Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name Loperamide Hydrochloride USP
Commercial Name Not available.
Product Use Not available
Restrictions On Use Not available

Product Code 55-2357

Company
PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 Acute Toxicity, oral Category 3

Signal Word DANGER

Hazard Statement(s) Toxic if swallowed.

Pictogram(s) or Symbol(s)

Precautionary Statement(s):

Prevention Wash thoroughly after handling.
Response If swallowed: Immediately call a poison center/doctor. Rinse mouth.
Storage Store locked up
Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Loperamide hydrochloride
% By Weight 100
CAS# 34552-83-5
Molecular Weight 513.51 g/mole
Chemical Formula C29H33ClN2O2.HCl
Synonym(s) Imodium

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Loperamide hydrochloride	34552-83-5	100	Not available.	ORAL (LD50):Acute: 185mg/kg [Rat].105 mg/kg[Mouse]. 41.5mg/kg [Guineapig].

Section 4: First-Aid Measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin Contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye Contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Symptoms/Effects

Acute Gastrointestinal disturbances. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Delayed Gastrointestinal disturbances. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Immediate Medical Attention

Provide general supportive measures and treat symptomatically. Administer activated charcoal as a slurry. Use narcotic antagonists, such as naloxone, to treat and reverse opioids adverse effects as necessary. Support respiratory functions and provide prolonged and careful monitoring.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials

Unsuitable Extinguishing Media

Not available

Products of Combustion

No unusual fire or explosion hazards noted

Firefighters Special Equipment and Precautions

Wear suitable protective equipment As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials

Section 6: Accidental Release Measures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. Methods and materials for containment and cleaning up: Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS. Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

Section 7: Handling and Storage

Handling: As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Storage: Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Exposure Limits Not available.

Engineering Controls	No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.
Personal Protection	Eye/face protection: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. Skin protection Hand protection: Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Other: Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Respiratory protection: Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene consideration: Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

Section 9: Physical and Chemical Properties

Appearance	White yellow. solid. (Powdered solid.)
Odor	Not available.
Odor Threshold	Not available.

Melting Point	428 - 442.4 °F (220 - 228 °C)	**pH**	Not available.
Freezing Point	Not available.	**Vapor Pressure**	Not applicable.
Boiling Point/Range	Not available.	**Vapor Density**	Not available.
Decomposition temperature	Not available.	**Viscosity**	Not available.
Partition Coefficient: n-octanol/water	5.13	**Evaporation Rate**	Not available.
Flash Point	Not available.	**Autoignition temperature**	734 °F (390 °C)
Flammability	Not available.	**Flammability or Explosive Limits:**	
		Lower	Not available.
		Upper	Not available.

Solubility(ies)	Slightly soluble in water.
Other	Chloroform: Slightly soluble. Dilute acids: Slightly soluble. Isopropyl alcohol: Very slightly soluble. Methanol: Freely soluble. Chemical family Piperidine derivative. Molecular formula C29H33ClN2O2 . HCl Molecular weight 513.5

Section 10: Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport
Chemical Stability	The product is stable.
Hazardous Polymerization	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	Contact with incompatible materials
Incompatible Materials	Strong oxidizing agents. Bases. Reducing agents. Acids.
Hazardous Decomposition Products	Cl-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information

RTECS TM4960000

Acute Toxicity
Toxic if swallowed Oral LD50 Mouse 105 mg/kg Rat 185 mg/kg

Skin Corrosion/Irritation
Not available

Serious Eye Damage/Irritation
Not available

Respiratory or Skin Sensitization
Not available

Germ Cell Mutagenicity
Not available

Carcinogenicity
Not available.

Reproductive Toxicity
Not available

Routes of Entry
Ingestion.

Symptoms Related to Exposure
Gastrointestinal disturbances. Dizziness. Weakness. Skin rash. Ringing in ears. Central nervous system depression. Cardiovascular effects

Potential Health Effects
Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects

Target Organ(s) Not available

Section 12: Ecological Information

Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistance and Degradability
Not available.

Bioaccumulative Potential
Octanol/water partition coefficient log Kow 5.13

Mobility in Soil
Not available

Other Adverse Effects
Not available

Section 13: Disposal Considerations

Waste Disposal
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Disposal of Container
Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal

Other Considerations
Not available

Section 14: Transport Information

DOT Classification
DOT CLASS 6.1: Poisonous material. UN number: UN2811 UN proper shipping name: Toxic solid, organic, n.o.s. (Loperamide Hydrochloride) Transport hazard class(es) Class 6.1 Subsidiary risk - Packing group III Packaging exceptions E1

Section 15: Regulatory Information

Regulations
US federal regulations: This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200 Toxic Substances Control Act (TSCA) TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053) Not listed. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. YesSARA 311/312 Hazardous chemical Acute toxicity (any route of exposure)Classified hazard categories SARA 313 (TRI reporting) Not regulated. Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Safe Drinking Water Act (SDWA) US state regulations California Proposition 65 California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

Other

WHMIS (Canada) CLASS D-1A: Material causing immediate and serious toxic effects (VERY TOXIC).;DSCL (EEC) R25-Toxic if swallowed. R36/37/38- Irritating to eyes, respiratory system and skin.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.;Splash goggles.

Section 16: Other Information

Not available