Annora

SAFETY DATA SHEET

Section 1: Identification	
Material **Recommended use**	Tolterodine Tartrate Tablets 1 mg & 2 mg Pharmaceutical product used for overactive bladder
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
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
Australian Hazard Classification(NOHSC)	Non-Hazardous Substance. Non-Dangerous Goods.
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.	
Section 3: Composition/Information on Ingredients	
Ingredients	Tolterodine Tartrate USP
CAS	124937-52-6
Section 4: First-Aid Measures	
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.
Skin Contact	Wash skin with soap and water. If irritation occurs or persists, get medical attention.
Eye Contact	Flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Section 5: Fire-Fighting Measures	
Suitable 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.
Special Exposure Hazards:	Not Applicable.
Section 6: Accidental Release Measures	
Measures for Cleaning and 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.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Section 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:	Store as directed by product packaging.

Section 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.
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.
Eyes:	Safety glasses or goggles.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Section 9: Physical and Chemical Properties	
Physical Form	Tablet
Description	**Tolterodine Tartrate Tablets 1 mg** are pale yellow, round, biconvex, film-coated tablets debossed with 'J' on one side and '157' on the other side. They are supplied as follows: Bottle of 60 tablets NDC 31722-805-60 Bottle of 500 tablets NDC 31722-805-05 Blister card of 10 unit dose tablets (ALU-ALU) NDC 31722-805-31 Blister pack of 100 (10x10) unit dose tablets (ALU-ALU) NDC 31722-805-01 Blister card of 10 unit dose tablets (PVC-PVDC) NDC 31722-805-32 Blister pack of 100 (10x10) unit dose tablets (PVC-PVDC) NDC 31722-805-02 **Tolterodine Tartrate Tablets 2 mg** are white, round, biconvex, film-coated tablets debossed with 'J' on one side and '158' on the other side. They are supplied as follows: Bottle of 60 tablets NDC 31722-806-60 Bottle of 500 tablets NDC 31722-806-05 Blister card of 10 unit dose tablets (ALU-ALU) NDC 31722-806-31 Blister pack of 100 (10x10) unit dose tablets (ALU-ALU) NDC 31722-806-01 Blister card of 10 unit dose tablets (PVC-PVDC) NDC 31722-806-32 Blister pack of 100 (10x10) unit dose tablets (PVC-PVDC) NDC 31722-806-02

Section 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.

Section 11: Toxicological Information	
Acute toxicity :	Not classified
Skin corrosion/irritation :	Not classified
Serious eye damage/irritation :	Not classified
Respiratory or skin sensitisation :	Not classified
Germ cell mutagenicity :	Not classified
Carcinogenicity :	Not classified
Reproductive toxicity :	Not classified
Specific target organ toxicity (single exposure) :	Not classified
Specific target organ toxicity (repeated exposure) :	Not classified
Aspiration hazard :	Not classified

Section 12: Ecological Information

Ecology - general: Soluble in Dimethyl formamide and in methanol.
Ecology - air: Not dangerous for the ozone layer (1999/45/EC).

Ecology - soil: The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.

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.

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

Section 15: Regulatory Information

OSHA Label:

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

Section 16: Other Information

Issue Date : 24-11-2021

Version : 00

Further information

Revision date: New issue

Revision note: New issue

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.

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