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

SAFETY DATA SHEET

Date: 11/30/2022
Generic Name: Diltiazem Hydrochloride Tablets, USP
Brand Equivalent: CARDIZEM ®

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1. IDENTIFICATION	
Product Name	Diltiazem Hydrochloride Tablets, USP 30 mg, 60 mg, 90 mg and 120 mg
Active substance	Diltiazem Hydrochloride
Synonyms	N/A
Formula	$C_{22}H_{26}N_2O_4S$. HCl
Intended Use	Chronic stable angina and angina due to coronary artery spasm
Chemical Name	(+)-5-[2-(Dimethylamino)ethyl]-cis-2,3-dihydro-3-hydroxy-2-(p methoxyphenyl) -1,5-benzothiazepin-4(5H)-one acetate (ester) monohydrochloride
How Supplied	**30 mg:** White, round shaped, film coated tablet **60 mg:** White to off white, round shaped, film coated tablet **90 mg:** White to off white, oval shaped, film coated tablet **120 mg:** White to off white, capsule shaped, film coated tablet
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723
2. HAZARDS IDENTIFICATION	
Fire and Explosion	Expected to be non-combustible
Health	No contraindication is reported
Environment	No information is available about the potential of this product to produce adverse environmental effects

3. COMPOSITION / INFORMATION ON INGREDIENTS		
Components	**CAS-No**	**Concentration (%w/w)**
Diltiazem Hydrochloride, USP	33286-22-5	13.67
Lactose Monohydrate, NF (Supertab 11SD)	5989-81-1	*
Microcrystalline Cellulose, NF (Avicel PH 102)	9004-34-6	*
Hypromellose, USP (Methocel K100 Premium LV CR)	9004-65-3	*
Hydroxypropyl Cellulose, NF (Klucel LXF)	9004-64-2	*
Colloidal Silicon Dioxide , NF(Aerosil 200 Pharma)	7631-86-9	*
Magnesium Stearate, NF	557-04-0	*
Opadry White YS-1-18202-A		
Opadry White YS-1-18202-A contains Hypromellose (6cP), USP Titanium Dioxide, USP Polyethylene Glycol 400,NF	 9004-65-3 13463-67-7 25322-68-3	*

* 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	
Eye contact	Flush eyes with plenty of water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin contact	Remove contaminated clothing and wash exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
Ingestion	Obtain medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
5. FIRE-FIGHTING MEASURES	
Fire and explosion hazards	NA
Fire Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Hazardous Combustion Products	Formation of Toxic gases is possible during heating or fire
Special Protective Actions For Fire-Fighters:	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus
6. ACCIDENTAL RELEASE MEASURES	
Health and safety precautions	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
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
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 be undertaken by trained personnel
7. HANDLING AND STORAGE	
Handling	If tablets or capsules are crushed or broken, avoid breathing dust and avoid contact with eyes, skin and clothing. Minimize dust generation and accumulation. Use with adequate ventilation.
Storage	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames
8. EXPOSURE CONTROLS/ PERSONNEL PROTECTION	
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling	

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9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance **Physical State** **Color**	tablets refer section 1
Odor **Odor** **Odor Threshold**	 No odor Not available
pH	Not available
Other information **Bulk density**	Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	Very soluble in water
Specific Gravity/ Relative Density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available
Thermal/Stability properties **Autoignition temperature**	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL **Explosive limits, UEL**	Not available Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	Not available
Oxidizing Potential	Not available
Vapor Properties **Vapor Density**	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

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10. STABILITY AND REACTIVITY	
Chemical Stability	Stable under normal conditions of use
Conditions to Avoid	Not available
Incompatible Materials	As a precautionary measures, keep away from strong oxidizers.
11. TOXICOLOGICAL INFORMATION	
Carcinogenicity	Not listed by IARC. Rats (ORL) up to 100 mg/kg/day and mice (ORL) up to 30 mg/kg/day. no evidence of carcinogenicity.
Mutagenesis	Not mutagenic in AMES Test.
Impairment of fertility	Doses 480 mg/day or 8 mg/kg/day for a 60 kg patient embryo and fetal lethality. Studies revealed a propensity to cause abnormalities of the skeleton, heart, retina, and tongue. early reductions individual pup weights and pup survival, prolonged delivery and increased incidence of stillbirths. Rat (male and female) ORL up to 100 mg/kg/day: no evidence of impaired fertility was observed.
12. ECOLOGICAL INFORMATION	
Ecotoxicity	No Ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Half-Life Elimination in Human: 3.5h. Not likely to bio accumulate : Log Po/w <3 (EC) or <4 (GHS).
Mobility in soil	Not available
Other adverse effects	Not available
13. DISPOSAL CONSIDERATIONS	
Waste Treatment/Disposal Methods	Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All protective clothing, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters.
Disposal Containers	Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

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Precautions To Be Followed During Waste Handling	Wear proper protective equipment when handling waste materials.
U.S. EPA Waste Number	Not applicable
14. TRANSPORT INFORMATION	
U.S. D.O.T	This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101
Transport CANADA Transportation Of Dangerous Goods Regulations	This product does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada.
IATA	This product does not meet the criteria as Dangerous Goods, per rules of IATA.
IMO Designation	This product is NOT classified as Dangerous Goods by the International Maritime Organization.
European Agreement Concerning The International Carriage of Dangerous Goods by Road (ADR):	This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.
Transport In Bulk According To The IBC CODE	Not applicable.
Environmental Hazards	This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN); components are not specifically listed in Annex III under MARPOL 73/78.
15. REGULATORY INFORMATION	
U.S. SARA Reporting Requirements	The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.
U.S. SARA Threshold Planning Quantity	There are no specific Threshold Planning Quantities for the components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.
U.S. SARA Hazard Categories (Section 311/312, 40 CFR 370-21):	ACUTE: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No
U.S. CERCLA Reportable Quantity (RQ)	Not applicable.
U.S. TSCA Inventory Status:	This product is regulated under Food and Drug Administration (FDA) standards; this product is not subject to requirements under TSCA

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Other U.S. Federal Regulations	Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.
California Safe Drinking Water and Toxic Enforcement Act (Proposition 65)	No component is on the California Proposition 65 Lists.
16. OTHER INFORMATION	
Recommended Restrictions for Use:	Not available
Prepared on	*08/19/2022*
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.