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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

BUDESONIDE

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

Emergency Telephone
+44 (0) 1235 239 670

SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

Budesonide micronised
22RS 16 alpha,17 alpha-Butylidenedioxypregna-1,4-diene-11 beta,21-diol-3,20-dione
Also valid for:
Pulmicort Turbuhaler
Rhinocort Turbuhaler
CAS No. : 51333-22-3

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

Use of the Substance/Mixture : Pharmaceutical active:, corticosteroid anti-inflammatory agent

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 4
Skin sensitisation : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure (Inhalation) : Category 1 (Adrenal gland)
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.

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H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs (Adrenal gland) 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.
Low Minimum Ignition Energy (MIE) - potential risk of explosion in the presence of ignition source.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Budesonide	51333-22-3	>= 90 - <= 100

SECTION 4. FIRST AID MEASURES

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

In case of skin contact : Take off immediately all contaminated clothing. After contact with skin, wash immediately with plenty of water. Obtain medical attention.

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- 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 : 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.
Causes damage to organs through prolonged or repeated exposure if inhaled.
- Notes to physician : Symptomatic treatment and supportive therapy as indicated. For further information consult the prescribing information.
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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.
Combustion propagates by burning with flame.
Not classified as flammable.
- 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 : Avoid contact with skin and eyes.
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Avoid breathing dust.
 Wear protective gloves.
 See Section 8.
 Minimize dust generation and accumulation.
 The material may form explosible dust-air mixture if dispersed.
 Dust clouds are extremely sensitive to ignition by electrostatic discharge or other ignition sources. Ensure good earthing of equipment and personnel.

Conditions for safe storage : Keep container tightly closed.
 Protect from light.
 Store at room temperature.

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/m ³	COM; HYG; Sk

Engineering measures : Use appropriate controls (e.g. containment, ventilation) as specified in the workplace risk assessment to ensure that the defined occupational exposure limit is not exceeded.
 Prevent entry into drains, sewers or watercourses.
 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 substance 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 substance if the risk assessment does not support the selection of other protection. If the substance 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,

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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	:	Crystalline powder
Colour	:	white to almost white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	224.0 - 231.5 °C with decomposition
Initial boiling point and boiling range	:	Not applicable
Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	Not classified as a flammability hazard
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	:	0.014 g/l practically insoluble
Solubility in other solvents	:	Freely soluble in:, Chloroform sparingly soluble in:, Ethanol practically insoluble in:, heptane
Partition coefficient: n-octanol/water	:	log Pow: 3.3

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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

Molecular weight : 430.50 g/mol

Minimum ignition energy : 1 - 3 mJ
Minimum Ignition Temperature (MIT): 450 - 500°C

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.

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.

11.1.2 Skin corrosion/irritation

Not classified based on available information.

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Components:

Budesonide:

Remarks: May cause slight skin irritation.

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.

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.

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.

11.1.6 Carcinogenicity

Not classified based on available information.

Components:

Budesonide:

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

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.

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11.1.8 STOT - single exposure

Not classified based on available information.

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)

11.1.9 STOT - repeated exposure

Causes damage to organs (Adrenal gland) 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.

11.1.10 Aspiration toxicity

Not classified based on available information.

Components:

Budesonide:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Budesonide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 13 mg/l

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Exposure time: 96 H
Method: OECD Test Guideline 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
Method: OECD Test Guideline 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

Persistence and degradability

Components:

Budesonide:

Biodegradability : Result: not rapidly degradable

BOD/ThOD : < 50 %

Bioaccumulative potential

Components:

Budesonide:

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

Mobility in soil

Components:

Budesonide:

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 legislation.
Waste, even small quantities, should never be poured down drains, sewers or water courses.
Dispose of contents/ container to an approved incineration

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plant.
Contaminated packaging : Empty container will retain 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

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.
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AICS : Not listed
ENCS : Not listed
ISHL : Not listed
IECSC : Not listed
TCSI : Not listed
TSCA : Not On TSCA Inventory

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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.

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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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