# SAFETY DATA SHEET

## 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
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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 cause sensitization of susceptible persons by skin contact.

## 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 sensitization | 1 | H317 |
| | Reproductive toxicity | 2 | H361 |
| | Specific target organ systemic 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 chemical 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 : < 86 °F |
| Specific end use(s) | : | Not applicable, refer to Section 1 |

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control parameters**

**Occupational Exposure Limit Value**

| Ingredients | Value | Control parameters | Comments |
|---|---|---|---|
| Budesonide | 0.01 mg/m3 | TWA | COM, HYG, Sk |
| This is an in-house standard for the active ingredient during manufacture. | | | |

**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**
NIOSH approved respiratory protection device consistent with the work place risk assessment. Consult a qualified safety and health professional for additional guidance, as needed.

**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 solution |
| Color | : | white to almost 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 products | : | No hazardous decomposition products are known. |

## 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 repeated exposure.(STOT) |
| Skin Contact | : | May cause slight skin irritation.<br>Can be absorbed through skin. |
| Eye Contact | : | May cause slight eye irritation.<br>May cause cataracts and viral infection. |
| Ingestion | : | Low acute oral toxicity. |
| Specific Target Organ Toxicity (STOT) | : | **Single exposure**<br>May cause effects as described under repeated exposure.(STOT)<br><br>**Repeated exposure**<br>Occasional nosebleeds have been reported., Prolonged overexposure may cause symptoms such as weakness, muscle aches, nausea and vomiting. |
| Sensitization | : | May cause sensitization of susceptible persons by skin contact. |
| Carcinogenicity | : | The substance is not considered to be carcinogenic. |
| 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<br>(OECD 201)<br>NOEC green algae 72 H 5.6 mg/l<br>EC50 Daphnia magna 48 H 14 mg/l<br>(OECD 202)<br>NOEC Daphnia magna 48 H 3.8 mg/l<br>LC50 Rainbow trout 96 H > 13 mg/l<br>(OECD 203)<br>NOEC Rainbow trout 96 H 13 mg/l |
| Effect on Effluent Treatment | : | No information available. |
| Persistence and degradability | : | Not rapidly degradable.<br><br>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

**Safety, health and environmental regulations/legislation specific for the substance or mixture**
TSCA (Toxic Substances Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation when manufactured, processed or distributed in commerce for use as a drug. CERCLA and SARA Regulations (40 CFR 302,355,370 and 372): This product does not contain any chemicals subject to applicable reporting requirements. Other Determined Regulations: California Proposition 65: This product does not contain a listed chemical. Discarded product is not considered a "hazardous waste" under RCRA, 40 CFR 261.

## 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 :

The Safety Data Sheet has been updated to adhere to Globally Harmonized System of Classification and Labelling of Chemicals (GHS)., This update affects most Sections of the Safety Data Sheet.

This Safety Data Sheet was prepared in accordance with Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)).

## 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 sensitization |

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

The information contained herein is based on data considered accurate and is offered solely for information, consideration and investigation. Company extends no warranties, makes no representations and assumes no responsibility as to the accuracy, completeness or suitability of this data for any third party use. The data on this Safety Data Sheet relates only to this product and does not relate to use with any other material or in any process. All chemical products should only be used by, or under the direction of, technically qualified personnel who are aware of the hazards involved and the necessity for reasonable care in handling. Hazard communication regulations require that employees must be trained on how to use a Safety Data Sheet as a source of hazard information.