# SAFETY DATA SHEET

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

**Product identifier**

# INDERAL TABLETS

**Details of the supplier of the safety data sheet** : ASTRAZENECA PTY LTD
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**Alternative Names**
Propranolol hydrochloride tablets

CAS No. : Not applicable
Use : management of hypertension, angina pectoris and dysrhythmias

## 2. HAZARDS IDENTIFICATION

### Classification of the substance or mixture

**Classification UN GHS**

| Hazard class | Category | Hazard statements |
|---|---|---|
| Acute toxicity | 5 | H303 |
| Reproductive toxicity | 1A | H360 |
| Effects on or via lactation | | H362 |
| Acute aquatic toxicity | 2 | H401 |
| Chronic aquatic toxicity | 2 | H411 |
| | | # Refer to Section 16 'Other Information' |

**Label elements**

**Signal word**
Danger

**Hazard statements**

H303 : May be harmful if swallowed.

H360 : May damage the unborn child.

H362 : May cause harm to breast-fed children.

H411 : Toxic to aquatic life with long lasting effects.

**Precautionary statements**

| | | |
|---|---|---|
| P201 | | Obtain special instructions before use. |
| P264 | | Wash hands thoroughly after handling. |
| P273 | | Avoid release to the environment. |
| P281 | | Use personal protective equipment as required. |
| P308 + P313 | : | IF exposed or concerned: Get medical advice/ attention. |
| P501 | : | Dispose of contents/ container to an approved incineration plant. |

**Other hazards**

May cause lowering of blood pressure. May cause irritation to skin and eyes. Rare cases of skin sensitisation have been reported. In rare cases, this product may present a risk of bronchospasm in individuals with asthma. The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Mixture:**

| **Component** | **%** | **CAS No.** | | |
|---|---|---|---|---|
| Propranolol hydrochloride | 10 - 30 | 318-98-9 | | |
| | **Hazard class** # | | **Category** | **Hazard statements** # |
| | Acute toxicity | | 4 | H302 |
| | Reproductive toxicity | | 1A | H360 |
| | Effects on or via lactation | | | H362 |
| | Acute aquatic toxicity | | 2 | H401 |
| | Chronic aquatic toxicity | | 2 | H411 |
| **Component** | **%** | **CAS No.** | | |
| Celluloses | 0 - 5,4 | - | | |
| | **Hazard class** # | | **Category** | **Hazard statements** # |
| | - | | - | - |

# 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 | : | Wash skin with soap and water. |
| Eye Contact | : | Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention if ill effects remain. |
| Ingestion | : | Wash out mouth with water and give 200-300ml of water to drink. Obtain medical attention if ill effects occur. Do NOT induce vomiting as a First-Aid measure. |

**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) | : | Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture. |
| Special hazards arising from the substance or mixture | : | If involved in a fire, it may burn and 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. Prevent fire extinguishing water from contaminating surface water or the ground water system. |

## 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Ensure suitable personal protection during removal of spillages. See Section 8. Avoid dispersal of dust in the air. |
| Environmental Precautions | : | Prevent entry into drains, sewers or watercourses. Collect spillage. |
| Methods and material for containment and cleaning up | : | Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water. Avoid release to the environment. See section 13. |

## 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| Precautions for safe handling | : | Avoid contact with skin and eyes. Wash hands after use. Minimize dust generation and accumulation. The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate. |
| Conditions for safe storage, including any incompatibilities | : | Keep container tightly closed and dry. Keep away from moisture. Protect from light.<br><br>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 |
|---|---|---|---|
| Propranolol hydrochloride | 0,5 mg/m3 | LTEL 8hr TWA | COM, HYG |
| Cellulose (Total Inhalable Dust) | 10 mg/m3 | LTEL 8hr TWA | WEL |
| Cellulose (Total Inhalable Dust) | 20 mg/m3 | STEL 15min | WEL |
| Cellulose (Respirable Dust) | 4 mg/m3 | LTEL 8hr TWA | WEL |

**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, sewers or watercourses.See Section 6 for environmental precautions.
**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 an air fed hood if the risk assessment does not support the selection of other protection.

**Skin protection**
Use impervious clothing to protect against direct contact with the product or for repeated, excessive handling use full chemical protective suit 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.

