ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
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SAFETY DATA SHEET

Date: 12/09/20

Generic Name: Celecoxib Capsules

Brand Equivalent: Celebrex®

SECTION 1: IDENTIFICATION	
Product Name	Celecoxib Capsules, 50 mg, 100 mg, 200 mg & 400 mg
Active substance	Celecoxib
Synonyms	N/A
Formula	$C_{17}H_{14}F_3N_3O_2S$
Therapeutic Class:	Non-steroidal anti-inflammatory drug (NSAID)
Chemical Name	4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl] benzenesulfonamide
Chemical Class	Diaryl-substituted pyrazole
How Supplied	50 mg capsules are Opaque white capsules, with reverse printed white on red band with markings “SG” on cap and “156” on body 100 mg capsules are opaque white capsules, with reverse printed white on blue band with markings “SG” on cap and “157” on body. 200 mg capsules are opaque white capsules, with reverse printed white on gold band with markings “SG” on cap and “158” on body. 400 mg capsules are opaque white capsules, with reverse printed white on green band with markings “SG” on cap and “159” on body.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

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2. HAZARDS IDENTIFICATION:

GHS – Classification
Reproductive Toxicity: Category 1B
Specific target organ systemic toxicity (repeated exposure): Category 2
Chronic aquatic toxicity: Category 1
EU Classification:
EU Indication of danger: Toxic to reproduction, Category 2 Harmful
EU Risk Phrases:
R61 - May cause harm to the unborn child.
R53 - May cause long-term adverse effects in the aquatic environment.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
Label Elements
Signal Word: Danger
Hazard Statements:
H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure H410 – Very toxic to aquatic life with long lasting effects
Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards: No data available
Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

3. Composition/Information on ingredients		
Components	**CAS-No**	**Concentration (%w/w)**
Celecoxib, USP	169590-42-5	74.07%
Lactose Monohydrate, NF(80M)	64044-51-5	*
Croscarmellose Sodium, NF (VIVASOL GF)	74811657	*
Povidone, USP(Plasdone K-29 /32)	9003-39-8	
Sodium Lauryl Sulfate, NF (Kolliphor SLS Fine)	151-21-3	
Magnesium Stearate, NF	557-04-0	

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

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4. FIRST AID MEASURES	
Eye contact	In case of eye contact Flush with water while holding eyelids open for at least 15 minutes. Seek medical attentionimmediately.
Skin contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
Ingestion	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.
Most important symptoms/effects, acute and delayed	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information
Indication of immediate medical attention and special treatment needed	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
OVER DOSAGE	No overdoses of celecoxib were reported during clinical trials. Doses up to 2400 mg/day for up to 10 days in 12 patients did not result in serious toxicity. Symptoms following acute NSAID overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactic reactions have been reported with therapeutic Ingestion of NSAIDs, and may occur following an overdose. Patients should be managed by symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. No information is available regarding the removal of celecoxib by hemodialysis, but based on its high degree of plasma protein binding (>97%) dialysis is unlikely to be useful in overdose. 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.

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5. FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Extinguish fires with CO2, extinguishing powder, foam, or water.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
Special protective equipment and precautions for firefighters	Wear self-contained breathing apparatus and protective clothing.

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions,	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.

7. HANDLING AND STORAGE	
Precautions for safe handling	All employees who handle this material should be thoroughly trained to handle it safely. Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoidcontact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Washthoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical andprocedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potentialpoints of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systemsor other equivalent controls. Refer to Section 12 - Ecological Information, for

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	information on potential effects on the environment .
Conditions for safe storage, including any incompatibilities	Containers of this material must be properly labeled. Recommended Storage Temperature: Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature]. Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.
Specific End Use	This is a human pharmaceutical
Protective Practices During Maintainence Of Contaminated Equipment	When cleaning non-disposable equipment, wear appropriate personal protective equipment.

8. Exposure controls/Personal protection	
Exposure Limits/Control Parameters: Engineering Controls	Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used. General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures.
Workplace Exposure Limits/ Control Parameters	There are no occupational exposure limits for this product.
Personal Protective Equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Respiratory Protection	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
Eye/face protection	Wear splash goggles or safety glasses as appropriate for the task.
Skin protection	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Hand protection	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance **Physical State** **Color**	 Capsule As described in Section 1.
Odour **Odour** **Odor Threshold**	 Practically odorless Not applicable.
pH	Not available
Other information **Bulk density**	 Not available
Evaporation rate	Not available
Melting point/freezing point	158°C (°F) Celecoxib
BOILING POINT @ 760 mmHg	529.0±60.0 (°F) Celecoxib
Flash point	Not applicable
Flammability limit – lower (%)	Not available.
Flammability limit – upper (%)	Not available.
Explosive limit - lower (%)	Not available
Explosive limit - upper (%)	Not available
Vapor pressure	Not available
Vapor density	No data available.
Relative Density	Not available
Solubility (water)	Soluble in water @ 25°C: 0.06 mg/mL Celecoxib
Partition coefficient (n-Octanol/water)	3.53 Celecoxib
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Other information **Explosive properties**	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing.

