Material Safety Data Sheet
ANSI Format

Inderal Solid Products

Preparation Date 30-Nov-2006 **Revision Date** 01-Apr-2008 **Revision Number** 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	Inderal Solid Products
Common Name	Not available
Chemical Name	Not applicable
Synonyms	Inderal LA Long-Acting Capsules, Inderal Tablets, Inderide, Propranolol Hydrochloride
Product Use	Pharmaceutical product
Classification	Cardiovascular Drug, Beta-adrenergic
Supplier	Wyeth P.O. Box 8299 Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400
Emergency Telephone Number	Chemtrec USA, Puerto Rico, Canada 1-800-424-9300 Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical Tablet or Capsule **Physical State** Solid **Odor** Not available

Potential Physical Hazards Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Inhalation	May cause irritation of respiratory tract.
Ingestion	The most common effects may include low blood pressure/hypotension, low heart rate, lightheadedness, dizziness, paresthesia of hands, thrombocytopenic purpura, insomnia, lassitude, weakness, fatigue, catatonia, visual disturbances, hallucinations, vivid dreams, disorientation for time and place, short-term memory loss, emotional lability, and slightly clouded sensorium. May cause harm to the unborn child. Please see Patient Package Insert for further information.
Therapeutic Target Organ(s)	Cardiovascular system, Kidneys.
	Not listed by OSHA, NTP or IARC.

Potential Environmental Effects There is no known ecological information for this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Hydrochlorothiazide	58-93-5	0 - 25 mg/tablet or capsule
Propranolol Hydrochloride	318-98-9	10 - 160 mg/tablet or capsule
Inactive Ingredients	Not applicable	Remainder

4. FIRST AID MEASURES

Eye Contact In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

Skin Contact Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

Inhalation Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

Ingestion If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties Presumed to be a combustible particulate solid.

Extinguishing Media

Suitable Extinguishing Media Use water spray, foam, dry chemical or carbon dioxide.

Unsuitable Extinguishing Media Do NOT use water jet.

Fire Fighting Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.

Hazardous Combustion Products Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

Methods for Containment Not available

Methods for Cleaning up Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name	**Exposure Guideline**
Hydrochlorothiazide	250 mcg/m^3
Propranolol Hydrochloride	50 mcg/m^3

Engineering Controls Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.

Personal Protective Equipment

Eye/face Protection Provide eye protection based on risk assessment.

Skin Protection Wear nitrile or latex gloves. Wear protective garment.

Respiratory Protection Base respirator selection on a risk assessment.

General Hygiene Considerations When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.

Other Limit access to only personnel trained in the safe handling of this material Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Pharmaceutical Tablet or Capsule	**Physical State**	Solid
Color	Various	**Odor**	Not available
Odor Threshold	Not available		
pH	Not applicable		
Specific Gravity	Not applicable	**Water Solubility**	Not available
Solubility	Not applicable	**Evaporation Rate**	Not applicable
Partition Coefficient (n-octanol/water)	Not available	**Vapor Pressure**	Not applicable
Boiling Point	Not applicable	**Autoignition Temperature**	Not applicable
Flash Point	Not available	**Method**	None
Melting Point	Not available		
Flammability Limits in Air	**Upper** Not applicable	**Lower** Not applicable	
Explosion Limits	**Upper** Not applicable	**Lower** Not applicable	

10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature.
Conditions to Avoid	No data available
Materials to Avoid	No materials to be especially mentioned.
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Hydrochlorothiazide

LD50 Oral	1175 mg/kg rats 2750 mg/kg mice
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Propranolol Hydrochloride

LD50 Oral	466 mg/kg rats
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Multiple Dose Toxicity

Hydrochlorothiazide

No Toxicologic Effect Dose/Species/Study Length:	See Carcinogenicity

Propranolol Hydrochloride

No Toxicologic Effect Dose/Species/Study Length:	See below

Maximum Tolerated Dose (MTD), Oral

Hydrochlorothiazide

Carcinogenicity	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of Carcinogenicity in rats or female mice. There was equivocal evidence of hepatocarcinogenicity in male mice.
Genetic Toxicity	Non genotoxic, based on a weight of evidence, but some assays have shown some activity. No evidence of mutagenicity was observed in a battery of *in vitro* and *in vivo* assays.
Reproductive Toxicity	Did not show reproductive toxicity effects in mice or rats.
Developmental Toxicity	No teratogenic effects were observed in mice and rats.

Propranolol Hydrochloride

Carcinogenicity	Long-term studies in rats revealed no evidence of carcinogenicity.
Genetic Toxicity	Based on differing results from AMES tests performed by different laboratories, there is equivocal evidence for a genotoxic effect of Propranolol in bacteria.
Reproductive Toxicity	Studies in rats were found to have no effect on fertility and reproductive performance.
Developmental Toxicity	Studies in rats conducted indicated that this compound did not cause birth defects but can affect growth and development of fetus and newborns.

Hydrochlorothiazide

Target Organ(s) of Toxicity No data available

Propranolol Hydrochloride

Target Organ(s) of Toxicity No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information Not available

Ecotoxicity Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT)	Not regulated
Canadian Transport of Dangerous Goods (TDG)	Not regulated
International Civil Aviation Organization (ICAO)	Not regulated
International Air Transport Association (IATA)	Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)	Not regulated
Transport of Dangerous Goods by Rail (RID)	Not regulated
Transport of Dangerous Goods by Road (ADR)	Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)	Not regulated

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status
This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

This product does not contain any HAPs.

State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

Canada
Not classified

WHMIS Hazard Class
Non-controlled

European Union
In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By	Wyeth Department of Environment, Health & Safety
Format	This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References	Product Package Insert
Revision Summary	Changes to Section 2

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