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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

Label Elements

Signal Word: Not required
Hazard Statements: Non-hazardous in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>DIPHENOXYLATE AND ATROPIN TABLETS</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3. COMPOSITION / INFORMATION ON INGREDIENTS

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

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 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
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.
SAFETY DATA SHEET

Material Name: Diphenoxylate and Atropine Tablets
Revision date: 02-Oct-2018

Diphenoxylate and Atropin Tablets

Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

6.3 Methods and Material for Containment and Cleaning Up

6.3.1 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.

6.3.2 Additional Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

7.1 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.

7.2 Conditions for Safe Storage, Including any Incompatibilities

7.2.1 Storage Conditions: Store as directed by product packaging.

7.2.2 Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

8.1.1 Diphenoxylate Hydrochloride

- Pfizer OEL TWA-8 Hr: 25µg/m³

8.1.2 Atropine sulfate anhydrous

- Pfizer OEL TWA-8 Hr: 2.5µg/m³

8.1.3 Sucrose

- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Australia TWA 10 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Bulgaria OEL - TWA 10.0 mg/m³
- Estonia OEL - TWA 10 mg/m³
- France OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 10 mg/m³
- Latvia OEL - TWA 5 mg/m³
- Lithuania OEL - TWA 10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**OSHA - Final PELs - TWAs:**
- 15 mg/m³

**Portugal OEL - TWA**
- 10 mg/m³

**Spain OEL - TWA**
- 6 mg/m³
- 10 mg/m³

**Talc (non-asbestiform)**
- ACGIH Threshold Limit Value (TWA) 2 mg/m³
- Australia TWA 2.5 mg/m³
- Austria OEL - MAKs 2 mg/m³
- Belgium OEL - TWA 2 mg/m³
- Bulgaria OEL - TWA 1.0 fiber/cm³ 6.0 mg/m³ 3.0 mg/m³

**Czech Republic OEL - TWA**
- 2.0 mg/m³

**Denmark OEL - TWA**
- 0.3 fiber/cm³

**Finland OEL - TWA**
- 0.5 fiber/cm³

**Greece OEL - TWA**
- 10 mg/m³
- 2 mg/m³

**Hungary OEL - TWA**
- 2 mg/m³

**Ireland OEL - TWAs**
- 10 mg/m³
- 0.8 mg/m³

**Lithuania OEL - TWA**
- 2 mg/m³
- 1 mg/m³

**Netherlands OEL - TWA**
- 0.25 mg/m³

**OSHA - Final PELs - Table Z-3 Mineral D:**
- 20 mppcf

**Poland OEL - TWA**
- 4.0 mg/m³
- 1.0 mg/m³

**Portugal OEL - TWA**
- 2 mg/m³

**Romania OEL - TWA**
- 2 mg/m³

**Slovakia OEL - TWA**
- 2 mg/m³
- 10 mg/m³

**Slovenia OEL - TWA**
- 2 mg/m³

**Spain OEL - TWA**
- 2 mg/m³

**Sweden OEL - TWAs**
- 2 mg/m³
- 1 mg/m³

**Switzerland OEL - TWAs**
- 2 mg/m³

**Magnesium stearate**
- Lithuania OEL - TWA 5 mg/m³
- Sweden OEL - TWAs 5 mg/m³

**Light mineral oil (liquid paraffin)**
- Germany - TRGS 900 - TWAs 5 mg/m³
- Germany (DFG) - MAK 5 mg/m³

**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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
<th>Color:</th>
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</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
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</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

**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
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
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

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 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/m³

**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.
11. TOXICOLOGICAL INFORMATION

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

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  NOAEL  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  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)

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)

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

Diphenoxylate Hydrochloride

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- U.S. Drug Enforcement Administration:
- 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
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name: Diphenoxylate and Atropine Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>U.S. Drug Enforcement Administration:</strong></td>
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<tr>
<td>- Schedule IV Controlled Substance</td>
</tr>
<tr>
<td>- Schedule V Controlled Substance</td>
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<tr>
<td><strong>Inventory - United States TSCA - Sect. 8(b)</strong></td>
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<tr>
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<tr>
<td><strong>Australia (AICS):</strong></td>
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<tr>
<td>- Present</td>
</tr>
<tr>
<td><strong>EU EINECS/ELINCS List</strong></td>
</tr>
<tr>
<td>- 200-235-0</td>
</tr>
</tbody>
</table>

**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: 209-150-3

**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

**Acacia**

- 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

**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

### 16. OTHER INFORMATION

Text of CLP/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

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

**Reasons for Revision:**
Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

**Revision date:**
02-Oct-2018

**Prepared by:**
Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc 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**