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

Product Identifier

Material Name: Propranolol Hydrochloride Tablets

Trade Name: Inderal; Propranolol Hydrochloride

Chemical Family: Non-selective beta-adrenergic antagonist

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product for the treatment of high blood pressure (hypertension) angina

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Acute Oral Toxicity: Category 4
Reproductive Toxicity: Category 2

US OSHA Specific - Classification
Physical Hazard: Combustible Dust

EU Classification:
EU Indication of danger: Harmful
Toxic to Reproduction: Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

Label Elements

Signal Word: Warning
Hazard Statements:
H302 - Harmful if swallowed
H361d - Suspected of damaging the unborn child
May form combustible dust concentrations in air
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Precautionary Statements:
- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P281 - Use personal protective equipment as required
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P330 - Rinse mouth
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
Australian Hazard Classification (NOHSC):

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Not Listed</td>
<td>Acute Tox.4 (H302) Rep. 2 (H361d)</td>
<td>10, 20, 40, 60, or 80 mg***</td>
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<td>209-150-3</td>
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</table>

<table>
<thead>
<tr>
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<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
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<td>FD&amp;C Yellow No. 6; (Sunset yellow)</td>
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</tbody>
</table>
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**Page:** 3  
**Version:** 1.0

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**Additional Information:**

* Proprietary

*** per tablet/capsule/lozenge/suppository

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

## 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:**

Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

**Ingestion:**

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:**

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms and Effects of Exposure:**
For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:**
None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:**
None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:**

Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:**
Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

**Fire / Explosion Hazards:**
Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Environmental Precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and Material for Containment and Cleaning Up**

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PZ02570
Measures for Cleaning / Collecting: Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Propranolol hydrochloride
Pfizer OEL TWA-8 Hr: 40µg/m³

Microcrystalline cellulose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
      4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³
      5 mg/m³

Magnesium stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

PZ02570
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment:

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablet
Odor: None
Molecular Formula: Mixture

Solvent Solubility: Ethanol Soluble
Water Solubility: No data available
Solubility: Water Soluble
pH: No data available
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available
Partition Coefficient: (Method, pH, Endpoint, Value)

Microcrystalline cellulose
No data available

Lactose
No data available

Magnesium stearate
No data available

Stearic acid
No data available

FD&C Yellow No. 6; (Sunset yellow)
No data available

D & C yellow No. 10
No data available

FD & C Blue No. 1
No data available

D&C Red #30
No data available

Propranolol hydrochloride
No data available

Decomposition Temperature (°C): No data available

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available

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Upper Explosive Limits (Liquid) (% by Vol.):  No data available
Lower Explosive Limits (Liquid) (% by Vol.):  No data available

10. STABILITY AND REACTIVITY

Reactivity:  No data available
Chemical Stability:  Stable under normal conditions of use.
Possibility of Hazardous Reactions
   Oxidizing Properties:  No data available
   Conditions to Avoid:  Fine particles (such as dust and mists) may fuel fires/explosions.
   Incompatible Materials:  As a precautionary measure, keep away from strong oxidizers
   Hazardous Decomposition Products:  No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
Short Term:  Accidental ingestion may cause effects similar to those seen in clinical use.
Known Clinical Effects:  Effects reported during clinical use include dizziness, headache, lethargy, changes in blood pressure, nausea, and abdominal pain. Clinical use may cause changes in heart rate. Adverse clinical reactions include the development of hypersensitivity and/or irritation leading to rashes, itching, and burning. Clinical use may cause Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis).

Acute Toxicity: (Species, Route, End Point, Dose)

Microcrystalline cellulose
   Rat  Oral  LD50  > 5000 mg/kg
   Rabbit  Dermal  LD50  > 2000 mg/kg

Magnesium stearate
   Rat  Oral  LD50  > 2000 mg/kg
   Rat  Inhalation  LC50  > 2000 mg/m³

Stearic acid
   Rat  Oral  LD50  > 4640 mg/kg
   Rabbit  Dermal  LD50  > 5000mg/kg

FD&C Yellow No. 6; (Sunset yellow)
   Rat  Oral  LD50  > 10,000 mg/kg
   Mouse  Oral  LD50  > 6,000mg/kg

D & C yellow No. 10
   Rat  Oral  LD50  2000 mg/kg

Propranolol hydrochloride
   Rat  Oral  LD50  466 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose
   Skin Irritation  Rabbit  Non-irritating
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11. TOXICOLOGICAL INFORMATION

Eye Irritation  Rabbit  Non-irritating

Stearic acid
Skin Irritation  Rabbit  Moderate
Eye Irritation  Rabbit  Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Stearic acid
30 Week(s)  Rat  Oral 300 ppm  LOAEL  Adipose tissue

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Propranolol hydrochloride
Embryo / Fetal Development  Rat  Oral 150 mg/kg/day  LOAEL  Embryotoxicity, Neonatal toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Stearic acid
In Vitro Bacterial Mutagenicity (Ames)  Salmonella  Negative
Unscheduled DNA Synthesis  E. coli  Negative

Propranolol hydrochloride
In Vitro Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vitro Mammalian Cell Mutagenicity  Rat Hepatocyte  Negative
In Vivo Micronucleus  Rat Hepatocyte  Negative
In Vivo Chromosome Aberration  Bone Marrow Mouse  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Stearic acid
26 Week(s)  Rat  Subcutaneous  0.5 mg/kg/week  NOAEL  Not carcinogenic
52 Week(s)  Mouse  Subcutaneous  0.05 mg/kg/week  LOAEL  Tumors

Propranolol hydrochloride
18 Month(s)  Rat  Oral  150 mg/kg/day  NOAEL  Not carcinogenic
18 Month(s)  Mouse  Oral  150 mg/kg/day  NOAEL  Not carcinogenic

Carcinogen Status:
None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

FD&C Yellow No. 6; (Sunset yellow)
IARC:
Group 3 (Not Classifiable)

FD & C Blue No. 1
IARC:
Group 3 (Not Classifiable)
12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewaster.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

D&C Red #30
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
<tr>
<td>Propranolol hydrochloride</td>
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<tr>
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- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **EU EINECS/ELINCS List**: Not Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Description</th>
<th>Class</th>
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</thead>
<tbody>
<tr>
<td>Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed</td>
<td>Present</td>
</tr>
<tr>
<td>Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child</td>
<td>Present</td>
</tr>
</tbody>
</table>

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Revision date: 21-May-2015
Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet