

## SAFETY DATA SHEET

Section 1: Identification	
<b>Material</b>	Solifenacin Succinate Tablets 5 mg and 10 mg
<b>Recommended use</b>	Pharmaceutical product
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.</b> , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii)	
Section 3: Composition/Information on Ingredients	
<b>Ingredients</b>	Solifenacin (succinate)
CAS	242478-38-2
Section 4: First-Aid Measures	
<b>General</b>	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).
<b>Inhalation</b>	Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.
<b>Skin Contact</b>	Gently wash with plenty of soap and water. Obtain medical attention if irritation develops or persists.
<b>Eye Contact</b>	Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
<b>Ingestion</b>	Do not induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.
<b>Symptoms/Injuries:</b>	
<b>Injuries</b>	Pharmaceutical. When handling in workplace settings, in quantities that are most likely above the therapeutic dose, this product may be harmful if absorbed through the eyes, skin, or respiratory tract.
<b>Inhalation</b>	If tablet is crushed: May cause respiratory irritation
<b>Skin contact</b>	If tablet is crushed: May cause skin irritation.
<b>Eye contact</b>	If tablet is crushed: May cause eye irritation.
<b>Ingestion</b>	Dry mouth, constipation, blurred vision, (accommodation a abnormalities), urinary retention, dry eyes.
Section 5: Fire-Fighting Measures	
<b>Suitable extinguishing media</b>	Alcohol resistant foam. Water spray
<b>Hazardous Combustion Products:</b>	Not considered flammable but may burn at high temperatures.
<b>Fire Fighting Procedures</b>	Use water spray or fog for cooling exposed containers
<b>Fire / Explosion Hazards:</b>	Product is not explosive.
Section 6: Accidental Release Measures	
<b>Health and Safety Precautions</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

<b>Measures for Cleaning / Collecting</b>	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.
<b>Measures for Environmental Protections</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills</b>	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

<b>Handling:</b>	Minimize dust generation and accumulation. Avoid breathing dust and avoid contact with eyes, skin, and clothing. 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.
<b>Storage:</b>	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

## Section 8: Exposure Controls/Personal Protection

<b>Environmental Exposure Controls</b>	Refer to available public information for specific Member State Occupational Exposure Limits.
<b>Engineering Controls</b>	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.
<b>Personal Protective Equipment</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations- preferred, Maintain eyewash facilities in the work area.
<b>Eyes</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection</b>	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

## Section 9: Physical and Chemical Properties

<b>Physical Form</b>	Tablet						
<b>Colour</b>	White to off-white color						
<b>Description</b>	<p>Solifenacin Succinate Tablets, 5 mg are white to off-white color, round, biconvex tablets debossed "V" on one side and "18" on other side. They are supplied as follow:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">Bottle of 30</td> <td>NDC 31722-027-30</td> </tr> <tr> <td>Bottle of 90</td> <td>NDC 31722-027-90</td> </tr> <tr> <td>Carton of 100 (10x10 Unit-dose)</td> <td>NDC 31722-027-31</td> </tr> </table> <p>Solifenacin Succinate Tablets, 10 mg are white to off-white color, round, biconvex tablets debossed "V" on one side and "19" on other side.</p>	Bottle of 30	NDC 31722-027-30	Bottle of 90	NDC 31722-027-90	Carton of 100 (10x10 Unit-dose)	NDC 31722-027-31
Bottle of 30	NDC 31722-027-30						
Bottle of 90	NDC 31722-027-90						
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	Bottle of 30 Bottle of 90 Carton of 100 (10x10 Unit-dose)	NDC 31722-028-30 NDC 31722-028-90 NDC 31722-028-31
<b>Section 10: Stability and Reactivity</b>		
<b>Reactivity</b>	Hazardous reactions will not occur under normal conditions.	
<b>Chemical Stability</b>	Stable under normal conditions	
<b>Oxidizing Properties</b>	No data available	
<b>Conditions to Avoid</b>	Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.	
<b>Hazardous Decomposition Products</b>	Carbon oxides (CO, CO <sub>2</sub> ). Nitrogen oxides.	
<b>Incompatible Materials</b>	Strong acids, strong bases, strong oxidizers	
<b>Section 11: Toxicological Information</b>		
<b>Carcinogenesis, Mutagenesis, Impairment of Fertility</b>	Solifenacin succinate was not mutagenic in the in vitro Salmonella typhimurium or Escherichia coli microbial mutagenicity test or chromosomal aberration test in human peripheral blood lymphocytes with or without metabolic activation, or in the in vivo micronucleus test in rats. No increase in tumors was found following the administration of solifenacin succinate to male and female mice for 104 weeks at doses up to 200 mg/kg/day (5 and 9 times human exposure at the maximum recommended human dose [MRHD], respectively), and male and female rats for 104 weeks at doses up to 20 and 15 mg/kg/day, respectively (<1 times exposure at the MRHD)	
<b>Short Term Known Clinical Effects</b>	Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, drowsiness, muscle weakness, gastrointestinal disturbances, liver effects, and hypersensitivity reactions.	
<b>Section 12: Ecological Information</b>		
<b>Toxicity</b>	No data available	
<b>Environmental Overview</b>	Environmental properties have not been investigated. Releases to the environment should be avoided.	
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Section 13: Disposal Considerations</b>		
<b>Waste treatment method</b>	Dispose of contents and container according to local, regional, national, and international regulations.	
<b>Section 14: Transport Information</b>		
<b>UN-Number DOT,IMDG,IATA</b>	<b>Not Regulated</b>	
<b>UN proper shipping name DOT,IMDG,IATA</b>	<b>Not Regulated</b>	
<b>Transport hazard class(es) DOT,AND,IMDG,IATA</b>	<b>Not Regulated</b>	
<b>Class</b>		
<b>Packing group</b>		

<b>DOT, IMDG, IATA</b>	<b>Not Regulated</b>
<b>Environmental hazards</b>	<b>Not applicable</b>
<b>Special precautions for user</b>	<b>Not applicable</b>
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC code</b>	<b>Not applicable</b>
<b>UN "Model regulation"</b>	<b>Not Regulated</b>
<b>Section 15: Regulatory Information</b>	
No further relevant information available.	
<b>Section 16: Other Information</b>	
<p><b>Issue Date : 02-07-2022</b></p> <p><b>Version : 00</b></p> <p><b>Further information</b></p> <p><b>Revision date: New issue</b></p> <p><b>Revision note: New issue</b></p> <p>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.</p> <p>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.</p>	