



SAFETY DATA SHEET

Revision date: 19-Mar-2015

Version: 4.0

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

Product Identifier

Material Name: Tolterodine Tartrate Tablets

Trade Name: Detrol; Detrusitol; Tolterodin Pfizer

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used for overactive bladder

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
United Kingdom
+00 44 (0)1304 616161

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

EU Classification:

EU Indication of danger: Not classified

Label Elements

Other Hazards No data available
Australian Hazard Classification (NOHSC): Non-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

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|----------------------------|------------|-----------------------|-------------------|--------------------|---|
| Magnesium stearate | 557-04-0 | 209-150-3 | Not Listed | Not Listed | * |
| Microcrystalline cellulose | 9004-34-6 | 232-674-9 | Not Listed | Not Listed | * |

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3. COMPOSITION / INFORMATION ON INGREDIENTS

| | | | | | |
|----------------------------|-------------|------------|------------------------------|---|------|
| Silica colloidal, Ph. Eur. | 112945-52-5 | Not Listed | Not Listed | Not Listed | * |
| Titanium dioxide | 13463-67-7 | 236-675-5 | Not Listed | Not Listed | * |
| Tolterodine L-Tartrate | 124937-52-6 | Not Listed | Repr. Cat. 3;R63 N;R51/53 | Repr. 2 (H361d) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411) | <2.5 |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|--|------------|-----------------------|-------------------|--------------------|---|
| Dibasic calcium phosphate, dihydrate USP | 7789-77-7 | Not Listed | Not Listed | Not Listed | * |
| Hydroxypropyl methylcellulose | 9004-65-3 | Not Listed | Not Listed | Not Listed | * |
| Sodium starch glycolate | 9063-38-1 | Not Listed | Not Listed | Not Listed | * |
| Stearic acid | 57-11-4 | 200-313-4 | 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 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.

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: Emits toxic fumes of carbon monoxide and nitrogen oxide.

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Fire / Explosion Hazards: Not applicable

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 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.

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.

Magnesium stearate

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

Microcrystalline cellulose

| | |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Estonia OEL - TWA | 10 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| | 4 mg/m ³ |
| Latvia OEL - TWA | 2 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---------------------------|----------------------|
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Romania OEL - TWA | 10 mg/m ³ |
| Russia OEL - TWA | 6 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Switzerland OEL -TWAs | 3 mg/m ³ |
| Vietnam OEL - TWAs | 10 mg/m ³ |
| | 5 mg/m ³ |

| | |
|----------------------------|---------------------|
| Silica colloidal, Ph. Eur. | |
| Austria OEL - MAKs | 4 mg/m ³ |

| | |
|---|------------------------|
| Titanium dioxide | |
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| ACGIH OELs - Notice of Intended Changes | Listed |
| Australia TWA | 10 mg/m ³ |
| Austria OEL - MAKs | 5 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Bulgaria OEL - TWA | 10.0 mg/m ³ |
| Denmark OEL - TWA | 6 mg/m ³ |
| Estonia OEL - TWA | 5 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Greece OEL - TWA | 10 mg/m ³ |
| | 5 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| | 4 mg/m ³ |
| Latvia OEL - TWA | 10 mg/m ³ |
| Lithuania OEL - TWA | 5 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Poland OEL - TWA | 10.0 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Romania OEL - TWA | 10 mg/m ³ |
| Russia OEL - TWA | 10 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Sweden OEL - TWAs | 5 mg/m ³ |
| Switzerland OEL -TWAs | 3 mg/m ³ |
| Vietnam OEL - TWAs | 6 mg/m ³ |
| | 5 mg/m ³ |

| | |
|------------------------|---------------------|
| Tolterodine L-Tartrate | |
| Pfizer OEL TWA-8 Hr: | 25µg/m ³ |

| | |
|---------------------------------------|--|
| Analytical Method: | Analytical method available for tolterodine. Contact Pfizer Inc for further information. |
| 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). |
| 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. |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 |
| Odor: | No data available. | Odor Threshold: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | 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)

Magnesium stearate

No data available

Microcrystalline cellulose

No data available

Hydroxypropyl methylcellulose

No data available

Silica colloidal, Ph. Eur.

