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

Material Name: Tolterodine Tartrate Tablets

| Trade Name: | Detrol®, Detrusitol® |
| Chemical Family: | Mixture |
| Intended Use: | Pharmaceutical product used for overactive bladder |

2. HAZARDS IDENTIFICATION

Appearance: White tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

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


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>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Silica colloidal, Ph. Eur.</td>
<td>112945-52-5</td>
<td>Not Listed</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 N;R51/53</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.

Magnesium stearate
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Lithuania OEL - TWA 5 mg/m³
- Sweden OEL - TWAs 5 mg/m³

Microcrystalline cellulose
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Australia TWA 10 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Estonia OEL - TWA 10 mg/m³
- France OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 10 mg/m³
- Latvia OEL - TWA 2 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Portugal OEL - TWA 10 mg/m³
- Spain OEL - TWA 10 mg/m³

Silica colloidal, Ph. Eur.
- Austria OEL - MAKs 4 mg/m³

Titanium dioxide
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Australia TWA 10 mg/m³
- Austria OEL - MAKs 5 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Bulgaria OEL - TWA 10.0 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION


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.

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:** Tablet  
**Color:** White  
**Molecular Formula:** Mixture  
**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)

Mg stearate
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

Microcrystalline cellulose
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

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

Stearic acid
- Rat Oral LD50 > 4640 mg/kg
- Rabbit Dermal LD50 > 5000 mg/kg

Titanium dioxide
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD50 50 mg/kg

Tolterodine L-Tartrate
- Mouse Oral LD50 > 200 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)

Microcrystalline cellulose
- Skin Irritation Rabbit Non-irritating
- Eye Irritation Rabbit Non-irritating

Stearic acid
- Skin Irritation Rabbit Moderate
- Eye Irritation Rabbit Mild

Tolterodine L-Tartrate
- Skin Irritation Rabbit Non-irritating
- Skin Sensitization - GPMT Guinea Pig No effect

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

Stearic acid
- 30 Week(s) Rat Oral 300 ppm LOAEL Adipose tissue

Tolterodine L-Tartrate
- 26 Week(s) Mouse Oral 10 mg/kg/day NOAEL None identified
- 52 Week(s) Dog Oral 0.5 mg/kg/day NOAEL None identified
11. TOXICOLOGICAL INFORMATION

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

**Tolterodine L-Tartrate**
- Reproductive & Fertility - Females: Mouse, Oral, 20 mg/kg/day, NOAEL, No effects at maximum dose
- Reproductive & Fertility - Males: Mouse, Oral, 30 mg/kg/day, NOAEL, No effects at maximum dose
- Embryo / Fetal Development: Mouse, Oral, 20 mg/kg/day, NOAEL, Embryotoxicity, Teratogenic

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

- **Stearic acid**
  - *In Vitro* Bacterial Mutagenicity (Ames): *Salmonella*, Negative
  - Unscheduled DNA Synthesis: *E. coli*, Negative

- **Tolterodine L-Tartrate**
  - Bacterial Mutagenicity (Ames): *Salmonella*, *E. coli*, Negative
  - *In Vivo* Chromosome Aberration: Human Lymphocytes, Negative
  - *In Vivo* Micronucleus: Mouse, Negative

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

- **Stearic acid**
  - 26 Week(s): Rat, Subcutaneous, 0.5 mg/kg/week, NOAEL, Not carcinogenic
  - 52 Week(s): Mouse, Subcutaneous, 0.05 mg/kg/week, LOAEL, Tumors

- **Tolterodine L-Tartrate**
  - Not specified: Mouse, Oral, 30 mg/kg/day, Maximally Tolerated Dose, Not carcinogenic

Carcinogen Status:

- Silica colloidal, Ph. Eur.
  - IARC: Group 3 (Not Classifiable)

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

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Dibasic calcium phosphate, dihydrate USP
California Proposition 65: Not Listed
Australia (AICS): Present

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
### 15. REGULATORY INFORMATION

**Magnesium stearate**
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 209-150-3

**Microcrystalline cellulose**
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 232-674-9

**Silica colloidal, Ph. Eur.**
- California Proposition 65: Not Listed
- Australia (AICS): Present

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

**Stearic acid**
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-313-4

**Titanium dioxide**
- California Proposition 65: Not Listed
carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 236-675-5

**Tolterodine L-Tartrate**
- California Proposition 65: Not Listed

### 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 11 - Toxicology Information. Updated Section 15 - Regulatory Information.
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End of Safety Data Sheet