Version	Revision Date:	SDS Number:	Date of last issue: 26.03.2019
5.1	07.04.2020	2959	Date of first issue: 23.05.2018

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

'SYMBICORT' pMDI

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
PO Box 131
66 Talavera Rd, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names
'Vannair' pMDI
'Rapihaler' pMDI
'Frévia' pMDI
CAS No. : Not applicable

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

Use of the Substance/Mixture : Treatment of asthma

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Gases under pressure : Liquefied gas

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H280 Contains gas under pressure; may explode if heated.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P273 Avoid release to the environment.

Response:

P391 Collect spillage.

Disposal:

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

Other hazards which do not result in classification

SUSPENSION IN DELIVERY DEVICE:
As a result of the physical presentation of the product, the risk to health in the normal handling of the product is expected to be low.
Exposure to the content of crushed container may cause adverse health effects.
Liquid splashes or spray may cause freeze burns to skin and eyes.
High exposures by inhalation may produce anaesthetic effects.
Higher concentrations may cause asphyxiation due to the reduced oxygen content of the atmosphere.
Can be absorbed through skin causing systemic toxic effects.
See Section 11.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
1,1,1,2,3,3,3-heptafluoropropane (HFC 227)	431-89-0	98 -100
Budesonide	51333-22-3	0.06 -0.243
Formoterol fumarate dihydrate	43229-80-7	0.007

SECTION 4. FIRST AID MEASURES

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

In case of skin contact : Thaw affected areas with water.
Remove contaminated clothing.
Caution: clothing may adhere to the skin in the case of freeze burns
After contact with skin, wash immediately with plenty of warm 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 immediate medical attention.

If swallowed : Unlikely route of exposure.
Wash out mouth with water and give 200-300ml of water to drink.
Do NOT induce vomiting.
Obtain immediate medical attention.

Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11

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.

Water spray should be used to cool containers.

Unsuitable extinguishing media	:	Do not use water jet.
Specific hazards during firefighting	:	Thermal decomposition will evolve toxic and corrosive vapours. Heating of containers may cause pressure rise with risk of explosion.
Special protective equipment for firefighters	:	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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Ensure adequate ventilation. Do not breathe vapour. Ensure suitable personal protection during removal of spillages. See Section 8.
Environmental precautions	:	Avoid release of gas to the environment. Collect spillage.
Methods and materials for containment and cleaning up	:	Isolate the source of the leak if safe to do so. Ventilate area. Allow small spillages to evaporate provided there is adequate ventilation. Take care to avoid broken containers. Transfer spilled containers to a suitable container for disposal. See section 13.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling	:	Avoid contact with skin and eyes. Avoid inhalation. Liquid splashes or spray may cause freeze burns to skin and eyes. See Section 8. Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use.
Conditions for safe storage	:	Keep container tightly closed in a dry and well-ventilated place. Do not freeze. Keep away from heat and direct sunlight. Store away from incompatible materials (see Section 10).
Recommended storage temperature	:	< 25 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Budesonide	51333-22-3	TWA	0.01 mg/m3	COM; HYG; Sk
Formoterol fumarate dihydrate	43229-80-7	TWA	0.0002 mg/m3	COM; HYG

Engineering measures : 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, sewers or watercourses.
See Section 6 for environmental precautions.

Personal protective equipment

Respiratory protection : If needed, use suitable respiratory equipment.

Eye protection : Wear appropriate eye protection.

Skin and body protection : Wear appropriate protective clothing and gloves.

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 : Liquefied gas

Colour : colourless

Odour : odourless

Odour Threshold : No data available

pH	:	No data available
Melting point/range	:	No data available
Initial boiling point and boiling range	:	-16.5 °C
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	The product is not flammable.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	390 hPa (20 °C)
Relative vapour density	:	No data available
Relative density	:	1.41 (25 °C)
Solubility(ies)		
Water solubility	:	0.23 g/l (25 °C)
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	log Pow: 2.3
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No known reactivity hazard under normal conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidising agents alkali metals

alkaline earth metals

Conditions to avoid	:	Contains gas under pressure; may explode if heated.
Incompatible materials	:	Light metals Alkali metals Alkaline earth metals Powdered metals Oxidizing agents
Hazardous decomposition products	:	Hydrogen fluoride

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Acute oral toxicity	:	Remarks: Low acute oral toxicity.
Acute inhalation toxicity	:	Remarks: High atmospheric concentrations may lead to anaesthetic effects.
Acute dermal toxicity	:	Remarks: Spray may cause freeze burns.

Budesonide:

Acute oral toxicity	:	LD50 Oral (Rat): 400 mg/kg Assessment: The component/mixture is moderately toxic after single ingestion.
Acute inhalation toxicity	:	Remarks: May cause effects as described under single exposure.(STOT)
Acute dermal toxicity	:	Remarks: Can be absorbed through skin causing systemic toxic effects.

Formoterol fumarate dihydrate:

Acute oral toxicity	:	Remarks: May cause effects as described under single exposure.(STOT)
Acute inhalation toxicity	:	LC50 (Rat): 1.35 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	Remarks: No information available.

11.2 Skin corrosion/irritation

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Remarks : Spray may cause freeze burns.

Budesonide:

Remarks : May cause slight skin irritation.

Formoterol fumarate dihydrate:

Remarks : No information available.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Remarks : Spray may cause freeze burns.

Budesonide:

Remarks : May cause slight eye irritation.
May cause corneal ulcers and reduced visual function.
May cause cataracts and viral infection.

Formoterol fumarate dihydrate:

Remarks : No information available.

11.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Remarks : No information available.

Budesonide:

Result : May cause sensitisation by skin contact.

