging the unborn child.
 H370 : Causes damage to organs.
 H372 : Causes damage to organs through prolonged or repeated exposure.
 H412 : Harmful to aquatic life with long lasting effects.

The following sections contain revisions or new statements :

Minor changes:., 3, 16

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.