SAFETY DATA SHEETS

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SAFETY DATA SHEET

Product: Diphenoxylate Hydrochloride and Atropine Sulfate Tablets USP, 2.5mg/0.025mg

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

Distributed by:
Leading Pharma LLC
3 Oak Road,
Fairfield, NJ 07004
Phone: 973-276-9600
Fax: 973-276-9656

Manufactured by:
Leading Pharma LLC
3 Oak Road,
Fairfield, NJ 07004

This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research and manufacture. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SMS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

Material Name: Diphenoxylate Hydrochloride and Atropine Sulfate Tablets USP, 2.5mg/0.025mg

Trade Name:	Not Applicable
Chemical Family:	Mixture
Intended Use:	Finished Pharmaceutical Medication: Antidiarrheal agent

SECTION 2 — HAZARDS IDENTIFICATION

Appearance:	White to off-white, round, tablet debossed with "LP" over "910" on one side and plain on the other side.
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information:	
Short Term:	Accidental ingestion may cause effects similar to those seen in clinical use.
Long Term:	Use of this drug is habit forming. Addiction may occur.
Known Clinical Effects:	Ingestion of this material may cause effects similar to those seen in clinical use including numbness of extremities, constipation, respiratory depression, state of intense good feeling (euphoria), dry mouth, anxiety, headache, changes in heart rate, drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.
EU Indication of danger:	Not classified
Australian Hazard Classification (NOHSC):	Hazardous Substance. Non-Dangerous Goods.
Note:	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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SECTION 3 — COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures:

COMPOSITION		
Chemical Name	**Identifiers**	**%**
Diphenoxylate Hydrochloride	CAS: 3810-80-8	<5%
Atropine Sulfate	CAS: 55-48-1	<2%
Microcrystalline Cellulose, NF (Pharmacel PH 101)	CAS: 9004-34-6	45% - 50%
Pregelatinized Starch, NF (Starch 1500)	CAS: 9057-07-2	5% - 15%
Lactose Monohydrate, NF (Fast Flo 316)	CAS: 64044-51-5	35% - 45%
Colloidal Silicon Dioxide, NF (Cab-O-Sil)	CAS: 7631-86-9	<2%
Stearic Acid, NF	CAS: 57-11-4	<2%

SECTION 4 — 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. Flush area with large amounts of water. Use soap. Seek medical attention.

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.

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

SECTION 5 — FIRE FIGHTING MEASURES

Fire and Explosion Hazards: Assume that this product is capable of sustaining combustion.

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

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

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

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

Measures for Cleaning/ Collecting: Contain the source of spill if it is safe to do so. Collect the spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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

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.

SECTION 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 thoroughly after handling. 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.

Storage: Store as directed by product packaging.

SECTION 8 — EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Diphenoxylate Hydrochloride:

Manufacturer OEL:	25ug/m3

Atropine Sulfate:

Manufacturer OEL:	25ug/m3

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA):	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Estonia OEL - TWA	10 mg/m^3
France OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3

Latvia OEL - TWA	2 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Romania OEL - TWA	10 mg/m^3
Spain OEL - TWA	10 mg/m^3

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.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent).

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent).

SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White to off-white, round, tablet debossed with "LP" over "910" on one side and plain on the other side.
Physical state:	Solid.
Form:	Tablet.
Color:	White
Odor:	Not Available
Odor threshold:	Not Available
Molecular Formula:	Mixture
Molecular Weight:	Mixture
pH	Not Available
Melting point/freezing point	Not Available
Boiling Point	Not Available

Flash point	Not Available
Evaporation rate	Not Available
Flammability (solid, gas)	Not Available
Upper/lower flammability or explosive limits	
Flammability limit – lower (%)	Not Available
Flammability limit – upper (%)	Not Available
Explosive limit – lower (%)	Not Available
Explosive limit – upper (%)	Not Available
Vapor pressure	Not Available
Vapor density	Not Available
Relative density	Not Available
Solubility(ies)	
Solubility (water)	Not Available
Partition coefficient (n-octanol/water)	Not Available
Auto-ignition temperature	Not Available
Decomposition temperature	Not Available
Viscosity	Not Available
Other information	
Density	Not Available

SECTION 10 — STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical Stability: Material is stable under recommended conditions.

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.

SECTION 11 — TOXICOLOGICAL INFORMATION

Information on toxicological effects:

General Information: The information included in this section describes the potential hazards of the individual Ingredients.

Short Term: Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term: Use of this drug is habit forming. Addiction may occur.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including numbness of extremities, constipation, respiratory depression, state of intense good feeling (euphoria), dry mouth, anxiety, headache, changes in heart rate, drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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Acute toxicity (Species, Route, End Point Dose)

Diphenoxylate Hydrochloride

Rat	Oral	LD50	221 mg/kg
Mouse	IP	LD50	> 320mg/kg

Atropine Sulfate

Rat	Oral	LD50	600 mg/kg
Rat	Sub-tenon injection (eye)	LD50	215mg/kg
Rat	Intravenous	LD50	37mg/kg
Mouse	Oral		468mg/kg

Microcrystalline cellulose

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

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

Microcrystalline cellulose

Skin Irritation	Rabbit	Non-Irritation
Eye Irritation	Rabbit	Non-irritating

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

Diphenoxylate Hydrochloride

2 Week(s)	Rat	Oral	48 mg/kg/day	LOEL	Gastrointestinal System, Bladder
1 Month(s)	Rat	Oral	32 mg/kg/day	LOAEL	Central Nervous System

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

Diphenoxylate Hydrochloride

Reproductive & Fertility	Rat	Oral	20 mg/kg/day	NOAEL	No effects at maximum dose
Embryo/Fetal Development	Rabbit	Oral	20 mg/kg/day	NOAEL	Not Teratogenic

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

Diphenoxylate Hydrochloride

Cell Transformation Assay	Rodent germ cell	Negative

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

SECTION 12 — ECOLOGICAL INFORMATION

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

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SECTION 13 — DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of contents/container in accordance with local/ regional/ national/ international 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 wastewater 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 wastewater.

SECTION 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.

SECTION 15 — REGULATORY INFORMATION

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

Diphenoxylate Hydrochloride

CERCLA/SARA 313 Emission reporting:	Not Listed
California Proposition 65:	Not Listed
U.S. Drug Enforcement Administration:	Schedule II (Schedule V when in combination with other drugs)
Australia (AICS):	Present
EU EINECS/ELINCS List:	223-287-7

Atropine sulfate anhydrous

CERCLA/SARA 313 Emission reporting:	Not Listed
California Proposition 65:	Not Listed
U.S. Drug Enforcement Administration:	Schedule IV Controlled Substance Schedule V Controlled Substance
Inventory - United States TSCA - Sect. 8(b):	Present
Australia (AICS):	Present
EU EINECS/ELINCS List:	200-235-0

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b):	Present
Australia (AICS):	Present
EU EINECS/ELINCS List:	232-674-9

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SECTION 16 — OTHER INFORMATION

Leading Pharma believes that the information contained in this 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