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

SAFETY DATA SHEET

Date: 07/24/18

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

Brand Equivalent: RELAFEN ®

SECTION 1: IDENTIFICATION	
Product Name	Nabumetone Tablets, USP 500 mg & 750 mg
Active substance	Nabumetone
Synonyms	N/A
Formula	$C_{15}H_{16}O_2$
Intended Use	Nonsteroidal anti-inflammatory drug
Chemical Name	4-(6-methoxynaphthalen-2-yl)butan-2-one
How Supplied	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.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
Fire and Explosion	Expected to be non-combustible
Health	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.
Hazard statements	
Precautionary statements	Refer to HAZARDS IDENTIFICATION section.

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3. Composition/Information on ingredients		
Components	**CAS-No**	**Concentration (%w/w)**
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.

4. FIRST AID MEASURES	
General advice	Immediate medical attention is required. If symptoms persist, call a physician.
Eye contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.
Skin contact	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.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Ingestion	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.
Notes to Physician	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.
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.

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

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 Precautions	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.
Container Requirements	Store in the original primary packaging as provided.
Storage Conditions	Store at 25°C.
Specific use(s)	Human pharmaceutical use

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8. Exposure controls/Personal protection	
Engineering Controls and Ventilation	Use NIOSH approved respirator if exposed to vapors/dust/aerosol.
Respiratory Protection	Chemical resistant protective gloves
Eye protection	Safety glasses with side-shields
Hand protection	Laboratory: laboratory coat.
Skin and body Protection	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.
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 White Film coated Tablets
Odor **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
Log Octanol/Water Partition Coeff [log Kow]	 Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	very slightly 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	372.3 °C
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	78.0-82 °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 normal conditions
Conditions to Avoid	Extremes of temperature and direct sunlight.
Incompatible products	Strong oxidizing agents
Hazardous Decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx)
Hazardous Reactions	Carbon oxides

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

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.
Other information	Disposal by incineration is recommended.

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

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

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	
Revision	00
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