



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Tolterodine System Suitability Mixture</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1671479	
<b>Recommended use</b>	For analytical laboratory use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
<b>Telephone</b>	Customer Service	301-881-0666
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Sensitization, skin	Category 1
	Reproductive toxicity	Category 2
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



<b>Signal word</b>	Warning
<b>Hazard statement</b>	May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child.
<b>Precautionary statement</b>	
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection. Contaminated work clothing must not be allowed out of the workplace.
<b>Response</b>	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If exposed or concerned: Get medical advice/attention.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	Potent pharmacologically active material.

## 3. Composition/information on ingredients

### Mixture

Chemical name	Common name and synonyms	CAS number	%
Tolterodine Tartrate		124937-52-6	>85
Related Impurities		No Data	>4
6-Methyl-4-phenylchroman-2-one		40546-94-9	~1

#### 4. First-aid measures

<b>Inhalation</b>	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and plenty of water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically.
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

#### 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

#### Industrial Use Components

#### Type

#### Value

Tolterodine Tartrate (CAS  
124937-52-6)

TWA

25 micrograms/m3

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

##### Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

##### Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

#### Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

## 9. Physical and chemical properties

### Appearance

Appearance descriptions are general information and not specific to any USP lot.

#### Physical state

Solid.

#### Form

Powder.

#### Color

White. Off-white.

### Odor

Not available.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

Not available.

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not available.

### Upper/lower flammability or explosive limits

#### Flammability limit - lower (%)

Not available.

#### Flammability limit - upper (%)

Not available.

#### Explosive limit - lower (%)

Not available.

#### Explosive limit - upper (%)

Not available.

### Vapor pressure

Not available.

<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	May cause an allergic skin reaction.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Knowledge about health hazard is incomplete.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Component: Blurred vision. Dizziness. Drowsiness. Dry mouth. Dry skin. Headache. Gastrointestinal disturbances. Fatigue.
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### Information on toxicological effects

#### Acute toxicity

Components	Species	Test Results
Tolterodine Tartrate (CAS 124937-52-6)		
<b>Oral</b>		
LD50	Rat	> 200 mg/kg
<b>Skin corrosion/irritation</b>	Knowledge about health hazard is incomplete.	
<b>Serious eye damage/eye irritation</b>	Knowledge about health hazard is incomplete.	
<b>Local effects</b>		
Tolterodine Tartrate		Irritation test Result: Not irritating. Species: Rabbit Organ: Skin.

#### Respiratory or skin sensitization

<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Skin sensitization</b>	May cause an allergic skin reaction.	
6-Methyl-4-phenylchroman-2-one		Local lymph node assay Result: Sensitizing. Species: Mouse
Tolterodine Tartrate		Sensitization Result: Not sensitizing. Species: Guinea pig Organ: Skin.

<b>Germ cell mutagenicity</b>	Knowledge about mutagenicity is incomplete.	
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#### Mutagenicity

Tolterodine Tartrate	Ames test (E. coli) Result: Negative.
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**Mutagenicity**  
Tolterodine Tartrate

Ames test (Salmonella typhimurium)  
Result: Negative.  
Micronucleus test  
Result: Negative.  
Species: Mouse  
Mutagenicity, Chromosomal aberration in human lymphocyte  
Result: Negative.

**Carcinogenicity**  
Tolterodine Tartrate

Knowledge about carcinogenicity is incomplete.  
20 - 30 mg/kg/day Carcinogenicity  
Result: Negative: Not carcinogenic.  
Species: Rat  
30 mg/kg/day Carcinogenicity  
Result: Negative: Not carcinogenic.  
Species: Mouse

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity**

Suspected of damaging fertility or the unborn child.  
A component of this material caused adverse fetal effects in animal studies.

**Reproductivity**

Tolterodine Tartrate

0.8 mg/kg/day Reproductivity  
Result: No embryotoxicity or teratogenicity was observed.  
Species: Rabbit  
20 mg/kg/day Reproductivity  
Result: No anomalies or malformations were observed.  
Species: Mouse  
30 - 40 mg/kg/day Reproductivity  
Result: Showed embryoletality, reduced fetal weight, and increased incidences of fetal abnormalities.  
Species: Mouse

**Specific target organ toxicity - single exposure**

Knowledge about health hazard is incomplete.

**Specific target organ toxicity - repeated exposure**

Knowledge about health hazard is incomplete.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**Further information**

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

## 12. Ecological information

**Ecotoxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

**Persistence and degradability**

No data is available on the degradability of any ingredients in the mixture.

**Bioaccumulative potential**

No data available.

**Mobility in soil**

No data available.

**Other adverse effects**

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

**Disposal instructions**

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

**Local disposal regulations**

Dispose in accordance with all applicable regulations.

**Hazardous waste code**

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products**

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging**

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**14. Transport information****DOT**

Not regulated as dangerous goods.

**IATA**

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

**General information** It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

**15. Regulatory information**

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**Toxic Substances Control Act (TSCA)****TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories** Respiratory or skin sensitization  
Reproductive toxicity

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations****California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

<b>Issue date</b>	09-06-2013
<b>Revision date</b>	03-27-2023
<b>Version #</b>	05
<b>Disclaimer</b>	<p>USP materials are sold for analytical laboratory use only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.</p>