SAFETY DATA SHEETS

This SDS packet was issued with item:

078947739

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078944638

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: Naproxen Tablets, USP 250 mg, 375 mg & 500mg

Brand Equivalent: Naprosyn® (naproxen) Tablets

SECTION 1: IDENTIFICATION	
Product Name	Naproxen Tablets, USP 250 mg, 375 mg & 500 mg
Active substance	Naproxen
Synonyms	N/A
Formula	$C_{14}H_{14}O_3$
Intended Use	Anti-inflammatory, Analgesic
Chemical Name	(S)-6-methoxy-α-methyl-2-naphthaleneacetic acid
How Supplied	250 mg: Light yellow, round shaped tablets debossed with "SG" along with break-line on one side and "434" on the other side. 375 mg: Light yellow, capsule shaped tablets debossed with "SG" on one side and "435" on the other side. 500 mg: Light yellow, oblong shaped tablets debossed with "SG" along with break-line on one side and "436" on the other side.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723
2. HAZARDS IDENTIFICATION	
Not considered hazardous when handled under normal conditions.	
EMERGENCY OVERVIEW	
Caution Statement:	Each Naproxen Tablet intended for oral administration contains Naproxen, USP and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

NOTE:

Cardiovascular Risk: NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. Naproxen tablets are contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk: NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients

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are at greater risk for serious gastrointestinal events.	
Routes of Entry	Oral
Effects of Overexposure	Tablets are intended for human consumption under guidance of a physician. Intact Tablets are not considered hazardous under normal handling procedures.
Medical conditions Aggravated by Long Term Exposure	For nonsteroidal anti-inflammatory drugs (NSAIDs): Gastrointestinal ulceration or bleeding, Hypertension, Kidney impairment, Blood disorders, Cardiovascular thrombotic events, Stroke, Central nervous system effects, Coma.
Carcinogenicity	Naproxen - Not listed by IARC, NTP and OSHA.

3. Composition/Information on ingredients

Components	CAS-No	Concentration (%w/w)
Naproxen, USP	22204-53-1	92.6%
Croscarmellose Sodium, NF (Vivasol®GF)	74811657	*
Ferric Oxide Yellow, NF	51274001	*
Povidone USP (Kollidon®90F)	9003398	*
Magnesium Stearate, NF	557040	*

* 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

Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
Skin contact	Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.
Inhalation	Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.
Ingestion	Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.
Notes to Physician	Naproxen is a nonsteroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic properties. The mechanism of action of the naproxen anion, like that of other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition.
Overdose Treatment	Patients should be managed by symptomatic and supportive care following a NSAID overdose. There are no specific antidotes. Hemodialysis does not decrease the plasma concentration of naproxen because of the high degree of its protein binding. Emesis and/or activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose. Forced diuresis, alkalinization of urine or hemoperfusion may not be useful due to high protein binding.

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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.

5. FIRE-FIGHTING MEASURES	
Flammable Properties	Not available
Suitable extinguishing media	Water spray, CO2, dry chemical or alcohol resistant foam.
Unusual Fire & Explosion Hazards	Emits toxic fumes under fire conditions
Special Fire Fighting Procedures	Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.
Protective Measures	Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

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	Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.
Container Requirements	Store in the original primary packaging as provided.
Storage	Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.
Specific use(s)	Human pharmaceutical use

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8. Exposure controls/Personal protection	
Protective Measures	Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.
Respiratory Protection	Use a NIOSH approved respirator or an alternate approved dust mask should be used.
Eye protection	Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	Chemical resistant gloves
Skin and body Protection	Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust. Avoid contact with skin, eyes and clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance **Physical State** **Color** **Form**	Tablets Light Yellow Uncoated 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	Non-hygroscopic
Log Octanol/Water Partition Coeff [log Kow]	3.18
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	Low soluble
Specific Gravity/ Relative Density	Not available
Viscosity, dynamic	Not available

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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	152 °C
Oxidizing Potential	Not available
Vapor Properties **Vapor Density**	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

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 oxidizers, Strong Bases and Strong Acids.
Hazardous Decomposition products	Thermal decomposition or combustion may liberate irritating gases or vapors.
Hazardous Reactions	Carbon oxides

11. Toxicological Information	
Routes of Entry	Ingestion, Inhalation, Eye contact, Skin contact
Inhalation	No data available
Ingestion	No data available
Skin Corrosion/ irritation	No data available
Serious eye damage/eye irritation	No data available
Respiratory sensitizer/Skin sensitizer	No data available
Carcinogenesis	A 2-year study was performed in rats to evaluate the carcinogenic potential of naproxen at rat doses of 8, 16, and 24 mg/kg/day (50, 100, and 150 mg/m2). The maximum dose used was 0.28 times the systemic exposure to humans at the

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	recommended dose. No evidence of tumorigenicity was found
Mutagenesis	No data available
Impairment of Fertility	No data available
Other information	Medically adverse effects reported with Naproxen include: heartburn, abdominal pain, nausea, constipation, diarrhea, dyspepsia, stomatitis, headache, dizziness, drowsiness, lightheadedness, vertigo, pruritus (itching), skin eruptions, ecchymoses, sweating, purpura, tinnitus, visual disturbances, hearing disturbances, edema, palpitations, dyspnea, thirst.

12. Ecological Information	
Acute toxicity to Fish	No data available.
Acute toxicity to Aquatic Invertebrates	No data available.
Toxicity to Aquatic Plants	Not available
Bioaccumulation	Not available
Mobility	Not available

13. Disposal considerations	
Waste Disposal	Dispose of waste must be in accordance with all applicable Federal, State and local laws.
Measures for Avoidance and Recovery	Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14. Transport Information	
DOT	Not Regulated
IMDG	Not Regulated
ICAO/IATA	Not Regulated
IMO	Not Regulated

15. Regulatory Information	
313 Toxic Release Inventory	No components listed on the SARA 313 inventory.
302 Extremely Hazardous Substance (40 CFR 355, Appendix A)	None
TSCA Inventory	None

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