



# MATERIAL SAFETY DATA SHEET

Revision date: 06-Jul-2011

Version: 2.0

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

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### Material Name: Diphenoxylate Hydrochloride and Atropine Sulfate Liquid

Trade Name:	Lomotil
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antidiarrheal agent

## 2. HAZARDS IDENTIFICATION

Appearance: Yellow liquid  
Signal Word: WARNING

Statement of Hazard: Flammable liquid and vapor.

### Additional Hazard Information:

Short Term: May cause eye irritation (based on components) . Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term: Use of this drug is habit forming. Addiction may occur. Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and congenital malformations. Ingestion of this material may cause effects similar to those seen in clinical use including constipation, respiratory depression, numbness of extremities, 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.

### Known Clinical Effects:

EU Indication of danger: Flammable

### EU Risk Phrases:

R10 - Flammable.

### Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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## 2. HAZARDS IDENTIFICATION

**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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Ethyl alcohol (ethanol)	64-17-5	200-578-6	F;R11	15
Citric acid	77-92-9	201-069-1	Xi; R36	*
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Diphenoxylate Hydrochloride	3810-80-8	223-287-6	Xn, R22	0.05
Atropine sulfate anhydrous	55-48-1	200-235-0	T+, R26/28	0.0005

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	Not Listed	*
Sodium Phosphate	7632-05-5	231-558-5	Not Listed	*
Cherry flavor, artificial	NOT ASSIGNED	Not Listed	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*
Sorbitol	6706-59-8	Not Listed	Not Listed	*

**Additional Information:** \* Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

## 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.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

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

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

**Fire / Explosion Hazards:** Flammable liquid. May generate flammable vapors. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

### 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 spill with absorbent material. 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.

### 7. HANDLING AND STORAGE

**General Handling:** Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Flammable liquid and vapor- keep away from ignition sources and clean up spills promptly. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin, and clothing. Use appropriate personal protective equipment. Wash thoroughly after handling. 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 Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Ethyl alcohol (ethanol)

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m <sup>3</sup>
Austria OEL - MAKs	1000 ppm
	1900 mg/m <sup>3</sup>
Belgium OEL - TWA	1000 ppm
	1907 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1000.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1000 mg/m <sup>3</sup>
Denmark OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estonia OEL - TWA	500 ppm
	1000 mg/m <sup>3</sup>
Finland OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
France OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	500 ppm
	960 mg/m <sup>3</sup>
Germany (DFG) - MAK	500 ppm
	960 mg/m <sup>3</sup>
Greece OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Hungary OEL - TWA	1900 mg/m <sup>3</sup>
Ireland OEL - TWAs	1000 ppm
	1900 mg/m <sup>3</sup>
Latvia OEL - TWA	1000 mg/m <sup>3</sup>
Lithuania OEL - TWA	500 ppm
	1000 mg/m <sup>3</sup>
Netherlands OEL - TWA	260 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	1000 ppm
	1900 mg/m <sup>3</sup>
Poland OEL - TWA	1900 mg/m <sup>3</sup>
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Slovakia OEL - TWA	500 ppm
	960 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Spain OEL - TWA	1000 ppm
	1910 mg/m <sup>3</sup>
Sweden OEL - TWAs	500 ppm
	1000 mg/m <sup>3</sup>
<b>Glycerin, USP</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Czech Republic OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
Finland OEL - TWA	20 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	50 mg/m <sup>3</sup> inhalable fraction
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
<b>Diphenoxylate Hydrochloride</b>	
Pfizer OEL TWA-8 Hr:	2.5µg/m <sup>3</sup>



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### 11. TOXICOLOGICAL INFORMATION

Mouse Intravenous LD 50 30 mg/kg

#### Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg  
Rat Oral LD50 7060 mg/kg  
Rat Inhalation LC50 10h 20,000 ppm

#### Diphenoxylate Hydrochloride

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

#### Atropine sulfate anhydrous

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

#### Citric acid

Rat Oral LD50 3000 mg/kg

#### Glycerin, USP

Mouse Oral LD50 4090 mg/kg  
Rat Oral LD50 12.6 g/kg  
Rabbit Dermal LD50 > 10 g/kg  
Rat Inhalation LC50 1hr > 570 mg/m<sup>3</sup>  
Rat Dermal LD 50 >21.9 g/kg

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

Rat Oral LD50 > 10,000 mg/kg  
Mouse Oral LD50 > 6,000 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

##### Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

##### Citric acid

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

##### Glycerin, USP

Eye Irritation Rabbit Mild

#### 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

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### 11. TOXICOLOGICAL INFORMATION

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

##### ATROPINE

Embryo / Fetal Development	Oral	50 mg/kg	LOAEL	Developmental toxicity, Maternal toxicity
Embryo / Fetal Development	Rat		Not Teratogenic	
Embryo / Fetal Development	Dog		Not Teratogenic	

##### 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)

##### ATROPINE

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
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##### Diphenoxylate Hydrochloride

Cell Transformation Assay	Rodent germ cell	Negative
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**Carcinogen Status:** See below

##### Ethyl alcohol (ethanol)

IARC: Group 1 (Carcinogenic to Humans)

OSHA: Listed

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

IARC: Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

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

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Ethyl alcohol (ethanol)

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC50/96h	12,900-15,300 mg/L
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##### Glycerin, USP

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LD50	96 Hours	50 mg/L
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<i>Daphnia magna</i> (Water Flea)	EC50	24 Hours	>500 mg/L
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**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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### 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 wastewater.

### 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

**EU Symbol:** None required  
**EU Indication of danger:** Flammable

**EU Risk Phrases:**  
R10 - Flammable.

**EU Safety Phrases:**  
S16 - Keep away from sources of ignition - No smoking.

**OSHA Label:**  
WARNING  
Flammable liquid and vapor.

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class B, Division 3  
Class D, Division 2, Subdivision B



#### Ethyl alcohol (ethanol)

California Proposition 65  
Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):

developmental toxicity initial date 10/1/87  
Present  
Present



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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List	200-578-6
<b>Citric acid</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1
<b>FD&amp;C Yellow No. 6; (Sunset yellow)</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	220-491-7
<b>Sodium Phosphate</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	231-558-5
<b>Water</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
<b>Glycerin, USP</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex V - Exemptions from the obligations of Register:	Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
EU EINECS/ELINCS List	200-289-5
<b>Diphenoxylate Hydrochloride</b>	
U.S. Drug Enforcement Administration:	Schedule II (Schedule V when in combination with other drugs)
Australia (AICS):	Present
EU EINECS/ELINCS List	223-287-6
<b>Atropine sulfate anhydrous</b>	
U.S. Drug Enforcement Administration:	Schedule IV Controlled Substance
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-235-0

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### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R11 - Highly flammable.  
R22 - Harmful if swallowed.  
R36 - Irritating to eyes.

#### **Data Sources:**

Publicly available toxicity information. Pfizer proprietary drug development information.

#### **Reasons for Revision:**

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information.

#### **Prepared by:**

Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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**