SAFETY DATA SHEET (SDS)

Celecoxib Capsules, 50 mg, 100 mg, 200 mg and 400 mg

Revision date: 22-Feb-2022 Version 2.0

1. IDENTIFICATION

Product Name: Celecoxib Capsules, 50 mg, 100 mg, 200 mg and 400 mg

Product Information: Celecoxib Capsules

Company Name: Cadila Pharmaceuticals Limited

Address: 1389, Dholka – 382225, District: Ahmedabad, Gujarat State, India.

Phone No.: 02714/221481

Fax No.: 02714/220315

2. HAZARD(S) IDENTIFICATION:

Fire and Explosion: Expected to be non-combustible.

Health: Celecoxib is contraindicated in the following patients:

- Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to celecoxib, any components of the drug product.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs, have been reported in such patients.
- In the setting of CABG surgery.
- In patients who have demonstrated allergic-type reactions to sulfonamides.

Environment: No information is available about the potential of this product to produce adverse environmental effects.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name: 4-[5-(4-Methylphenyl)-3-(trifluoromethyl)-1*H*-pyrazol -1-yl] benzenesulfonamide

Product Code: Not applicable

Hazardous Ingredients / Components: Not Applicable

CAS No.: 169590-42-5

Other Components:

Inactive Ingredients	Exposure Limit	CAS No.
Lactose monohydrate	Not Found	10039-26-6
Magnesium stearate	Not Found	557-04-0
Polyvinyl pyrrolidone	Not Found	9003-39-8
Crospovidone	Not Found	9003-39-8
Sodium lauryl sulphate	Not Found	151-21-3
Gelatin	Not Found	9000-70-8
Titanium dioxide	Not Found	13463-67-7
Iron oxide red	Not Found	1309-37-1
Iron oxide yellow	Not Found	1309-33-7
FD&C Blue 1	Not Found	3844-45-9
FD&C Red 40	Not Found	25956-17-6
Shellac	Not Found	9000-59-3
Black Iron Oxide	Not Found	1317-61-9
Propylene Glycol	Not Found	57-55-6
Potassium Hydroxide	Not Found	1310-58-3
Dehydrated Alcohol	Not Found	64-17-5
Isopropyl Alcohol	Not Found	67-63-0
Butyl Alcohol	Not Found	71-36-3
Strong Ammonia Solution	Not Found	1336-21-6

4. FIRST – AID MEASURES

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO_2, extinguishing powder, foam, or water.

Specific hazards arising from the substance or mixture:

- 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: Formation of toxic gases is possible during heating or fire.

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

Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use

appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage: Store at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

8. EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Personal protection equipment:

- ***Eye Protection*:** Safety glasses
- ***Protective Gloves***: Compatible chemical-resistant gloves
- ***Other Protective Clothing*:** Lab coat

Respiratory Equipment (Specify Type): NIOSH approved respirator, as conditions warrant.

- ***Work/ Hygienic:*** Do not take internally. Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower. Wash thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Celecoxib capsules 50 mg

Celecoxib 50 mg capsules are white to off-white powder filled in size “4” hard gelatin capsule with red opaque cap imprinted “C85” and white opaque body imprinted “50”.

Celecoxib capsules 100 mg

Celecoxib 100 mg capsules are white to off-white powder filled in size “3” hard gelatin capsule with blue opaque cap imprinted “C86” and white opaque body imprinted “l00”.

Celecoxib capsules 200 mg

Celecoxib 200 mg capsules are white to off-white powder filled in size “2” hard gelatin capsule with gold opaque cap imprinted “C87” and white opaque body imprinted “200”.

Celecoxib capsules 400 mg

Celecoxib 400 mg capsules are white to off-white powder filled in size “00” hard gelatin capsule with green opaque cap imprinted “C88” and white opaque body imprinted “400”.

Odour	Not Applicable
pH	Not Applicable
Melting Point	Not Applicable
Boiling Point	Not Applicable
Flash Point	Not Applicable
Evaporation Rate	Not Applicable
Flammability (solid, gas)	Not Applicable
Explosive Limits	Not Applicable
Vapor Density (vs. Air = 1)	Not Applicable
Pressure (vs. Air or mm Hg)	Not Applicable
Specific Gravity (Water = 1)	Not Applicable
Solubility in Water	Practically insoluble
Solubility Notes	Not Applicable
Octanol/Water Partition Coefficient	Not Applicable
Autoignition Point	Not Applicable
Decomposition Temperature	Not Applicable
Viscosity	Not Applicable
Other Information:	Practically insoluble in water, freely soluble to soluble in anhydrous ethanol, soluble in methylene chloride.
Molecular formula:	$C_{17}H_{14}F_3N_3O_2S$

Molecular weight: 381.4 g/mol

10. STABILITY AND REACTIVITY

Reactivity: Not Applicable

Stability Note(s): Stable under normal conditions of use.

Possibility of Hazardous Reactions:

- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGY INFORMATION

Toxicological Effects: The toxicological effects of this product have not been thoroughly studied. Celecoxib - Toxicity Data: Subcutaneous TDLO (mouse): 1 mg/kg; Oral TDLO (rat): 0.1 mg/kg; Oral TDLO (mouse): 5 mg/kg; Intraperitoneal TDLO (rat): 1 mg/kg; Intraperitoneal TDLO (mouse): 20 mg/kg; Oral TDLo (human): 5.71 mg/kg;

Chronic Toxicological: Celecoxib – Investigated as a tumorigen. Only select Registry of Toxic Effects of Chemical Substance (RTECS) data is presented here. See actual entry in RTECS for complete information. Celecoxib RTECS number: DB2944937.

12. ECOLOGICAL INFORMATION

Toxicity: Avoid release into the environment. Runoff from fire control or dilution water may cause pollution

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method: Dispose in accordance with local, state, and federal regulations.

14. TRANSPORT INFORMATION

The product is not dangerous substance when shipping via under USDOT, EUADR/RD, IATA, or ICAO Regulations.

Additional Transport Information: Transport in accordance with local, state, and federal regulations.

15. REGULATORY INFORMATION

Generic Medicine. Approved by USFDA on November 14, 2019 & the ANDA Number is 208701.

16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Cadila Pharmaceutical Limited shall not be held liable for any damage resulting from handling or from contact with the above product.

Cadila Pharmaceutical Limited reserves the right to revise this SDS.

End of Safety Data Sheet