



# SAFETY DATA SHEET

Revision date: 04-Apr-2015

Version: 3.1

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

### Product Identifier

**Material Name:** Diphenoxylate and Atropine Tablets

**Trade Name:** Lomotil Tablets; Lofenoxal Tablets

**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product used as antidiarrheal agent

### 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

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
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+00 44 (0)1304 616161  
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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** Not classified as hazardous

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Not required

**Hazard Statements:** Non-hazardous in accordance with international standards for workplace safety.

### Other Hazards

No data available

**Australian Hazard Classification (NOHSC):**

Hazardous Substance. Non-Dangerous Goods.

### 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

### Hazardous

DIPHENOXYLATE AND ATROPIN TABLETS

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Diphenoxylate Hydrochloride	3810-80-8	223-287-6	Xn, R22	Acute Tox.3 (H301)	4
Atropine sulfate anhydrous	55-48-1	200-235-0	T+ R26/28	Acute Tox. 2 (H300) Acute Tox. 2 (H330)	0.04
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Light mineral oil (liquid paraffin)	8042-47-5	232-455-8	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sorbitol	6706-59-8	Not Listed	Not Listed	Not Listed	*
Acacia	9000-01-5	232-519-5	Not Listed	Not Listed	*

**Additional Information:**

\* Proprietary  
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. 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.

**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**

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

**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

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect 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.

**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 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.

### 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.

### Diphenoxylate Hydrochloride

Pfizer OEL TWA-8 Hr: 25µg/m<sup>3</sup>

### Atropine sulfate anhydrous

Pfizer OEL TWA-8 Hr: 2.5µg/m<sup>3</sup>

### Sucrose

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>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

#### Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup>
Australia TWA	2.5 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Belgium OEL - TWA	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 fiber/cm <sup>3</sup>
	6.0 mg/m <sup>3</sup>
	3.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	2.0 mg/m <sup>3</sup>
Denmark OEL - TWA	0.3 fiber/cm <sup>3</sup>
Finland OEL - TWA	0.5 fiber/cm <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	2 mg/m <sup>3</sup>
Hungary OEL - TWA	2 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	0.8 mg/m <sup>3</sup>
Lithuania OEL - TWA	2 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.25 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m <sup>3</sup>
	1.0 mg/m <sup>3</sup>
Portugal OEL - TWA	2 mg/m <sup>3</sup>
Romania OEL - TWA	2 mg/m <sup>3</sup>
Slovakia OEL - TWA	2 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Spain OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	2 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	2 mg/m <sup>3</sup>

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

#### Light mineral oil (liquid paraffin)

ACGIH Threshold Limit Value (TWA)	5 mg/m <sup>3</sup>
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#### Exposure Controls

<b>Engineering Controls:</b>	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.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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:** None required 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Tablets	<b>Color:</b>	White
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

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

#### Acacia

No data available

#### Sorbitol

No data available

#### Talc (non-asbestiform)

No data available

#### Magnesium stearate

No data available

#### Light mineral oil (liquid paraffin)

No data available

#### Sucrose

No data available

#### Diphenoxylate Hydrochloride

No data available

#### Atropine sulfate anhydrous

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

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

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

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### 10. STABILITY AND REACTIVITY

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

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients.
<b>Short Term:</b>	Accidental ingestion may cause effects similar to those seen in clinical use.
<b>Long Term:</b>	Use of this drug is habit forming. Addiction may occur.
<b>Known Clinical Effects:</b>	Ingestion of this material may cause effects similar to those seen in clinical use including constipation, numbness of extremities, 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.

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

##### Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

##### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### Light mineral oil (liquid paraffin)

Rat Oral LD50 > 5000 mg/kg

##### Sucrose

Rat Oral LD50 29.7 g/kg

##### Diphenoxylate Hydrochloride

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

##### Atropine sulfate anhydrous

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

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### 11. TOXICOLOGICAL INFORMATION

#### Acacia

Eye Irritation Rabbit Severe

#### Light mineral oil (liquid paraffin)

Eye Irritation Rabbit Non-irritating  
Skin Irritation Rabbit Non-irritating  
Skin Sensitization - GPMT Guinea Pig Negative

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

##### Light mineral oil (liquid paraffin)

90 Day(s) Rat Oral 1800 mg/kg/day NOEL Liver

##### Diphenoxylate Hydrochloride

2 Week(s) Rat Oral 48 mg/kg/day LOEL Gastrointestinal System, Bladder  
1 Month(s) Rat Oral 32 mg/kg/day LOEL 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 NOEL No effects at maximum dose  
Embryo / Fetal Development Rabbit Oral 20 mg/kg/day NOEL Not Teratogenic

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

##### Light mineral oil (liquid paraffin)

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vitro* Mammalian Cell Mutagenicity Mouse Lymphoma Negative

##### Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

##### 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.  
See below

#### Talc (non-asbestiform)

IARC: Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

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

#### Toxicity:

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

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### Light mineral oil (liquid paraffin)

*Lepomis macrochirus* (Bluegill Sunfish) OECD LC50 96 Hours > 10000 mg/L

**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 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

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

#### Canada - WHMIS: Classifications

#### **WHMIS hazard class:**

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.



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### 15. REGULATORY INFORMATION

**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	223-287-6

**Atropine sulfate anhydrous**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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

**Sucrose**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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	200-334-9

**Sorbitol**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

**Talc (non-asbestiform)**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

**Magnesium stearate**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

**Light mineral oil (liquid paraffin)**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-455-8

**Acacia**

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CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-519-5

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed  
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed  
Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled

Xn - Harmful  
T+ - Very toxic

R22 - Harmful if swallowed.  
R26/28 - Very toxic by inhalation and if swallowed.

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

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients. Updated Section 15 - Regulatory Information.

**Revision date:** 04-Apr-2015  
Product Stewardship Hazard Communication

**Prepared by:** 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**