Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10.07.2017	23490	Date of first issue: 10.07.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

ALVESCO INHALER

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

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names
Ciclesonide MDI
CAS No. : Not applicable

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

Use of the Substance/Mixture : Corticosteroid for the treatment of asthma and allergic rhinitis.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Gases under pressure : Liquefied gas

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H280 Contains gas under pressure; may explode if heated.

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 or failed inhaler 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)

1,1,1,2-tetrafluoroethane (HFA 134a)	811-97-2	>= 90 - <= 100
Ethanol	64-17-5	>= 1 - < 10
Ciclesonide	126544-47-6	>= 0.1 - < 1

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 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 as a First-Aid measure. 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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions,	:	Ensure suitable personal protection during removal of

protective equipment and emergency procedures : spillages.
Ensure adequate ventilation.
Do not breathe vapour.

Environmental precautions : Avoid release of gas to the environment.

Methods and materials for containment and cleaning up : Isolate the source of the leak if safe to do so.
Allow small spillages to evaporate provided there is adequate ventilation.
Ventilate area.
Transfer spilled containers to a suitable container for disposal.
Take care to avoid broken containers.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Avoid contact with skin and eyes.
Avoid inhalation.
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.
Keep in a cool, well ventilated place.
Keep away from heat and direct sunlight.
Store away from incompatible materials (see Section 10).

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
1,1,1,2-tetrafluoroethane (HFA 134a)	811-97-2	TWA	1,000 ppm 4,240 mg/m3	AU OEL
Ethanol	64-17-5	TWA	1,000 ppm 1,880 mg/m3	AU OEL
		STEL	1,000 ppm	ACGIH
Ciclesonide	126544-47-6	TWA	0.001 mg/m3	COM

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.

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	:	Aerosol containing a liquefied gas
Colour	:	clear, colourless
Odour	:	slight, ethereal
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	Not applicable
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	The product is not flammable.
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available

Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	Not applicable

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 violently if in contact with alkali metals and alkaline earth metals - sodium, potassium and barium.
Conditions to avoid	:	Contains gas under pressure; may explode if heated. Avoid heat, flames, sparks and other sources of ignition.
Incompatible materials	:	Strong acids and strong bases Strong oxidizing agents finely divided metals
Hazardous decomposition products	:	hydrogen fluoride by thermal decomposition and hydrolysis.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1.1 Acute toxicity

Not classified based on available information.

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

Acute oral toxicity	:	Remarks: No information available.
Acute inhalation toxicity	:	LC50 (Rat): 1,500 mg/l Exposure time: 4 H
Acute dermal toxicity	:	Remarks: No information available.

Ethanol:

Acute oral toxicity	:	Remarks: No information available.
Acute inhalation toxicity	:	Remarks: May cause effects as described under single exposure.(STOT)

Acute dermal toxicity : Remarks: Unlikely to be hazardous by skin absorption.

Ciclesonide:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Acute inhalation toxicity : Remarks: No information available.

Acute dermal toxicity : Remarks: No information available.

11.1.2 Skin corrosion/irritation

Not classified based on available information.

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

Remarks: May cause slight skin irritation.
Spray may cause freeze burns.

Ethanol:

Remarks: Slight/mild irritant.
Prolonged or frequent contact may cause defatting of the skin resulting in redness, irritation and dermatitis.

Ciclesonide:

Remarks: No information available.

11.1.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

Remarks: May cause slight eye irritation.
Spray may cause freeze burns.

Ethanol:

Remarks: The vapour and liquid are irritant.
May cause strong stinging and burning sensation.

Ciclesonide:

Remarks: Unlikely to cause eye irritation.

11.1.4 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-tetrafluoroethane (HFA 134a):

Remarks: Unlikely to cause skin sensitisation.

Ethanol:

Remarks: No information available.

Ciclesonide:

Remarks: It is not a skin sensitiser in vivo.
Unlikely to cause skin sensitisation.

11.1.5 Germ cell mutagenicity

Not classified based on available information.

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

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

Ethanol:

Germ cell mutagenicity - Assessment : No information available.

Ciclesonide:

Germ cell mutagenicity - Assessment : The substance is not considered to be genotoxic.

11.1.6 Carcinogenicity

Not classified based on available information.

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

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

Ethanol:

Carcinogenicity - Assessment : No information available.

Ciclesonide:

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

11.1.7 Reproductive toxicity

Not classified based on available information.

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

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

Ethanol:

Reproductive toxicity - Assessment : No information available.

Ciclesonide:

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

11.1.8 STOT - single exposure

Not classified based on available information.

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

Exposure routes: Inhalation
Remarks: May cause irritation to the respiratory system.
High exposures by inhalation may produce anaesthetic effects.
Higher concentrations may cause asphyxiation due to the reduced oxygen content of the atmosphere.

Ethanol:

Exposure routes: Inhalation, Ingestion
Remarks: The vapour has anaesthetic properties and when inhaled at high concentrations, it may cause respiratory irritation, headache, fatigue, dizziness and incoordination.
Minute amounts aspirated into the lungs during ingestion may cause pulmonary injury.

Ciclesonide:

Remarks: May cause coughing and hoarseness.

11.1.9 STOT - repeated exposure

Not classified based on available information.

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

Remarks: No information available.

Ethanol:

Exposure routes: Inhalation
Target Organs: Liver
Remarks: Repeated exposure to high levels may produce adverse effects on the liver.

Ciclesonide:

Remarks: May cause adverse effects related to glucocorticoid activity such as: suppression of

serum cortisol levels, effects on thymus, spleen, adrenal glands, lymphoid tissues and blood forming tissues with change in hematology.

11.1.10 Aspiration toxicity

Not classified based on available information.

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

No information available.

Ethanol:

No data available

Ciclesonide:

No information available.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

Toxicity to fish	:	(Oncorhynchus mykiss (rainbow trout)): 450 mg/l Exposure time: 96 H Test Type: LC50
Toxicity to daphnia and other aquatic invertebrates	:	(Daphnia magna (Water flea)): 980 mg/l Exposure time: 48 H Test Type: EC50

Ethanol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 13,500 - 14,900 mg/l Exposure time: 96 H LC50 (Danio rerio (zebra fish)): 14,200 mg/l Exposure time: 96 H
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 9,200 - 14,900 mg/l Exposure time: 48 H Test Type: static test

Ciclesonide:

Toxicity to fish	:	Remarks: The substance showed no toxicity to fish at the solubility limit.
Toxicity to daphnia and other aquatic invertebrates	:	Remarks: No toxicity at the limit of solubility

Persistence and degradability

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

Biodegradability : Remarks: Not readily biodegradable.

Ethanol:

Biodegradability : Remarks: The substance is substantially biodegradable in water.
There is evidence of photodegradation in air.

Ciclesonide:

Biodegradability : Remarks: Not readily biodegradable.

Bioaccumulative potential

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

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

Ethanol:

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

Ciclesonide:

Bioaccumulation : Remarks: No information available.

Mobility in soil

Components:

1,1,1,2-tetrafluoroethane (HFA 134a):

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

Distribution among environmental compartments : Remarks: The product evaporates readily.

Ethanol:

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

Distribution among environmental compartments : Remarks: The substance has a photochemical ozone creation potential.

Ciclesonide:

Mobility : Remarks: No information available.

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

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

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.
Ciclesonide		126544-47-6
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 - 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

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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