SAFETY DATA SHEET

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

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

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

Material Name: Tolterodine Tartrate Modified Release Capsules

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>Detrol LA, Detrusitol LA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms:</td>
<td>Detrol SR, Detrusitol SR</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used for overactive bladder</td>
</tr>
</tbody>
</table>

2. HAZARDS IDENTIFICATION

Appearance: Capsules

Additional Hazard Information:

Short Term: Accidental ingestion may cause effects similar to those seen in clinical use.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on fetus.

Known Clinical Effects: May cause effects similar to those seen in clinical use including dry mouth, blurred vision, constipation, and upset stomach.

EU Classification

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC):


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.

PZ01872
3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oleic acid</td>
<td>112-80-1</td>
<td>204-007-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Tolterodine L-Tartrate</td>
<td>124937-52-6</td>
<td>Not Listed</td>
<td>Repr. Cat. 3; R63</td>
<td>&lt;2.5</td>
</tr>
</tbody>
</table>

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 eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:**
Wash skin with soap and water. If irritation occurs or persists, get 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:**
Emits toxic fumes of carbon monoxide and nitrogen oxide.

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

**Fire / Explosion Hazards:**
Not applicable
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 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.

7. HANDLING AND STORAGE

General 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 hands and any exposed skin after removal of PPE. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

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.

Oleic acid

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
</tbody>
</table>

Propylene glycol

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>474 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>470 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>7 mg/m³</td>
</tr>
</tbody>
</table>

Starch

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Tolterodine Tartrate Modified Release Capsules
Revision date: 13-Sep-2013

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>OEL - TWA</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

**Sucrose**

<table>
<thead>
<tr>
<th>Material Name</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

**Titanium dioxide**

<table>
<thead>
<tr>
<th>Material Name</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

**Tolterodine L-Tartrate**

<table>
<thead>
<tr>
<th>Material Name</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer OEL TWA-8 Hr:</td>
<td>25µg/m³</td>
</tr>
</tbody>
</table>

**Analytical Method:** Analytical method available for tolterodine. Contact Pfizer Inc for further information.

**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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Physical State: Capsule
Molecular Formula: Mixture
Color: No data available.
Molecular Weight: Mixture

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)

FD&C Blue No. 2
Rat Oral LD50 2 g/kg
Mouse Oral LD50 2500 mg/kg

Tolterodine L-Tartrate
Mouse Oral LD50 > 200 mg/kg

Hydroxypropyl methylcellulose
Rat Oral LD50 > 10,000 mg/kg

Sucrose
Rat Oral LD50 29.7 g/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Name</th>
<th>Route</th>
<th>Species</th>
<th>Dose</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute Toxicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Oral</td>
<td>Mouse</td>
<td>22,000 mg/kg</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td>Tolterodine L-Tartrate</td>
<td>Oral</td>
<td>Mouse</td>
<td>10 mg/kg/day</td>
<td>None identified</td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>Dog</td>
<td>0.5 mg/kg/day</td>
<td>None identified</td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>Dog</td>
<td>0.5 mg/kg/day</td>
<td>None identified</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Route</th>
<th>Species</th>
<th>Dose</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tolterodine L-Tartrate</td>
<td>Dermal</td>
<td>Rabbit</td>
<td></td>
<td>Non-irritating</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Guinea Pig</td>
<td></td>
<td>No effect</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Dermal</td>
<td>Rabbit</td>
<td></td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye</td>
<td></td>
<td>Mild</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Route</th>
<th>Species</th>
<th>Dose</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tolterodine L-Tartrate</td>
<td>Oral</td>
<td>Mouse</td>
<td>20 mg/kg/day</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>Dog</td>
<td>20 mg/kg/day</td>
<td>No effects at maximum dose</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Route</th>
<th>Species</th>
<th>Dose</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tolterodine L-Tartrate</td>
<td>Oral</td>
<td>Mouse</td>
<td>20 mg/kg/day</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>Dog</td>
<td>20 mg/kg/day</td>
<td>No effects at maximum dose</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tolterodine L-Tartrate</td>
<td>Salmonella</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>E. coli</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Sucrose

<table>
<thead>
<tr>
<th>Name</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Salmonella</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

<table>
<thead>
<tr>
<th>Name</th>
<th>Route</th>
<th>Species</th>
<th>Dose</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tolterodine L-Tartrate</td>
<td>Oral</td>
<td>Mouse</td>
<td>30 mg/kg/day</td>
<td>Maximally Tolerated Dose</td>
</tr>
</tbody>
</table>

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
11. TOXICOLOGICAL INFORMATION

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)
OSHA: Listed

12. ECOLOGICAL INFORMATION

Environmental Overview: This mixture contains material that is toxic to aquatic life. See Aquatic toxicity data of the active ingredient, below:

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

Tolterodine L-Tartrate

Daphnia magna (Water Flea) OECD LC50 48 Hours 1.7 mg/L
Pseudokirchneriella subcapitata (Green Alga) EC50 72 Hours 20 mg/L

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 Indication of danger: Not classified

OSHA Label:

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A
15. REGULATORY INFORMATION

Ethylcellulose  
California Proposition 65  Not Listed  
Inventory - United States TSCA - Sect. 8(b)  Present  
Australia (AICS):  Present  

FD&C Blue No. 2  
California Proposition 65  Not Listed  
Inventory - United States TSCA - Sect. 8(b)  Present  
Australia (AICS):  Present  
EU EINECS/ELINCS List  212-728-8  

Gelatin  
California Proposition 65  Not Listed  
Inventory - United States TSCA - Sect. 8(b)  Present  
Australia (AICS):  Present  
EU EINECS/ELINCS List  232-554-6  

Hydroxypropyl methylcellulose  
California Proposition 65  Not Listed  
Inventory - United States TSCA - Sect. 8(b)  Present  
Australia (AICS):  Present  
Standard for the Uniform Scheduling for Drugs and Poisons:  Schedule 4  

Medium Chain Fatty Acid Triglyceride  
California Proposition 65  Not Listed  

Oleic acid  
California Proposition 65  Not Listed  
Inventory - United States TSCA - Sect. 8(b)  Present  
Australia (AICS):  Present  
EU EINECS/ELINCS List  204-007-1  

Propylene glycol  
California Proposition 65  Not Listed  
Inventory - United States TSCA - Sect. 8(b)  Present  
Australia (AICS):  Present  
EU EINECS/ELINCS List  200-338-0  

Shellac  
California Proposition 65  Not Listed  
Inventory - United States TSCA - Sect. 8(b)  Present  
Australia (AICS):  Present  

PZ01872
15. REGULATORY INFORMATION

EU EINECS/ELINCS List 232-549-9

Simethicone
- California Proposition 65: Not Listed
- Australia (AICS): Present

Starch
- 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 232-679-6

Sucrose
- 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

Titanium dioxide
- California Proposition 65: carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
- 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 236-675-5

Tolterodine L-Tartrate
- California Proposition 65: Not Listed

Ferric oxide yellow
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List 257-098-5

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R63 - Possible risk of harm to the unborn child.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources:
Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 15 - Regulatory Information.
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