


**SAFETY DATA SHEET**

Date: 12/05/2015

Generic Name: Carisoprodol Tablets, USP 350 mg

Brand Equivalent: SOMA Tablets

<b>SECTION 1: IDENTIFICATION</b>	
<b>Product Name</b>	Carisoprodol Tablets, USP 350 mg
<b>Active substance</b>	Carisoprodol
<b>Synonyms</b>	N/A
<b>Formula</b>	C <sub>12</sub> H <sub>24</sub> N <sub>2</sub> O <sub>4</sub>
<b>Intended Use</b>	For the relief of discomfort associated with acute, painful musculoskeletal conditions in adults.
<b>Chemical Name</b>	N-isopropyl-2-methyl-2-propyl-1,3-propanediol dicarbamate
<b>Manufacturer Name &amp; Address</b>	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
<b>Telephone No.</b>	631-434-2723

<b>2. HAZARDS IDENTIFICATION</b>	
<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Acute toxicity, oral Category 4
<b>OSHA hazard(s)</b>	Not classified.
<b>Symbol</b>	 GHS07
<b>Signal word</b>	Warning
<b>Hazard statements</b>	May form combustible dust concentrations in air. H302 - Harmful if swallowed
<b>Precautionary statements</b>	P264 - Wash hands, forearms, and other exposed areas thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell. P330 - Rinse mouth. P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.
<b>Other Hazards</b>	Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. Most common adverse reactions are drowsiness, dizziness, and headache.
<b>Unknown Acute Toxicity (GHS-US)</b>	No data available

<b>3. Composition/Information on ingredients</b>		
<b>Components</b>	<b>CAS-No</b>	<b>Concentration (%w/w)</b>
Carisoprodol, USP	78-44-4	72.46
Microcrystalline Cellulose, NF (Avicel PH 101)	9004-34-6	8.90
Lactose Monohydrate, NF (80 M)	64044-51-5	4.45
Pregelatinized Starch, NF (Starch 1500)	9005-25-8	4.45
Croscarmellose Sodium, NF (Vivasol)	74811-65-7	4.97
Povidone USP (Plasdone K 29/32)	9003-39-8	3.73
Silicon Dioxide, NF (Syloid 244FP)	7631-86-9	0.31
Magnesium Stearate, NF	557-04-0	0.72

<b>4. FIRST AID MEASURES</b>	
<b>First-aid Measures General</b>	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).
<b>Inhalation</b>	The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.
<b>Skin Contact</b>	Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.
<b>Eye Contact</b>	The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
<b>Ingestion</b>	Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.
<b>Indication of immediate medical attention and special treatment needed</b>	If exposed or concerned, get medical advice and attention

<b>5. FIRE-FIGHTING MEASURES</b>	
<b>Suitable extinguishing media</b>	Water spray, dry chemical, foam, carbon dioxide
<b>Unsuitable extinguishing media</b>	Do not use a heavy water stream. Use of heavy stream of water may spread fire.
<b>Specific hazards arising from the chemical</b>	<b>Fire Hazard:</b> Combustible Dust. <b>Explosion Hazard:</b> Dust clouds can be explosive <b>Reactivity:</b> Hazardous reactions will not occur under normal conditions
<b>Precautionary Measures Fire</b>	Exercise caution when fighting any chemical fire
<b>Fire-fighting instructions</b>	Use water spray or fog for cooling exposed containers.
<b>Protection During Firefighting</b>	Do not enter fire area without proper protective equipment, including respiratory protection

<b>6. ACCIDENTAL RELEASE MEASURES</b>	
<b>Personal precautions, protective equipment and emergency procedures</b>	<b>General Measures:</b> Avoid all unnecessary exposure.
<b>For Emergency Responders</b>	<b>Protective Equipment:</b> Use appropriate personal protection equipment (PPE). <b>Emergency Procedures:</b> Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.
<b>For Non-emergency Personnel</b>	<b>Protective Equipment:</b> Use appropriate personal protection equipment (PPE). <b>Emergency Procedures:</b> Evacuate unnecessary personnel.
<b>Methods and materials for containment and cleaning up</b>	<b>For Containment:</b> Contain and collect as any solid. <b>Methods for Cleaning Up:</b> Clean up spills immediately and dispose of waste safely. Avoid actions that cause dust to become airborne during clean-up such as dry sweeping or using compressed air. Use HEPA vacuum or thoroughly wet with water to clean-up dust. Use PPE described in Section 8.

<b>7. HANDLING AND STORAGE</b>	
<b>Precautions for safe handling</b>	<p><b>Additional Hazards When Processed:</b> Use only as directed by the information identified in the package insert.</p> <p><b>Precautions for Safe Handling:</b> Avoid creating or spreading dust.</p> <p><b>Hygiene Measures:</b> Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.</p>
<b>Conditions for Safe Storage, Including Any Incompatibilities</b>	<p><b>Storage Conditions:</b> Store tightly closed in a dry, cool and well-ventilated place.</p> <p><b>Incompatible Products:</b> Strong acids. Strong bases. Strong oxidizers.</p> <p><b>Storage Temperature:</b> 20 - 25 °C (68 - 77 °F)</p>
<b>Specific use(s)</b>	For the relief of discomfort associated with acute, painful musculoskeletal conditions in adults. Pharmaceutical.