No data available

Sodium starch glycolate

No data available

Stearic acid

No data available

Titanium dioxide

No data available

Dibasic calcium phosphate, dihydrate USP

No data available

Tolterodine L-Tartrate

Predicted Log P 5.24

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

10. STABILITY AND REACTIVITY

Reactivity: No data available

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10. STABILITY AND REACTIVITY

| | |
|---|--|
| 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: | 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. |

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

Magnesium stearate

| | | | |
|-----|------------|------|--------------------------|
| Rat | Oral | LD50 | > 2000 mg/kg |
| Rat | Inhalation | LC50 | > 2000 mg/m ³ |

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 | > 5000mg/kg |

Titanium dioxide

| | | | |
|-----|--------------|------|--------------|
| Rat | Oral | LD50 | > 7500 mg/kg |
| Rat | Subcutaneous | LD50 | 50 mg/kg |

Tolterodine L-Tartrate

| | | | |
|-------|------|-------|-------------|
| Mouse | Oral | LD 50 | > 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 |
|-----------------|--------|----------|

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11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Mild

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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 LOEL Adipose tissue

Tolterodine L-Tartrate

26 Week(s) Mouse Oral 10 mg/kg/day NOEL None identified
52 Week(s) Dog Oral 0.5 mg/kg/day NOEL None identified

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

Tolterodine L-Tartrate

Reproductive & Fertility-Females Mouse Oral 20 mg/kg/day NOEL No effects at maximum dose
Reproductive & Fertility-Males Mouse Oral 30 mg/kg/day NOEL No effects at maximum dose
Embryo / Fetal Development Mouse Oral 20 mg/kg/day NOEL 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 NOEL Not carcinogenic
52 Week(s) Mouse Subcutaneous 0.05 mg/kg/week LOEL Tumors

Tolterodine L-Tartrate

Not specified Mouse Oral 30 mg/kg/day Maximally Tolerated Dose Not carcinogenic

Carcinogen Status: See below

Silica colloidal, Ph. Eur.

IARC: Group 3 (Not Classifiable)

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

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12. ECOLOGICAL INFORMATION

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

Toxicity:

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

Persistence and Degradability: No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Tolterodine L-Tartrate

Predicted Log P 5.24

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

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15. REGULATORY INFORMATION

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



| | |
|--|---------------------------------------|
| Dibasic calcium phosphate, dihydrate USP | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | Not Listed |
| 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 |
| Microcrystalline cellulose | |
| 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 XVII - Restrictions on Certain Dangerous Substances: | Use restricted. See item 9[f]. powder |
| EU EINECS/ELINCS List | 232-674-9 |
| Silica colloidal, Ph. Eur. | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | Not Listed |
| Hydroxypropyl methylcellulose | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| 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 |
| EU EINECS/ELINCS List | Not Listed |
| Sodium starch glycolate | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |

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15. REGULATORY INFORMATION

| | |
|--|---|
| EU EINECS/ELINCS List | Not Listed |
| Titanium dioxide | |
| CERCLA/SARA 313 Emission reporting California Proposition 65 | Not Listed carcinogen initial date 9/2/11 airborne, unbound particles of respirable size |
| Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List | Present Present 236-675-5 |
| Tolterodine L-Tartrate | |
| CERCLA/SARA 313 Emission reporting California Proposition 65 EU EINECS/ELINCS List | Not Listed Not Listed Not Listed |
| Stearic acid | |
| CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List | Not Listed Not Listed Present Present 200-313-4 |

16. OTHER INFORMATION

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

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

Toxic to Reproduction: Category 3
N - Dangerous for the environment

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 7 - Handling and Storage. Updated Section 16 - Other Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Revision date: 19-Mar-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

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