ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
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SAFETY DATA SHEET

Date: 12/17/2015

Generic Name: Metformin Hydrochloride Tablets

Brand Equivalent: GLUCOPHAGE®

SECTION 1: IDENTIFICATION	
Product Name	Metformin Hydrochloride Tablets, USP
Active substance	Metformin Hydrochloride
Synonyms	N/A
Formula	$C_{14}H_{11}N_5HCl$
Intended Use	Anti-Hyperglycemic Agent
Chemical Name	N,N-Dimethylimidodicarbonimidic diamide hydrochloride
How Supplied	500 mg and 850 mg tablets are round, white to off-white film coated tablets whereas 1000 mg tablets are white to off-white oval shaped film coated tablets.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

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2. HAZARDS IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.
EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

See Section 16 for full classification information of product and components. **EMERGENCY OVERVIEW: Product Description:** This product consists of oval-shaped white to off-white or brick red mottled tablets. **Health Hazards:** In the workplace, exposure to dusts of damaged tablets may cause irritation to skin, eyes and respiratory system. Non-therapeutic ingestion may be harmful. In therapeutic use, the most common adverse effects have included diarrhea, nausea, vomiting, abdominal bloating, abdominal cramping or pain, flatulence, infection and anorexia. Rarely, lactic acidosis can occur, which is a serious metabolic adverse effect. These effects may be possible as a result of workplace exposure. Refer to Section 11 (Toxicological Information) for additional information on adverse effects. **Flammability Hazards:** This product is combustible and can ignite if highly heated or if exposed to direct flame. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including calcium, carbon, iron, titanium and nitrogen oxides and hydrogen chloride). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** May cause harm to aquatic organisms if accidentally released. All environmental release should be avoided. **Emergency Recommendations:** Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

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3. Composition/Information on ingredients		
Components	**CAS-No**	**Concentration (%w/w)**
Metformin HCl granules DC 95% (COMPRESSO MF 95P) *	1115-70-4	98.04
Sheff coat white which contains		
Hydroxy propyl cellulose 3cps	9004-65-3	1.96
Hydroxy propyl cellulose 6cps	9004-65-3	
Titanium dioxide	13463-67-7	
Polyethylene glycol 400	25322-68-3	
Polysorbate 80	9005-65-6	

4. FIRST AID MEASURES	
Skin or Eye Exposure	Flush affected area with water for 20 minutes.
Inhalation	Remove victim to fresh air if dusts are inhaled.
Ingestion	Call Physician or Poison Control Center. Give victim up to three glasses of water. Do not induce vomiting.
Injection	Not a likely route of exposure.
Medical Conditions Aggravated by Exposure	Pre-existing hepatic disease, a past history of lactic acidosis (of any cause), renal impairment, cardiac failure requiring pharmacological therapy, chronic hypoxic lung and those disorders to target organs described in Section 11 may be aggravated upon exposure to this product.
Indication of immediate medical attention and Special Treatment if needed	Treat symptoms and eliminate exposure.

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5. FIRE-FIGHTING MEASURES	
Flash Point	Not available
Auto ignition Temperature	Not available.
Flammable Limits (in air by volume, %)	Not applicable
Fire Extinguishing Media	All types acceptable.
Unsuitable Fire Extinguishing Media	None known
Special Hazards Arising From The Substance	This product must be substantially pre-heated before ignition can occur. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including calcium, carbon, iron, titanium and nitrogen oxides and hydrogen chloride).
Special Protective Actions For Fire-Fighters	Firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

6. ACCIDENTAL RELEASE MEASURES	
Personal Precautions, Protective Equipment & Emergency Procedures	Spill kits should be kept in or near material handling areas. Avoid generating airborne aerosols of this product during spill response procedures.
Protective Equipment Small Spills	Nitrile or other appropriate gloves, labcoat or other protective clothing and eye protection
Large Spills:	Double nitrile or other appropriate gloves, protective clothing (i.e., disposable Tyvek coveralls) and eye/face protection. When there is any danger of airborne aerosols being generated, use a full-face respirator equipped with a High Efficiency Particulate (HEPA) filter or Self-Contained Breathing Apparatus (SCBA).
Methods For Clean-Up & Containment Small Spills	Clean with wet absorbent pads and dispose of properly. Decontaminate the spill area using a bleach and detergent solution and rinse with clean water
Large Spills	Restrict access to the spill areas. Clean with wet absorbent pads and dispose of properly. Decontaminate the spill area using a bleach and detergent solution and rinse with clean water. Do not apply chemical in-activators as they may produce hazardous by-products
All Spills	Place all spill residues in an appropriate, labeled container and seal. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered material and report spill per regulatory requirements.
Environmental Precautions	Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

