Version	Revision Date:	SDS Number:	Date of last issue: -
4.0	29.08.2017	20321	Date of first issue: 29.08.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

SYMBICORT MIXTURE FOR TURBUHALER

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
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Alternative Names
Budesonide/formoterol mixture with lactose
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 and COPD

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral)	:	Category 4
Skin sensitisation	:	Category 1
Reproductive toxicity	:	Category 2
Specific target organ toxicity - single exposure (Inhalation)	:	Category 2 (Heart)
Specific target organ toxicity - repeated exposure (Inhalation)	:	Category 1 (Adrenal gland)
Specific target organ toxicity - repeated exposure (Inhalation)	:	Category 2 (Heart)
Acute aquatic toxicity	:	Category 3
Chronic aquatic toxicity	:	Category 3

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H361 Suspected of damaging fertility or the unborn child.
H371 May cause damage to organs (Heart) if inhaled.
H372 Causes damage to organs (Adrenal gland) through prolonged or repeated exposure if inhaled.
H373 May cause damage to organs (Heart) through prolonged or repeated exposure if inhaled.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P281 Use personal protective equipment as required.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

Disposal:

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

Other hazards which do not result in classification

Can be absorbed through skin causing systemic toxic effects.
May cause palpitation, trembling, headache and widening of the bronchii.
May form explosible dust-air mixture if dispersed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Budesonide	51333-22-3	>= 30 - < 40
Formoterol fumarate dihydrate	43229-80-7	>= 1 - < 10

SECTION 4. FIRST AID MEASURES

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

Obtain medical attention.

In case of skin contact	:	Remove contaminated clothing. Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention.
In case of eye contact	:	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. May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child. May cause damage to organs if inhaled. Causes damage to organs through prolonged or repeated exposure if inhaled.
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	:	Thermal decomposition will evolve toxic and corrosive vapours.
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 suitable personal protection during removal of spillages. Avoid dispersal of dust in the air.
Environmental precautions	:	Prevent entry into drains, sewers or watercourses. Collect spillage.
Methods and materials for containment and cleaning up	:	Moisten spillages with water. Transfer to a container for disposal. Wash the spillage area with water.

Avoid release to the environment.

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 may be extremely sensitive to ignition by electrostatic discharge and other ignition sources. Ensure good earthing of equipment and personnel.

Conditions for safe storage : Keep container tightly closed.

Recommended storage temperature : < 30 °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.
See Section 6 for environmental precautions.

Personal protective equipment

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

Eye protection : Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

Skin and body protection : Use full chemical protective suit to protect against direct contact with the product if the risk assessment does not support the selection of other protection. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid. Take note of the information given by the PPE producer/supplier concerning permeability and

breakthrough times and special workplace conditions.

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.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	white to almost white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
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 : 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 : No data available

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 : 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.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,026 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 H
Test atmosphere: dust/mist
Method: Calculation method

Components:

Budesonide:

Acute oral toxicity : LD50 Oral (Rat): 400 mg/kg
Remarks: Harmful if swallowed.

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: Low acute oral toxicity.

Acute inhalation toxicity : LC50 (Rat): 1.35 mg/l
Exposure time: 4 H

Acute dermal toxicity : Remarks: No information available.

11.1.2 Skin corrosion/irritation

Not classified based on available information.

Components:

Budesonide:

Remarks: May cause slight skin irritation.

Formoterol fumarate dihydrate:

Remarks: No information available.

11.1.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

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.

11.1.4 Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Budesonide:

Result: May cause sensitisation by skin contact.

Formoterol fumarate dihydrate:

Remarks: No information available.

11.1.5 Germ cell mutagenicity

Not classified based on available information.

Components:

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.

11.1.6 Carcinogenicity

Not classified based on available information.

Components:

Budesonide:

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

Formoterol fumarate dihydrate:

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

11.1.7 Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Components:

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.

11.1.8 STOT - single exposure

May cause damage to organs (Heart) if inhaled.

Components:

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.

11.1.9 STOT - repeated exposure

Causes damage to organs (Adrenal gland) through prolonged or repeated exposure if inhaled.
May cause damage to organs (Heart) through prolonged or repeated exposure if inhaled.

Components:

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.

11.1.10 Aspiration toxicity

Not classified based on available information.

Components:

Budesonide:

No data available

Formoterol fumarate dihydrate:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Budesonide:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 13 mg/l Exposure time: 96 H Remarks: (OECD 203) NOEC (Oncorhynchus mykiss (rainbow trout)): 13 mg/l Exposure time: 96 H
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 14 mg/l Exposure time: 48 H Remarks: (OECD 202) NOEC (Daphnia magna (Water flea)): 3.8 mg/l Exposure time: 48 H
Toxicity to algae	:	NOEC (green algae): 5.6 mg/l Exposure time: 72 H

Formoterol fumarate dihydrate:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 120 mg/l Exposure time: 96 H Method: OECD Test Guideline 203 NOEC (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

NOEC (Daphnia magna (Water flea)): 55 mg/l
Exposure time: 48 H
Method: OECD Test Guideline 202

Toxicity to algae : ErC50 (Selenastrum capricornutum (green algae)): 94 mg/l
Exposure time: 72 H
Method: OECD Test Guideline 201

Persistence and degradability

Components:

Budesonide:

Biodegradability : Result: not rapidly degradable

BOD/ThOD : < 50 %

Formoterol fumarate dihydrate:

Biodegradability : Remarks: Not rapidly degradable.

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

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.

Budesonide	51333-22-3
Formoterol fumarate dihydrate	43229-80-7

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

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.