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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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.

Known Clinical Effects: 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.

EU Indication of danger: Flammable

EU Risk Phrases: R10 - Flammable.

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
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<th>%</th>
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<tbody>
<tr>
<td>Ethyl alcohol (ethanol)</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>F, R11</td>
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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.
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)

<table>
<thead>
<tr>
<th></th>
<th>ACGIH Threshold Limit Value (STEL)</th>
<th>Australia TWA</th>
<th>Austria OEL - MAKs</th>
<th>Belgium OEL - TWA</th>
<th>Bulgaria OEL - TWA</th>
<th>Czech Republic OEL - TWA</th>
<th>Denmark OEL - TWA</th>
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<tr>
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<td>1000 ppm</td>
<td>1000 ppm</td>
<td>1880 mg/m³</td>
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DIPHENOXYLATE AND ATROPINE
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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<th>Country</th>
<th>Standard</th>
<th>Exposure Limit</th>
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<tr>
<td>Finland OEL - TWA</td>
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<td>1900 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
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<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
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<tr>
<td>Hungary OEL - TWA</td>
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<td>Latvia OEL - TWA</td>
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<tr>
<td>Lithuania OEL - TWA</td>
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<td>1000 mg/m³</td>
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<tr>
<td>Netherlands OEL - TWA</td>
<td>260 mg/m³</td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>1900 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>1000 ppm</td>
<td></td>
</tr>
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<td>Romania OEL - TWA</td>
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<td>1900 mg/m³</td>
</tr>
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<td>Slovakia OEL - TWA</td>
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<tr>
<td>Sweden OEL - TWAs</td>
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<td>1000 mg/m³</td>
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</tbody>
</table>

**Diphenoxylate Hydrochloride**
- **Pfizer OEL TWA-8 Hr:** 25μg/m³

**Atropine sulfate anhydrous**
- **Pfizer OEL TWA-8 Hr:** 2.5μg/m³

**Glycerin, USP**
- ACGIH Threshold Limit Value (TWA) | 10 mg/m³
- ACGIH OELs - Notice of Intended Changes | Listed
- **Australia TWA** | 10 mg/m³
- **Belgium OEL - TWA** | 10 mg/m³
- **Czech Republic OEL - TWA** | 10 mg/m³
- **Estonia OEL - TWA** | 10 mg/m³
- **Finland OEL - TWA** | 20 mg/m³
- **France OEL - TWA** | 10 mg/m³
- **Germany (DFG) - MAK** | 50 mg/m³
- **Greece OEL - TWA** | 10 mg/m³
- **Ireland OEL - TWAs** | 10 mg/m³
- **OSHA - Final PELS - TWAs:** | 15 mg/m³
- **Poland OEL - TWA** | 10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**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:** 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

<table>
<thead>
<tr>
<th>Physical State:</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
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<tr>
<td>Color:</td>
<td>Yellow</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

**Boiling Point (°C):** 78.5 based on lowest component boiling point: Ethanol

**Vapor Density (g/ml):** 1.59 (Ethanol)

**Flash Point (Liquid) (°C):** >38 (estimated)

**Upper Explosive Limits (Liquid) (% by Vol.):** 19%

**Lower Explosive Limits (Liquid) (% by Vol.):** 3.3%

10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.

**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

11. TOXICOLOGICAL INFORMATION

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

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

**ATROPINE**

- **Rat**
  - Oral LD 50 500 mg/kg
  - Sub-tenon injection (eye) LD 50 280 mg/kg
  - Intravenous LD 50 73 mg/kg

- **Mouse**
  - Oral LD 50 75 mg/kg
  - Intravenous LD 50 30 mg/kg
## 11. TOXICOLOGICAL INFORMATION

**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/m³
- Rat Dermal LD50 > 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

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

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) Salmonella Negative

Diphenoxylate Hydrochloride

Cell Transformation Assay Rodent germ cell Negative

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)

Oncorhynchus mykiss (Rainbow Trout) LC50/96h 12,900-15,300 mg/L

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LD50 96 Hours 50 mg/L
Daphnia magna (Water Flea) EC50 24 Hours >500 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.
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
carcinogen initial date 4/29/11
developmental toxicity initial date 10/1/87
Inventory - United States TSCA - Sect. 8(b)
Present
## 15. REGULATORY INFORMATION

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<thead>
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<th>Material</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
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<tr>
<td>Diphenoxylate Hydrochloride</td>
<td>Schedule II (Schedule V when in combination with other drugs)</td>
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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 8 - Exposure Controls / Personal Protection.

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