

**SAFETY DATA SHEET**

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 Date: 07/24/18

Generic Name: Nabumetone Tablets, USP 500 mg &amp; 750 mg

 Brand Equivalent: RELAFEN<sup>®</sup>  
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<b>SECTION 1: IDENTIFICATION</b>	
<b>Product Name</b>	Nabumetone Tablets, USP 500 mg & 750 mg
<b>Active substance</b>	Nabumetone
<b>Synonyms</b>	N/A
<b>Formula</b>	C <sub>15</sub> H <sub>16</sub> O <sub>2</sub>
<b>Intended Use</b>	Nonsteroidal anti-inflammatory drug
<b>Chemical Name</b>	4-(6-methoxynaphthalen-2-yl)butan-2-one
<b>How Supplied</b>	500 mg: White colored, Oval shaped, Biconvex, film coated tablets, debossed with 'SG' on one side '465' on other side. 750mg: White colored, Oval shaped, Biconvex, film coated tablets, debossed with 'SG' on one side '466' on other side.
<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>Fire and Explosion</b>	Expected to be non-combustible
<b>Health</b>	Nabumetone tablets are contraindicated in patients with known hypersensitivity to Nabumetone or product excipients. Nabumetone tablets should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking Aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients. Nabumetone tablets are contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.
<b>Hazard statements</b>	
<b>Precautionary statements</b>	Refer to HAZARDS IDENTIFICATION section.

<b>3. Composition/Information on ingredients</b>		
<b>Components</b>	<b>CAS-No</b>	<b>Concentration (%w/w)</b>
Nabumetone, USP	42924-53-8	78.3%
Sodium Starch Glycolate, NF/ (Type A) (Primojel)	9063-38-1	*
Sodium Lauryl Sulphate, NF (Kolliphor SLS fine)	151-21-3	*
Hypromellose, USP (Methocel E5 Premium LV)	9004-65-3	*
Microcrystalline Cellulose, NF (Avicel PH 102)	9004-34-6	*
Hypromellose, USP 5 cP	9004-65-3	*
Titanium Dioxide , USP	13463-67-7	*
Macrogol / Polyethylene Glycol 400, NF	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.

<b>4. FIRST AID MEASURES</b>	
<b>General advice</b>	Immediate medical attention is required. If symptoms persist, call a physician.
<b>Eye contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.
<b>Skin contact</b>	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Ingestion</b>	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Washout the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
<b>Notes to Physician</b>	Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of an anti-inflammatory.
<b>Self-protection of the first aider</b>	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.

<b>5. FIRE-FIGHTING MEASURES</b>	
<b>Flammable Properties</b>	Not available
<b>Suitable extinguishing media</b>	Dry chemical, Water spray, Foam
<b>Unsuitable extinguishing media</b>	Do NOT use water jet
<b>Protection of Firefighters</b>	Wear self-contained breathing apparatus and protective suit. Wear self contained breathing apparatus for fire fighting if necessary.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.
<b>Other information:</b>	Decontaminate protective clothing and equipment before reuse.

<b>6. ACCIDENTAL RELEASE MEASURES</b>	
<b>Personal precautions</b>	Use personal protective equipment as required. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.
<b>Environmental precautions</b>	Prevent release to drains and waterways. Prevent release to the environment.
<b>Containment Methods</b>	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).
<b>Cleanup Methods</b>	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.

<b>7. HANDLING AND STORAGE</b>	
<b>Handling Precautions</b>	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product. Use with local exhaust ventilation. Handle in accordance with good industrial hygiene and safety practice. Corrosive hazard. Wear protective gloves/clothing and eye/face protection. Thermal decomposition can lead to release of toxic/corrosive gases and vapors.
<b>Container Requirements</b>	Store in the original primary packaging as provided.
<b>Storage Conditions</b>	Store at 25°C.
<b>Specific use(s)</b>	Human pharmaceutical use

<b>8. Exposure controls/Personal protection</b>	
<b>Engineering Controls and Ventilation</b>	Use NIOSH approved respirator if exposed to vapors/dust/aerosol.
<b>Respiratory Protection</b>	Chemical resistant protective gloves
<b>Eye protection</b>	Safety glasses with side-shields
<b>Hand protection</b>	Laboratory: laboratory coat.
<b>Skin and body Protection</b>	Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust. Avoid contact with skin, eyes and clothing.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
<b>General Information</b>	
<i>Appearance</i>	Tablets
<b>Physical State</b>	
<b>Color</b>	White
<b>Form</b>	Film coated Tablets
<b>Odor</b>	Not available
<b>Odor Threshold</b>	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>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>	372.3 °C
<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>	78.0-82 °C
<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>	Not applicable
<b>Chemical Stability</b>	Stable under normal conditions
<b>Conditions to Avoid</b>	Extremes of temperature and direct sunlight.
<b>Incompatible products</b>	Strong oxidizing agents
<b>Hazardous Decomposition products</b>	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx)
<b>Hazardous Reactions</b>	Carbon oxides

<b>11. Toxicological Information</b>	
<b>Routes of Entry</b>	Ingestion, Inhalation, Eye contact, Skin contact
<b>Eye Irritation</b>	Not irritating to eyes
<b>Skin Irritation</b>	Irritation is not expected following direct contact.
<b>Target Organ Effects</b>	No specific target organ effects have been identified.
<b>Genetic Toxicity</b>	Not expected to be genotoxic under occupational exposure conditions.
<b>Carcinogenicity</b>	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
<b>Reproductive Toxicity</b>	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
<b>Developmental Toxicity</b>	Due to lack of data the classification is not possible
<b>Pharmacokinetics/Toxicokinetics</b>	Due to lack of data the classification is not possible
<b>Other Toxicity Information</b>	None known for occupational exposure.

<b>12. Ecological Information</b>	
<b>Ecotoxicity</b>	No ecotoxicity data noted for the ingredient(s).
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	Not available
<b>Mobility in soil</b>	Not available
<b>Other adverse effects</b>	Not available

<b>13. Disposal considerations</b>	
<b>Advice On Disposal And Packaging</b>	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.
<b>Other information</b>	Disposal by incineration is recommended.

<b>14. Transport Information</b>	
This material is not a dangerous good for the purpose of transportation in all modes.	

<b>15. Regulatory Information</b>	
<b>313 Toxic Release Inventory</b>	No components listed on the SARA 313 inventory.
<b>TSCA Inventory</b>	Not listed. Food, drug and cosmetic products are exempt from TSCA.

<b>16. Other information</b>	
<b>Recommended Restrictions for Use:</b>	Not available
<b>Prepared on</b>	
<b>Revision</b>	00
<b>Disclaimer</b>	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.