**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 | : | film-coated tablets, or, uncoated tablets |
| Colour | : | pink, or, 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 | : | No information available on acute toxicity.<br>May cause effects as described under single exposure.(STOT) |
| Skin Contact | : | May cause skin irritation after repeated exposure. |
| Eye Contact | : | Dust may cause irritation. |
| Ingestion | : | Low acute oral toxicity. |
| Specific Target Organ Toxicity (STOT) | : | **Single exposure**<br>Exposure routes: Oral, Inhalation<br>Propranolol reduces heart rate and lowers blood pressure., May cause dizziness, fatigue, gastrointestinal disturbances, coldness of the fingers and toes, and difficulty in breathing., In rare cases, this product may present a risk of bronchospasm in individuals with asthma.<br><br>**Repeated exposure**<br>Propranolol reduces heart rate and lowers blood pressure. |
| Sensitisation | : | Rare cases of skin sensitisation have been reported. |
| Carcinogenicity | : | No evidence of carcinogencity in animal studies. |
| Mutagenicity | : | No evidence of genotoxicity based on in vitro tests. |
| Reproductive toxicity | : | May damage the unborn child.<br>Foetal and neonatal toxicity in babies born to women receiving treatment during pregnancy has been reported.<br>Studies in animals have shown that high doses produce embryo/foetotoxic effects.<br>May cause harm to breast-fed children. |

## 12. ECOLOGICAL INFORMATION

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

| | | |
|---|---|---|
| Toxicity | : | EC50 Pseudokirchneriella subcapitata (green algae) 72 H growth rate 3,78 mg/l<br>EC50 Pseudokirchneriella subcapitata (green algae) 72 H biomass 0,78 mg/l<br>NOEC Pseudokirchneriella subcapitata (green algae) 72 H biomass 0,156 mg/l<br>EC50 bacteria, aerobic 3 H 10 - 100 mg/l<br>EC50 nitrifying bacteria 4 H > 100 mg/l<br>EC50 bacteria, anaerobic 15 d > 100 mg/l<br>EC50 Daphnia magna 48 H 1 - 10 mg/l<br>EC50 Daphnia magna 24 H 3,08 mg/l<br>(OECD 202)<br>NOEC Daphnia magna 9 d 0,055 mg/l<br>(US EPA 1994)<br>LC50 Rainbow trout 96 H (semi-static) 10 - 100 mg/l<br>NOEC Rainbow trout 10 d growth rate 1 mg/l<br>(OECD 215) |
| Effect on Effluent Treatment | : | No information available. |
| Persistence and degradability | : | The substance is substantially biodegradable. (Modified OECD 302B, >60% mineralisation, passing 10 day window) |
| 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. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal disposal is via incineration operated by an accredited disposal contractor. |
| Contaminated Packaging | : | Empty container will retain residue. Observe all hazard precautions. |

## 14. TRANSPORT INFORMATION

RESTRICTED FOR TRANSPORT

**ICAO/IATA**

| | | |
|---|---|---|
| UN No. | | 3077 |
| Proper Shipping Name | : | Environmentally hazardous substance, solid, n.o.s. (PROPRANOLOL HYDROCHLORIDE) |
| Class | : | 9 |
| Packing Group | : | III |

| | | |
|---|---|---|
| Environmental hazards | : | Environmentally hazardous |

**IMO/IMDG**

| | | |
|---|---|---|
| UN No. | | 3077 |
| Proper Shipping Name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (PROPRANOLOL HYDROCHLORIDE) |
| Class | : | 9 |
| Packing Group | : | III |
| Marine pollutant | : | Marine pollutant |

**ADR**

| | | |
|---|---|---|
| UN No. | | 3077 |
| Proper Shipping Name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (PROPRANOLOL HYDROCHLORIDE) |
| Class | : | 9 |
| Label(s) | : | 9 |
| Packing Group | : | III |
| Environmental hazards | : | Environmentally hazardous |

## 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.
H303 : May be harmful if swallowed.
H360 : May damage the unborn child.
H362 : May cause harm to breast-fed children.
H401 : Toxic to aquatic life.
H411 : Toxic to aquatic life with long lasting effects.

The following sections contain revisions or new statements :

Minor changes:, 8

## 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.