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7. HANDLING AND STORAGE	
Precautions for safe handling	All employees who handle this material should be thoroughly trained to handle it safely. Do not eat or drink while handling this material. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection)
Conditions for safe Storage	Containers of this material must be properly labeled. Recommended Storage Temperature: 20° to 25°C (68° to 77°F). Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.
Specific end use(S)	This is a human pharmaceutical.
Protective Practices During Maintainence of Contaminated Equipment	When cleaning nondisposable equipment, wear appropriate personal protective equipment.

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8. Exposure controls/Personal protection	
Exposure Limits/ Control Parameters Ventillation & Engineering Controls	Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used.
Protective Equipment:	*The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including* U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132), *equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02,* Z94.3-M1982, *Industrial Eye and Face Protectors and* CSA Standard Z195-02, *Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*
Respiratory Protection	None needed for normal handling of this product. For large spill response or tasks involving generation of aerosols, use the appropriate Self-Contained Breathing Apparatus (SCBA) pressure-demand or other positive-pressure mode.
Eye Protection	Wear splash goggles or safety glasses as appropriate for the task.
Hand Protection	Wear nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response.
Skin Protection	Use appropriate protective clothing for the task (e.g., lab coat, etc.).

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9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance **Physical State** **Color** **Form**	 solid white film coated tablets
Odour **Odour** **Odor Threshold**	 Not available 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	soluble
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
Decomposition Products	*Combustion:* Products of thermal decomposition may include calcium, carbon, iron, titanium and nitrogen oxides and hydrogen chloride. *Hydrolysis:* None known.
Materials with which Substance is Incompatible	Incompatible with strong oxidizing agents, and strong acids.
Possibility of Hazardous Reaction/Polymerization	Will not occur.
Conditions To Avoid	Exposure to or contact with extreme temperatures, incompatible chemicals.

11. Toxicological Information	
Symptoms of Exposure by Route of Exposure	The main expected routes of occupational exposure to this product are via inhalation of dusts, eye and skin contact. Exposure may also cause effects described under 'Other Potential Health Effects'.
Inhalation	Aerosols may irritate the nose and upper respiratory system. Symptoms may include sneezing, coughing, and nasal congestion.
Contact with Skin or Eyes	Mild irritation possible. Symptoms may include itching and redness and swelling
Skin Absorption	No information
Ingestion:	May irritate the mouth, throat, and gastrointestinal system.
Injection	Not a likely route of exposure
Carcinogenicity	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA
Reproductive Toxicity	Due to lack of data the classification is not possible
Developmental Toxicity	Due to lack of data the classification is not possible
Pharmacokinetics/Toxicokinetics	Due to lack of data the classification is not possible
Other Toxicity Information	Due to lack of data the classification is not possible

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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	Not available
Mobility in soil	Not available
Other adverse effects	Not available

13. Disposal considerations	
Advice on Disposal and Packaging	Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.

14. Transport Information	
U.S. Department of Transportation	This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.
International Air Transport Association (IATA)	This product does not meet the criteria as Dangerous Goods, per rules of IATA
International Maritime Organization (IMO) Designation	This product is NOT classified as Dangerous Goods by the International Maritime Organization.
Environmental Hazards	No component meets the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN); no component is specifically listed in Annex III under MARPOL 73/78.

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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 Threshhold Planning Quantity	There are no specific Threshold Planning Quantities for 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 standards; this product is not subject to requirements under TSCA
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 of this product is listed on the California Proposition 65 Lists.

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	*12/17/15*
Revision	01
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.