SAFETY DATA SHEET

AstraZeneca

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

PULMICORT SUSPENSION FOR RESPULES

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
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Alternative Names
Budesonide nebulising suspension (0.25 mg, 0.5 mg, 1 mg)

CAS No. : Not applicable
Use : A corticosteroid used in the treatment of asthma.

2. HAZARDS IDENTIFICATION

This mixture is not classified as hazardous for supply/use according to GHS v 4.0. May produce an allergic reaction. Can be absorbed through skin causing systemic toxic effects.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

Component	%	CAS No.		
Budesonide	0,01 - 0,05	51333-22-3		
	Hazard class #		**Category**	**Hazard statements #**
	Acute toxicity		4	H302
	Skin sensitisation		1	H317
	Reproductive toxicity		2	H361
	Specific target organ toxicity - repeated exposure		1	H372
	Acute aquatic toxicity		3	H402
	Chronic aquatic toxicity		3	H412

Refer to Section 16 'Other Information'

4. FIRST-AID MEASURES

Description of first aid measures

Inhalation : Remove patient from exposure. Obtain medical attention if ill effects occur.
Skin Contact : Remove contaminated clothing. Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention.
Eye Contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.

Ingestion : 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 if ill effects occur.

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

Indication of any immediate medical attention and special treatment needed
Symptomatic treatment and supportive therapy as indicated.For further detail consult the prescribing information.

5. FIRE-FIGHTING MEASURES

Extinguishing Media (suitable)	:	water spray, foam, dry powder or CO2.
Extinguishing Media (unsuitable)	:	-
Special hazards arising from the substance or mixture	:	If involved in a fire, it may emit noxious and toxic fumes.
Special protective actions for fire-fighters	:	A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Ensure suitable personal protection during removal of spillages. See Section 8.
Environmental Precautions	:	Prevent entry into drains.
Methods and material for containment and cleaning up	:	Absorb spillages onto sand, earth or any suitable adsorbent material. Wash the spillage area with water.

7. HANDLING AND STORAGE

Precautions for safe handling	:	Avoid contact with skin and eyes.
Conditions for safe storage, including any incompatibilities	:	Protect from light. Keep container standing upright.
		Storage temperature : < 30 °C
Specific end use(s)	:	Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Components	Value	Control parameters	Comments
Budesonide	0,01 mg/m3	LTEL 8hr TWA	COM, HYG, Sk

Exposure Controls
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.
Occupational exposure controls
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.
The information below 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.

Respiratory protection
Use a negative pressure air purifying respirator (half face mask) with filter class A if the risk assessment does not support the selection of other protection.

Skin protection
Avoid contact with skin. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form	:	aqueous suspension
Colour	:	white to off-white

Other information

No other data available

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	:	No hazardous decomposition products are known.

products

11. TOXICOLOGICAL INFORMATION

The following health hazard assessment is based on a consideration of the composition of this product.

Inhalation	:	May cause effects as described under single exposure.(STOT)
Skin Contact	:	May cause slight skin irritation. Can be absorbed through skin. May cause eruption-like acne.
Eye Contact	:	May cause slight eye irritation. May cause cataracts and viral infection. May cause corneal ulcers and reduced visual function.
Ingestion	:	Low acute oral toxicity.
Specific Target Organ Toxicity (STOT)	:	**Single exposure** Exposure routes: Inhalation 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 May cause eruption-like acne., May cause effects as described under repeated exposure.(STOT) **Repeated exposure** Exposure routes: Inhalation, Dermal, Oral Target Organs: Adrenal gland Repeated exposure may produce oedema (water retention), high blood pressure, blurred vision, peptic ulcers, demineralization of bone, fatigue and suppression of adrenal gland function.
Sensitisation	:	May produce an allergic reaction.
Carcinogenicity	:	No evidence of carcinogencity in animal studies.
Mutagenicity	:	There is no evidence of genotoxic potential in in vitro and in vivo tests.
Reproductive toxicity	:	The following information refers to active ingredient: Studies in animals have shown that repeated doses produce teratogenic effects.

12. ECOLOGICAL INFORMATION

No information on this formulation. The following information refers to active ingredient: Harmful to aquatic life with long lasting effects.

Toxicity	:	ErC50 green algae 72 H > 8,6 mg/l (OECD 201) NOEC green algae 72 H 5,6 mg/l EC50 Daphnia magna 48 H 14 mg/l (OECD 202) NOEC Daphnia magna 48 H 3,8 mg/l LC50 Rainbow trout 96 H > 13 mg/l (OECD 203) NOEC Rainbow trout 96 H 13 mg/l
Effect on Effluent Treatment	:	No information available.
Persistence and degradability	:	Not rapidly degradable. Biological Oxygen Demand (BOD/ThBOD) < 50 %
Bioaccumulative potential	:	The substance has low potential for bioaccumulation.
Mobility in soil	:	Water solubility>= 1 mg/l.
Other adverse effects	:	No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods	:	Disposal should be in accordance with local, state or national legislation.
Contaminated Packaging	:	Empty container will retain product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

NOT RESTRICTED FOR TRANSPORT

15. REGULATORY INFORMATION

In order to comply with legal duties it is necessary to consult local and national legislation.

16. OTHER INFORMATION

Hazard statements	H302 : Harmful if swallowed. H317 : May cause an allergic skin reaction. H361 : Suspected of damaging the unborn child. H372 : Causes damage to organs through prolonged or repeated exposure. H402 : Harmful to aquatic life. H412 : Harmful to aquatic life with long lasting effects.

The following sections contain revisions or new statements :

Full Review - minor changes, 2, 9, 11

GLOSSARY

COM	:	In-house occupational exposure limit
LTEL	:	Long-term exposure limit (8 hour TWA (time-weighted average))
STEL	:	Short-term exposure limit (15-minute TWA (time-weighted average))
TLV	:	Threshold Limit Value (ACGIH)
TLV-C	:	Threshold Limit Value - Ceiling limit (ACGIH)
HYG	:	An in-house analytical method for occupational exposure monitoring is available
Sk	:	Can be absorbed through skin, thus contributing to systemic effects
Sen	:	Capable of causing respiratory sensitisation

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.