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10. Stability and Reactivity	
Reactivity	Not available
Chemical Stability	Stable under normal conditions
Possibility of hazardous reactions	
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	May cause minimal eye irritation (based on animal data). May cause allergic reaction insensitive individuals.
Long Term	Repeat-dose studies in animals have shown a potential to cause adverse effects on gastrointestinal system, kidneys, and the developing fetus.
Known Clinical Effects	Ingestion of this material may cause effects similar to those seen in clinical use including gastrointestinal effects such as nausea, pain, heartburn, bleeding, ulceration, and perforation .Serious allergic reactions, including anaphylaxis, have been reported. Clinical use of this drug has caused swelling of face/extremities, hives, redness and swelling of the skin (urticaria), skin rash, chills yellowing of skin and eyes, headache, dizziness, vomiting, diarrhea, insomnia, increase in blood pressure (hypertension), respiratory infection, chest pain, heart attack(myocardial infarction), stroke, congestive heart failure, liver effects, kidney effects, changes in blood cell levels, Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis). It may also cause prolonged bleeding time.
Carcinogenesis, Mutagenesis, Impairment of Fertility	Celecoxib was not carcinogenic in rats given oral doses up to 200 mg/kg for males and 10 mg/kg for females (approximately 2-to 4 fold the human exposure as measured by the AUC 0-24 at 200 mg twice daily) or in mice given oral doses up to 25 mg/kg for males and 50 mg/kg for females (approximately equal to human exposure as measured by the AUC 0-24 at 200 mg twice daily) for two years.

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	Celecoxib was not mutagenic in an Ames test and a mutation assay in Chinese hamster ovary (CHO) cells, nor clastogenic in a chromosome aberration assay in CHO cells and an *in vivo* micronucleus test in rat bone marrow. Celecoxib did not impair male and female fertility in rats at oral doses up to 600 mg/kg/day (approximately 11-fold human exposure at 200 mg twice daily based on the AUC0-24).

12. Ecological Information	
Ecotoxicity	This product may be harmful or fatal to contaminated plant and animal-life (especially if large quantities are released). This product has not been tested for aquatic toxicity.
Persistence and degradability	This product has not been tested for persistence and biodegradability. No predicted values are available.
Bioaccumulative potential	This product has not been tested for bio-accumulation potential.
Mobility in soil	This product has not been tested for mobility in soils.
Other adverse effects	The components of this product are not listed as having ozone depletion potential.

13. Disposal considerations	
Disposal instructions	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.
Precautions to be followed during waste handling	Wear proper protective equipment when handling waste materials

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14. Transport Information	
The following refers to all modes of transportation unless specified below. This material is regulated for transportation as a hazardous material/dangerous good	
UN number	UN 3077
UN proper shipping name	Environmentally Hazardous Substance, Solid, n.o.s (celecoxib)
Transport hazard class(es)	9
Packing group	III
Environmental hazards	Marine Pollutant

15. Regulatory Information	
Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture	
Canada - WHMIS: Classifications WHMIS hazard class:	Class D, Division 2, Subdivision A Class D, Division 2, Subdivision B
Celecoxib CERCLA/SARA 313 Emission reporting California Proposition 65 Standard for the Uniform Scheduling for Drugs and Poisons EU EINECS/ELINCS List	 Not Listed Not Listed Schedule 4 Not Listed
Povidone CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS) EU EINECS/ELINCS List	 Not Listed Not Listed Present Not Listed Not Listed
Lactose NF, monohydrate CERCLA/SARA 313 Emission reporting California Proposition 65 Australia (AICS) REACH - Annex IV - Exemptions from the obligations of Register: EU EINECS/ELINCS List	 Not Listed Not Listed Present Present Not Listed
Sodium Lauryl Sulfate CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA -	 Not Listed Not Listed Present Present

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Sect. 8(b) Australia (AICS) Standard for the Uniform Scheduling for Drugs and Poisons EU EINECS/ELINCS List	Schedule 6 205-788-1
Croscarmellose sodium CERCLA/SARA 313 Emission reporting California Proposition 65 Australia (AICS) EU EINECS/ELINCS List	 Not Listed Not Listed Present Not Listed
Magnesium stearate CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS) EU EINECS/ELINCS List	 Not Listed Not Listed Present Present 209-150-3

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	*12/09/20*
Revision	00
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