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

SAFETY DATA SHEET

Date: 12/09/20

Generic Name: Ezetimibe Tablets USP 10 mg

Brand Equivalent: Zetia® (ezetimibe) Tablets 10 mg

SECTION 1: IDENTIFICATION	
Product Name	Ezetimibe Tablets USP 10 mg
Active substance	Ezetimibe
Synonyms	N/A
Formula	$C_{24}H_{21}F_2NO_3$
Intended Use	Indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with primary (heterozygous familial and non-familial) hypercholesterolemia
Chemical Name	(3R,4S)-1,4-fluorophenyl-3-[(3S-3-4-fluorophenyl)-3-hydroxypropyl]-4-(4-hydroxyphenyl)-2-azetidinone
How Supplied	10 mg: White capsule shaped tablets, debossed with "SG" on one side and "379" on other side.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723
2. HAZARDS IDENTIFICATION	
Not considered hazardous when handled under normal conditions.	
EMERGENCY OVERVIEW	
Caution Statement:	Each Ezetimibe Tablet intended for oral administration contains Ezetimibe, USP and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.
SWALLOWED Although ingestion is not thought to produce harmful effects, the material may still be damaging to the health of the individual following ingestion, especially where pre-existing organ **EYE** Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn).	

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Slight abrasive damage may also result.

SKIN

The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models).

Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

Open cuts, abraded or irritated skin should not be exposed to this material.

Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.

Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified using animal models).

Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified using animal models); nevertheless exposure by all routes should be minimized as a matter of course.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

Ezetimibe did not produce adverse effects on fertility in male or female rabbits, was not teratogenic in rabbits and rats, nor was it genotoxic in a bacterial mutagenicity study (Ames test) or the chromosomal aberration assay (HPBL) assay.

Routes of Entry	Oral
Effects of Overexposure	Tablets are intended for human consumption under guidance of a physician. Intact Tablets are not considered hazardous under normal handling procedures.
Medical conditions Aggravated by Long Term Exposure	
Carcinogenicity	

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3. Composition/Information on ingredients		
Components	**CAS-No**	**Concentration (%w/w)**
Ezetimibe, USP	163222-33-1	10%
Lactose Monohydrate, NF (80M)	64044-51-5	*
Sodium Starch Glycolate (Type A, NF (Explotab-A)	9063-38-1	*
Sodium Lauryl sulfate, NF (Kolliphor SLS fine)	151-21-3	*
Povidone USP (Plasdone K 29/32)	9003-39-8	
Magnesium Stearate, NF	557040	*

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

4. FIRST AID MEASURES	
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
Skin contact	Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.
Inhalation	Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.
Ingestion	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel. Get medical attention.
Notes to Physician	Treat symptomatically.
Overdose Treatment	In the event of an overdose, symptomatic and supportive measures should be employed.
Self-protection of the first aider	Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

5. FIRE-FIGHTING MEASURES	
Flammable Properties	Not available
Suitable extinguishing media	Water spray, CO2, dry chemical or alcohol resistant foam.
Unusual Fire & Explosion Hazards	Emits toxic fumes under fire conditions
Special Fire Fighting Procedures	Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.
Protective Measures	Prevent runoff from fire control or dilution from entering streams, Sewers, or drinking water supply.

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6. ACCIDENTAL RELEASE MEASURES	
Personal precautions	Use personal protective equipment as required. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.
Environmental precautions	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).
Cleanup Methods	Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and Pharmacologically similar materials.

7. HANDLING AND STORAGE	
Handling	Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.
Container Requirements	Store in the original primary packaging as provided.
Storage	Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.
Specific use(s)	Human pharmaceutical use

8. Exposure controls/Personal protection	
Protective Measures	Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.
Respiratory Protection	Use a NIOSH approved respirator or an alternate approved dust mask should be used.
Eye protection	Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	Chemical resistant gloves
Skin and body Protection	Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust. Avoid contact with skin, eyes and clothing.

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9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance **Physical State** **Color** **Form**	Tablets Refer section 1 Uncoated Tablets
Odor **Odor Threshold**	Not available Not available
pH	5 to 9
Other information **Bulk density**	 Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	hygroscopic
Log Octanol/0.1N HCl Partition Coeff	4.52
Log Octanol/pH 7 buffer Partition Coeff	4.51
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	Insoluble
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	161.8 – 165.9°C
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	
Reactivity	Not applicable
Chemical Stability	Stable under the prescribed storage conditions
Conditions to Avoid	Extremes of temperature
Incompatible products	Strong oxidizers
Hazardous Decomposition products	Oxides of carbon. Oxides of nitrogen. Hydrogen fluoride (HF)

11. Toxicological Information	
Routes of Entry	Ingestion, Inhalation, Eye contact, Skin contact
Inhalation	No data available
Ingestion	No data available
Skin Corrosion/ irritation	Prolonged contact may cause dryness of the skin.
Serious eye damage/eye irritation	Dust may cause slight irritation.
Respiratory sensitizer/Skin sensitizer	No data available
Carcinogenesis	
Mutagenesis	No data available
Impairment of Fertility	No data available
Other information	Adverse effects with Ezetimibe include: The most commonly reported adverse events include upper respiratory tract infections, joint pain, diarrhea, and tiredness. Serious side effects may include anaphylaxis, liver problems, depression, and muscle breakdown. Use in pregnancy and breastfeeding is of unclear safety.

12. Ecological Information	
Toxicity	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
Acute toxicity to Aquatic Invertebrates	No data available.
Toxicity to Aquatic Plants	Not available
Bioaccumulation	Not available
Mobility	Not available

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13. Disposal considerations	
Waste Disposal	Dispose of waste must be in accordance with all applicable Federal, State and local laws.
Measures for Avoidance and Recovery	Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14. Transport Information	
DOT	Not Regulated
IMDG	Not Regulated
ICAO/IATA	Not Regulated
IMO	Not Regulated

15. Regulatory Information	
313 Toxic Release Inventory	
302 Extremely Hazardous Substance (40 CFR 355, Appendix A)	
TSCA Inventory	

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	
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.