

Version 4.0 Revision Date: 27.03.2019 SDS Number: 13393 Date of last issue: 19.09.2017
Date of first issue: 19.09.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

OXIS MIXTURE FOR TURBUHALER

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD Emergency Telephone
PO Box 131 +44 (0) 1235 239 670
66 Talavera Rd, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

Formoterol fumarate dihydrate 0.5-1% in lactose
CAS No. : Not applicable

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

Use of the Substance/Mixture : bronchodilator

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Specific target organ toxicity - single exposure : Category 2

Specific target organ toxicity - repeated exposure : Category 2

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H371 May cause damage to organs.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements : **Prevention:**
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
Response:
P309 + P311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/ physician.
P314 Get medical advice/ attention if you feel unwell.
Disposal:
P501 Dispose of contents/ container to an approved waste

Version 4.0 Revision Date: 27.03.2019 SDS Number: 13393 Date of last issue: 19.09.2017
 Date of first issue: 19.09.2017

disposal plant.

Other hazards which do not result in classification

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

Components

Chemical name	CAS-No.	Concentration (% w/w)
Formoterol fumarate dihydrate	43229-80-7	0.5 -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 : 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
 May cause damage to organs.
 May cause damage to organs through prolonged or repeated exposure.
- 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 : If involved in a fire, it may burn and emit noxious and toxic fumes.
- Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

Version 4.0 Revision Date: 27.03.2019 SDS Number: 13393 Date of last issue: 19.09.2017
 Date of first issue: 19.09.2017

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

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
Formoterol fumarate dihydrate	43229-80-7	TWA	0.0002 mg/m ³	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.

Personal protective equipment

- Respiratory protection : Use an air fed hood 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 impervious clothing to protect against direct contact with

Version	Revision Date:	SDS Number:	Date of last issue: 19.09.2017
4.0	27.03.2019	13393	Date of first issue: 19.09.2017

the product if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

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	: No data available
Odour	: odourless
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 / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: Not applicable

SAFETY DATA SHEET



Version 4.0 Revision Date: 27.03.2019 SDS Number: 13393 Date of last issue: 19.09.2017
Date of first issue: 19.09.2017

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 Acute toxicity

Not classified based on available information.

Product:

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

Components:

Formoterol fumarate dihydrate:

Acute oral toxicity : Remarks: May cause effects as described under single

Version 4.0 Revision Date: 27.03.2019 SDS Number: 13393 Date of last issue: 19.09.2017
Date of first issue: 19.09.2017

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:

Formoterol fumarate dihydrate:

Remarks : No information available.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

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:

Formoterol fumarate dihydrate:

Remarks : No information available.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Components:

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:

Formoterol fumarate dihydrate:

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

Version Revision Date: SDS Number: Date of last issue: 19.09.2017
4.0 27.03.2019 13393 Date of first issue: 19.09.2017

11.7 Reproductive toxicity

Not classified based on available information.

Components:

Formoterol fumarate dihydrate:

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

11.8 STOT - single exposure

May cause damage to organs.

Components:

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

May cause damage to organs through prolonged or repeated exposure.

Components:

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:

Formoterol fumarate dihydrate:

No information available.

Version 4.0 Revision Date: 27.03.2019 SDS Number: 13393 Date of last issue: 19.09.2017
Date of first issue: 19.09.2017

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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 : 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:

Formoterol fumarate dihydrate:

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

Bioaccumulative potential

Components:

Formoterol fumarate dihydrate:

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

Mobility in soil

Components:

Formoterol fumarate dihydrate:

- Mobility : Remarks: Water solubility \geq 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

Version 4.0 Revision Date: 27.03.2019 SDS Number: 13393 Date of last issue: 19.09.2017
Date of first issue: 19.09.2017

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.

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.

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

REACH : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Formoterol fumarate dihydrate

AICS : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

SAFETY DATA SHEET



Version	Revision Date:	SDS Number:	Date of last issue: 19.09.2017
4.0	27.03.2019	13393	Date of first issue: 19.09.2017

TCSI : Not in compliance with the inventory

TSCA : Not On TSCA Inventory

SECTION 16. OTHER INFORMATION

Further information

Revision Date : 27.03.2019

Other information : Full Review - minor changes
3
11
12
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; 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

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

SAFETY DATA SHEET



Version	Revision Date:	SDS Number:	Date of last issue: 19.09.2017
4.0	27.03.2019	13393	Date of first issue: 19.09.2017

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.

AU / EN