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

SAFETY DATA SHEET

Date: 03/25/2020

Generic Name: Metaxalone Tablets, USP 400 mg and 800 mg.

Brand Equivalent: Skelaxin® (Metaxalone) Tablets, 400 mg 800 mg

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SECTION 1: IDENTIFICATION	
Product Name	Metaxalone Tablets, USP
Active substance	Metaxalone
Synonyms	N/A
Formula	$C_{12}H_{15}NO_3$
Intended Use	Metaxalone is a skeletal muscle relaxant indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions.
Chemical Name	5-(3,5-dimethylphenoxymethyl)-1,3-oxazolidin-2-one
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
Additional Hazard Information: Short Term:	Dust may cause irritation (based on components). The active ingredient is not acutely toxic.
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.
Statement of Hazard	Non-hazardous in accordance with international standards for workplace safety.
EU Classification **EU Indication of danger**	Harmful
GHS Classification	Acute oral toxicity: Category 4
Australian Hazard Classification (NOHSC):	Hazardous Substance. Non-Dangerous Goods.

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3. Composition/Information on ingredients		
Components	**CAS-No**	**Concentration (%w/w)**
Metaxalone, USP*	1665-48-1	82.051
Povidone, USP (Kollidon® 90F)	9003398	*
Corn Starch, NF (400L-Modified Food Starch)	9005258	*
Sodium Alginate, NF (Protanal PH 1322)	9005383	*
Alginic acid, NF (Protacid F 120 NM)	9005327	*
Ferric Oxide Red, NF	1309371	*
Copovidone, NF (Plasdone S-630)	25086899	*
Pregelatinized Starch, NF (Starch 1500)	9005-25-8	*
Magnesium Stearate, NF	557040	*
Isopropyl alcohol, USP*	67630	*

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

4. FIRST AID MEASURES	
Eye contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

5. FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Extinguish fires with CO2, extinguishing powder, foam, or Water.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures	During all fire fighting activities, wear appropriate protective equipment, including selfcontained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mist) may fuel fires/explosions.

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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 as directed by product packaging.

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.
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.

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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 **Physical State** **Color** **Form** **Molecular Formula**	 uncoated tablets light pink (400 mg), pink (800 mg) Round Tablets (400 mg) capsule shaped tablets(800 mg) Mixture
Odour **Odour** **Odor Threshold**	 Not available Not available
pH	Not available
Melting/Freezing Point (°C)	Not available
Boiling Point (°C)	Not available
Log Octanol/Water Partition Coeff [log Kow]	Not available
Evaporation rate	Not available
Viscosity	Not available
Vapor Pressure	Not available
Vapor Density	Not available
Relative Density	Not available
Decomposition Temperature (°C)	Not available
Other information **Bulk density**	 Not available
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	mixture
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Specific Gravity/ Relative Density	Not available
% Volatile	Not available
Thermal/Stability properties **Autoignition temperature**	 Not available
Explosive Limits, LEL **Explosive limits, UEL**	Not available Not available
Flammability (Solids)	Not available

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Flash point	Not available
Oxidizing Potential	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. Stability and Reactivity	
Reactivity	No data available
Chemical Stability	Stable under normal conditions
Oxidizing Properties	No data available
Conditions to Avoid	Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous Decomposition Products	No data available
Incompatible Materials	As a precautionary measure, keep away from strong oxidizers

11. Toxicological Information	
General Information	The information included in this section describes the potential hazards of the individual ingredients.
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
Other Toxicity Information	Due to lack of data the classification is not possible

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 waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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	*05/20/2021*
Revision	01
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