ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

SAFETY DATA SHEET

Date: 03/23/2019

Generic Name: Solifenacin succinate tablets, 5 mg and 10 mg.

Brand Equivalent: VESIcare® (Solifenacin succinate) Tablets, 5 mg and 10 mg

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SECTION 1: IDENTIFICATION	
Product Name	Solifenacin tablets, 5 mg and 10 mg
Active substance	Solifenacin succinate
Synonyms	N/A
Formula	C23H26N2O2•C4H6O4
Intended Use	treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency
Chemical Name	Butanedioic acid, compounded with (1S)-(3R)-1-azabicyclo[2.2.2]oct-3-yl 3,4-dihydro-1-phenyl-2(1H)-iso-quinolinecarboxylate (1:1)
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS 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)

3. Composition/Information on ingredients		5 mg	10 mg
Components	**CAS-No**	**Concentration (%w/w)**	
Solifenacin succinate	242478-38-2	3.27	
Lactose Monohydrate 80M, NF	64044-51-5	*	
Corn Starch 400L, NF	9005-25-8	*	
Hypromellose USP (Methocel E5 Premium LV)	9004653	*	
Magnesium Stearate, NF	557040	*	
SheffCoat Yellow 30714072	Mixture	*	
SheffCoat Pink 30714071	Mixture	*	

* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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4. FIRST AID MEASURES	
General	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).
Inhalation	Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.
Skin contact	Gently wash with plenty of soap and water. Obtain medical attention if irritation develops or persists.
Eye contact	Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
Ingestion	Do not induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.
Symptoms/Injuries:	
Injuries	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.
Inhalation	If tablet is crushed: May cause respiratory irritation
Skin contact	If tablet is crushed: May cause skin irritation.
Eye contact	If tablet is crushed: May cause eye irritation.
Ingestion	Dry mouth, constipation, blurred vision, (accommodation a abnormalities), urinary retention, dry eyes.
Chronic	Suspected of damaging the unborn child.
Indication of Any Immediate Medical Attention and Special Treatment Needed	
If you feel unwell, seek medical advice (show the label where possible).	

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5. FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Alcohol resistant foam. Water spray
Hazardous Combustion Products:	Not considered flammable but may burn at high temperatures.
Fire Fighting Procedures	Use water spray or fog for cooling exposed containers
Fire / Explosion Hazards:	Product is not explosive.

6. ACCIDENTAL RELEASE MEASURES	
Health and Safety Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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.
Measures for Environmental Protections	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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	
General Handling	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.
Storage Conditions	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

8. Exposure controls/Personal protection	
Environmental Exposure Controls	Refer to available public information for specific Member State Occupational Exposure Limits.
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.

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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- preferred, Maintain eyewash facilities in the work area.
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 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.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance	Film coated tablets
Physical State	
Color	5 mg –light yellow round shape tablets
Form	10 mg-light pink round shape tablets
Molecular Weight of active	480.55 g/mol
Solubility	610 mg/mL freely soluble at room temperature inwater, glacial acetic acid, dimethyl sulfoxide, and methanol

10. Stability and Reactivity	
Reactivity	Hazardous reactions will not occur under normal conditions.
Chemical Stability	Stable under normal conditions
Oxidizing Properties	No data available
Conditions to Avoid	Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.
Hazardous Decomposition Products	Carbon oxides (CO, CO2). Nitrogen oxides.
Incompatible Materials	Strong acids, strong bases, strong oxidizers

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11. Toxicological Information	
Carcinogenesis, Mutagenesis, Impairment of Fertility	Solifenacin succinate was not mutagenic in the in vitro Salmonella typhimuriumor Escherichia colimicrobial mutagenicity test or chromosomal aberration test in human peripheral blood lymphocytes with or without metabolic activation, or in the in vivomicronucleus 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)
Short Term **Known Clinical Effects**	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.
Acute Toxicity (Species, Route, End Point, Dose) **Alginic acid**	Due to lack of data the classification is not possible
Repeated Dose Toxicity	Due to lack of data the classification is not possible
Reproduction & Development Toxicity	No route specified Dose not specified, Not teratogenic, Negative
Genetic Toxicity	Due to lack of data the classification is not possible
Carcinogenicity	Not listed as a carcinogen by IARC, NTP or US OSHA
Additional Information	Solifenacin succinate had no effect on reproductive function, fertilityor early embryonic development of the fetus in male and female mice treated with 250 mg/kg/day (13 times exposure at the MRHD) of solifenacin succinate, and in male rats treated with 50 mg/kg/day (<1 times exposure at the MRHD) and female rats treated with 100 mg/kg/day (1.7 times exposure at the MRHD) of solifenacin succinate. Reproduction studies have been performed in mice, rats and rabbits. After oral administration of 14C-solifenacin succinate to pregnant mice, drug-related material was shown to cross the placental barrier. No embryotoxicity or teratogenicity was observed in mice treated with 30 mg/kg/day (1.2 times exposure at the maximum recommended human dose [MRHD]). Administration of solifenacin succinate to pregnant mice at doses of 100 mg/kg and greater (3.6 times exposure at the MRHD), during the major period of organ development resulted in reduced fetal body weights. Administration of 250 mg/kg (7.9 times exposure at the MRHD) to pregnant mice resulted in an

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	increased incidence of cleft palate. In utero and lactational exposures to maternal doses of solifenacin succinate of 100 mg/kg/day and greater (3.6 times exposure at the MRHD) resulted in reduced peripartum and postnatal survival, reductions in body weight gain, and delayed physical development (eye opening and vaginal patency).An increase in the percentage of male offspring was also observed in litters from offspring exposed to maternal doses of 250 mg/kg/day. No embryotoxic effects were observed in rats at up to 50 mg/kg/day (<1 times exposure at theMRHD) or in rabbits at up to 50 mg/kg/day (1.8 times exposure at the MRHD).There are no adequate and well-controlledstudies in pregnant women. Because animal reproduction studies are not always predictive of human response,solifenacin succinate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

12. Ecological Information	
Toxicity	No data available
Environmental Overview	Environmental properties have not been investigated. Releases to the environment should be avoided.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available
Mobility in soil	Not available
Other adverse effects	Not available

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13. Disposal considerations	
Waste treatment method	Dispose of contents and container according to local,regional, national, and international regulations.

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

15. Regulatory Information	
EU Indication of danger	Harmful

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	*03/23/2019*
Revision	00
Disclaimer	The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.