Formoterol fumarate dihydrate:

Remarks : No information available.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Germ cell mutagenicity - Assessment : There is no evidence of mutagenic potential in in vitro tests.

Budesonide:

Germ cell mutagenicity - Assessment : There is no evidence of genotoxic potential in in vitro and in vivo tests.

Formoterol fumarate dihydrate:

Germ cell mutagenicity - Assessment : There is no evidence of genotoxic potential in in vitro and in vivo tests.

11.6 Carcinogenicity

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Carcinogenicity - Assessment : No information available.

Budesonide:

Carcinogenicity - Assessment : No evidence of carcinogenicity in animal studies.

Formoterol fumarate dihydrate:

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

11.7 Reproductive toxicity

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Reproductive toxicity - Assessment : No toxicity to reproduction

Budesonide:

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

Formoterol fumarate dihydrate:

Reproductive toxicity - Assessment : Some embryofetal development effects in rats and rabbits at high doses.

11.8 STOT - single exposure

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Remarks : No specific effects reported.

Budesonide:

Exposure routes : Inhalation
Remarks : May cause Candida infections and mild irritation in the throat, coughing and hoarseness.
May cause effects as described under repeated exposure.(STOT)

Exposure routes : Dermal
Remarks : May cause eruption-like acne.
May cause effects as described under repeated exposure.(STOT)

Formoterol fumarate dihydrate:

Exposure routes : inhalation (dust/mist/fume)
Target Organs : Heart
Assessment : Causes damage to organs.

Exposure routes : Oral
Target Organs : Heart
Assessment : Causes damage to organs.

Remarks : These effects are derived from studies in animals.
Dust, if inhaled even in small amounts, can cause violent palpitation, trembling, headache and widening of the bronchii.
Rare cases of hypersensitivity reactions have been reported.

11.9 STOT - repeated exposure

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Remarks : No information available.

Budesonide:

Exposure routes : inhalation (dust/mist/fume)
Target Organs : Adrenal gland
Assessment : Causes damage to organs through prolonged or repeated exposure.

Exposure routes : Oral
Target Organs : Adrenal gland
Assessment : Causes damage to organs through prolonged or repeated exposure.

Exposure routes : Dermal
Target Organs : Adrenal gland
Assessment : Causes damage to organs through prolonged or repeated exposure.

Remarks : Repeated exposure may produce oedema (water retention), high blood pressure, blurred vision, peptic ulcers, demineralization of bone, fatigue and suppression of adrenal gland function.

Formoterol fumarate dihydrate:

Exposure routes : inhalation (dust/mist/fume)
Target Organs : Heart
Assessment : Causes damage to organs through prolonged or repeated exposure.

Exposure routes : Oral
Target Organs : Heart
Assessment : Causes damage to organs through prolonged or repeated exposure.

Remarks : Tachycardia and musculoskeletal and connective tissue disorders and muscle cramps have been reported. Common side effects reported from patients include palpitations, headache and tremor.

11.10 Aspiration toxicity

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

No information available.

Budesonide:

No data available

Formoterol fumarate dihydrate:

No information available.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Budesonide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 13 mg/l
End point: mortality
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 14 mg/l
End point: Immobilization
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants	:	EC50 (green algae): > 7.9 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (green algae): 7.9 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): 0.000032 mg/l End point: mortality Exposure time: 28 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 3.4 mg/l Exposure time: 21 d Test Type: Reproduction Test Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1,000
Toxicity to microorganisms	:	EC50 (activated sludge): > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Formoterol fumarate dihydrate:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 120 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 114 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Selenastrum capricornutum (green algae)): 94 mg/l Exposure time: 72 h Test Type: Growth inhibition Method: OECD Test Guideline 201

Persistence and degradability

Components:

Budesonide:

Biodegradability	:	aerobic Biodegradation: < 5 % Exposure time: 28 d Method: OECD Test Guideline 301F Result: not rapidly degradable
BOD/ThOD	:	< 50 %

Formoterol fumarate dihydrate:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 20.5 %
Exposure time: 28 d

Bioaccumulative potential

Components:

Budesonide:

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

Formoterol fumarate dihydrate:

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

Mobility in soil

Components:

Budesonide:

Mobility : Remarks: Water solubility >= 1 mg/l.

Distribution among environmental compartments : Remarks: No information available.

Formoterol fumarate dihydrate:

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

International Air Transport (IATA Requirements): See IATA Special Provision A98. International Maritime Transport (IMDG Requirements): See IMDG Special Provision 190. European Ground Transport (ADR/RID Requirements): See ADR Special Provision 190.

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	:	Marine pollutant

ADR

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

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.

Standard for the Uniform Scheduling of Medicines and Poisons	:	No poison schedule number allocated
Prohibition/Licensing Requirements	:	There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.
Montreal Protocol (Ozone Depleting Substances)	:	1,1,1,2,3,3,3-heptafluoropropane (HFC 227)

The components of this product are reported in the following inventories:

TCSI	:	Not listed
TSCA	:	Substance(s) not listed on TSCA inventory
AICS	:	Not listed
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Formoterol fumarate dihydrate Budesonide
ENCS	:	Not listed
ISHL	:	Not listed
KECI	:	Not listed
IECSC	:	Not listed
CHINV	:	Not in compliance with the inventory
REACH	:	Not in compliance with the inventory
TRINV	:	Not in compliance with the inventory

SECTION 16. OTHER INFORMATION

Further information

Revision Date	:	07.04.2020
Other information	:	Minor changes: 15
Date format	:	dd.mm.yyyy

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; CHINV - China Inventory; CMR - 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); TRINV - Turkey Inventory; 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

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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