<b>8. Exposure controls/Personal protection</b>	
<b>Respiratory Protection</b>	If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn.
<b>Eye protection</b>	Chemical safety goggles.
<b>Hand protection</b>	Wear chemically resistant protective gloves.
<b>Materials for Protective Clothing</b>	Chemically resistant materials and fabrics.
<b>Appropriate Engineering Controls</b>	Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
<b>General Information</b>	
<i>Appearance</i> <b>Physical State</b> <b>Color</b>	Tablet white
<i>Odour</i> <b>Odour</b> <b>Odor Threshold</b>	Not available Not available
<b>pH</b>	Not available
<i>Other information</i>	
<b>Bulk density</b>	Not available
<b>Evaporation rate</b>	Not available
<b>Molecular formula</b>	Not applicable
<b>Hydrolysis/Photolysis</b>	Not available
<b>Hygroscopicity</b>	Not available
<b>Molecular Weight</b>	Not applicable
<b>Log Octanol/Water Partition Coeff [log Kow]</b>	Not available
<b>Surface Tension</b>	Not available
<b>pKa</b>	Not available
<b>Particle Size</b>	Not available
<b>Solubility, Water</b>	very slightly soluble
<b>Specific Gravity/ Relative Density</b>	Not available
<b>Viscosity, dynamic</b>	Not available
<b>Viscosity, kinematic</b>	Not available
<b>% Volatile</b>	Not available
<i>Thermal/Stability properties</i>	
<b>Autoignition temperature</b>	Not available
<b>Boiling Point</b>	Not available
<b>Thermal decomposition</b>	Not available
<b>Explosive Limits, LEL</b>	Not available
<b>Explosive limits, UEL</b>	Not available
<b>Explosiveness</b>	Not available
<b>Flammability</b>	Not available
<b>Flash point</b>	Not available
<b>Melting Point</b>	Not available
<b>Oxidizing Potential</b>	Not available
<i>Vapor Properties</i>	
<b>Vapor Density</b>	Not available
<b>Vapor Pressure</b>	Not available
<b>Saturated Vapor Concentration</b>	Not available

<b>10. Stability and Reactivity</b>	
<b>Reactivity</b>	Hazardous reactions will not occur under normal conditions.
<b>Chemical Stability</b>	Stable under recommended handling and storage conditions (see section 7).
<b>Possibility of Hazardous Reactions</b>	Hazardous polymerization will not occur.
<b>Conditions to Avoid</b>	Direct sunlight. Extremely high or low temperatures. Generation of airborne dust.
<b>Incompatible Materials</b>	Strong acids, strong bases, strong oxidizers.
<b>Hazardous Decomposition Products</b>	Thermal decomposition generates: Carbon oxides (CO, CO <sub>2</sub> ). Nitrogen oxides.

<b>11. Toxicological Information</b>	
<b>Routes of Entry</b>	Ingestion, Inhalation, Eye contact, Skin contact
<b>Acute Toxicity</b>	Oral: Harmful if swallowed.
<b>Skin Corrosion/Irritation</b>	Not classified
<b>Serious Eye Damage/Irritation</b>	Not classified
<b>Respiratory or Skin Sensitization</b>	Not classified
<b>Germ Cell Mutagenicity</b>	Not classified
<b>Carcinogenicity</b>	Not classified
<b>Reproductive Toxicity</b>	Not classified
<b>Specific Target Organ Toxicity (Single Exposure)</b>	Not classified
<b>Specific Target Organ Toxicity (Repeated Exposure)</b>	Not classified
<b>Aspiration Hazard</b>	Not classified
<b>Symptoms/Injuries After Ingestion</b>	Harmful if swallowed.

<b>12. Ecological Information</b>	
<b>Ecology - General</b>	Not classified.
<b>Persistence and degradability</b>	No additional information available
<b>Bioaccumulative potential</b>	No additional information available
<b>Mobility in soil</b>	No additional information available
<b>Other adverse effects</b>	No additional information available

<b>13. Disposal considerations</b>	
<b>Waste treatment methods</b> <b>Sewage Disposal</b> <b>Recommendations</b>	Do not empty into drains; dispose of this material and its container in a safe way.
<b>Waste Disposal</b> <b>Recommendations</b>	Dispose of waste material in accordance with all local, regional, national, and international regulations.

<b>14. Transport Information</b>	
<b>In Accordance with DOT</b>	Not regulated for transport
<b>In Accordance with IMDG</b>	Not regulated for transport
<b>In Accordance with IATA</b>	Not regulated for transport

<b>15. Regulatory Information</b>	
<b>SARA Section 311/312</b> <b>Hazard Classes</b>	Delayed (chronic) health hazard

<b>16. Other information</b>	
<b>Recommended Restrictions for Use:</b>	Not available
<b>Prepared on</b>	
<b>Revision</b>	01
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