



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
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SAFETY DATA SHEET

Section 1: Identification

Material Name	Tolterodine Tartrate ER Capsules 2mg and 4mg
Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use:	Pharmaceutical product used for overactive bladder
Manufacturer	Hetero Labs Limited Unit III 22-110, Part-II, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854

Section 2: Hazard(s) Identification

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2

EU Classification:

EU Indication of danger: Not classified

Label Elements

Signal word

Warning

Hazard statement

H361d - Suspected of damaging the unborn child

Precautionary statement:

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P405 - Store locked up

P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

No data available

Australian Hazard Classification (NOHSC):

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.

Section 3: Composition/Information on Ingredients

Hazardous

Ingredient	CAS Number	EU EINECS/ELINC S List	EU Classification	GHS Classification	%
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Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*
Starch	9005-25-8	232-679-6	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
Propylene glycol	57-55-6	200-338-0	Not Listed	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	Not Listed	*
Oleic acid	112-80-1	204-007-1	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	Not Listed	*
Ethylcellulose	9004-57-3	Not Listed	Not Listed	Not Listed	*
Medium Chain Fatty Acid Triglyceride	Unassigned	Not Listed	Not Listed	Not Listed	*
Ferric oxide yellow	51274-00-1	257-098-5	Not Listed	Not Listed	*
Shellac	9000-59-3	232-549-9	Not Listed	Not Listed	*
Simethicone	8050-81-5	Not Listed	Not Listed	Not Listed	*
FD&C Blue No. 2	860-22-0	212-728-8	Not Listed	Not Listed	*
Gelatin	9000-70-8	232-554-6	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.				

Section 4: First-Aid Measures

Description of First Aid Measures

Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
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.
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



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Indication of the immediate medical attention and special treatment needed

Notes to Physician: None

Section 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.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 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 materials 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.

Section 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

Section 8: Exposure Controls/Personal Protection

Control Parameters



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Refer to available public information for specific member state Occupational Exposure Limits.

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³

Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Czech Republic OEL - TWA	4.0 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
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	4 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³

Tolterodine L-Tartrate

Pfizer OEL TWA-8 Hr	25µg/m ³
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Propylene glycol

Australia TWA	150 ppm
	474 mg/m ³
	10 mg/m ³
Ireland OEL - TWAs	150 ppm
	470 mg/m ³
	10 mg/m ³
Latvia OEL - TWA	7 mg/m ³
Lithuania OEL - TWA	7 mg/m ³

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	10mg/m ³
Austria OEL - MAKs	5mg/m ³
Belgium OEL - TWA	10mg/m ³
Bulgaria OEL - TWA	10.0mg/m ³
Denmark OEL - TWA	6mg/m ³



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Estonia OEL - TWA	5mg/m ³
France OEL - TWA	10mg/m ³
Greece OEL - TWA	10mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10mg/m ³
	4 mg/m ³
Latvia OEL - TWA	10mg/m ³
Lithuania OEL - TWA	5mg/m ³
OSHA - Final PELS - TWAs:	15mg/m ³
Poland OEL - TWA	10.0mg/m ³
Portugal OEL - TWA	10mg/m ³
Romania OEL - TWA	10mg/m ³
Russia OEL - TWA	10mg/m ³
Spain OEL - TWA	10mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³
Vietnam OEL - TWAs	6 mg/m ³
	5mg/m ³
Oleic acid	
Bulgaria OEL - TWA	10.0mg/m ³
Simethicone	OEB 1 (control exposure to the range of 1000ug/m ³ to 3000ug/m ³)
Pfizer Occupational Exposure Band (OEB):	
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.
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.
Section 9: Physical and Chemical Properties	
Physical state	Capsule
Color	Not data available.
Odor	Not data available.
Odor threshold	Not data available.
Molecular Formula:	Mixture
Solvent Solubility:	Not data available.



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pH:	Not data available.
Melting/Freezing Point (°C):	Not data available.
Boiling Point (°C):	Not data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	
Gelatin	Not data available.
FD&C Blue No. 2	Not data available.
Ethylcellulose	Not data available.
Hydroxypropyl methylcellulose	Not data available.
Medium Chain Fatty Acid	Not data available.
Triglyceride	
Oleic acid	Not data available.
Starch	Not data available.
Sucrose	Not data available.
Shellac	Not data available.
Titanium dioxide	Not data available.
Simethicone	Not data available.
Ferric oxide yellow	Not data available.
Propylene glycol	Not data available.
Tolterodine L-Tartrate	Predicted Log P 5.24
Decomposition Temperature (°C):	Not data available.
Evaporation Rate (Gram/s):	Not data available.
Vapor Pressure (kPa):	Not data available.
Vapor Density (g/ml):	Not data available.
Relative Density:	Not data available.
Viscosity:	Not data available.
Flammability:	
Autoignition Temperature (Solid) (°C):	Not data available.
Flammability (Solids):	Not data available.
Flash Point (Liquid) (°C):	Not data available.
Upper Explosive Limits (Liquid) (% by Vol.):	Not data available.
Lower Explosive Limits (Liquid) (% by Vol.):	Not data available.

Section 10: Stability and Reactivity

Reactivity	Not data available.
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

Section 11: Toxicological Information



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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)

FD&C Blue No. 2

Rat Oral LD50 2 g/kg
Mouse Oral LD50 2500mg/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
Rat Subcutaneous LD50 50 mg/kg

Propylene glycol

Rat Oral LD 50 22,000 mg/kg
Mouse Oral LD 50 24,900mg/kg
Rabbit Dermal LD 50 20,800mg/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)

Propylene glycol

Skin Irritation Rabbit Mild
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)

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

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



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Embryo / Fetal Development Mouse Oral 20 mg/kg/day NOAEL Embryotoxicity, Teratogenic

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

FD&C Blue No. 2

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* 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))

Tolterodine L-Tartrate

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

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

Section 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

Section 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.

Section 14: Transport Information

The following refers to all modes of transportation unless specified below.



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Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Sucrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	Not Listed Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

Hydroxypropyl methylcellulose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	Not Listed Present
Australia (AICS):	Present
Standard for the Uniform	Schedule 4

Scheduling

for Drugs and Poisons:

EU EINECS/ELINCS List	Not Listed
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Starch

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	Not Listed Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

Tolterodine L-Tartrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Ethylcellulose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed



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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Medium Chain Fatty Acid Triglyceride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Ferric oxide yellow	
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	257-098-5
Propylene glycol	
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	200-338-0
Shellac	
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	232-549-9
Simethicone	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Present
Titanium dioxide	
CERCLA/SARA 313 Emission reporting	Not Listed
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
EU EINECS/ELINCS List	236-675-5
Oleic acid	
CERCLA/SARA 313 Emission reporting	Not Listed



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California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	204-007-1
FD&C Blue No. 2	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	212-728-8
Gelatin	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	232-554-6

Section 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 2
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.

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS