

1. Identification

Product identifier	Celecoxib	
Other means of identification		
Catalog number	1098504	
Chemical name	4-[5-(4-Methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 1B
	Specific target organ toxicity, repeated exposure	Category 2 (gastrointestinal tract, cardiovascular system)
OSHA hazard(s)	Not classified.	

Label elements



Signal word	Danger
Hazard statement	May damage fertility or the unborn child. May cause damage to organs (gastrointestinal tract, cardiovascular system) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
CELECOXIB		169590-42-5	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
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Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Gastrointestinal ulceration or bleeding.
Indication of immediate medical attention and special treatment needed	Treatment of nonsteroidal anti-inflammatory drug (NSAID) overdose should be symptomatic and supportive and may include the following: Induce vomiting (DO NOT use syrup of ipecac) or perform gastric lavage. Administer activated charcoal as a slurry. For gastrointestinal hemorrhage, monitor stool guaiac and administer antacids or sucralfate. For mild/moderate allergic reactions, administer antihistamines with or without inhaled beta agonists, corticosteroids, or epinephrine. For severe allergic reactions, administer oxygen, antihistamines, epinephrine, or corticosteroids. Nephritis or nephrotic syndrome, thrombocytopenia, or hemolytic anemia may respond to glucocorticoid administration. For severe acidosis, administer sodium bicarbonate. Administer as required: plasma volume expanders for severe hypotension; diazepam or other benzodiazepine for convulsions; vitamin K1 for hypoprothrombinemia; and/or dopamine plus dobutamine intravenously to prevent or reverse early indications of renal failure. Forced diuresis, alkalinization of urine, and hemoperfusion may not be useful. (Poisindex) (USP DI)
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ .
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
CELECOXIB (CAS 169590-42-5)	TWA	1 mg/m ³

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to pale yellow powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	312.8 - 318.2 °F (156 - 159 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Insoluble.
Partition coefficient (n-octanol/water)	3.53
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Sulfonamide; Diaryl-substituted pyrazole.
Molecular formula	C ₁₇ H ₁₄ F ₃ N ₃ O ₂ S
Molecular weight	381.38

Solubility (other)

Soluble in acetone, in ethanol, in dimethylsulfoxide, and in ethyl acetate.

10. Stability and reactivity**Reactivity**

No reactivity hazards known.

Chemical stability

Material is stable under normal conditions.

Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid

None known.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx. F-.

11. Toxicological information**Information on likely routes of exposure****Ingestion**

Based on available data, the classification criteria are not met.

Inhalation

Due to lack of data the classification is not possible.

Skin contact

Based on available data, the classification criteria are not met.

Eye contact

Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics

Nausea. Heartburn. Abdominal pain. Diarrhea. Headache. Dizziness. Back pain. Skin rash. Upper respiratory tract infection. Black or bloody stools. Blood in vomit.

Delayed and immediate effects of exposure

Upper respiratory infection. Stevens-Johnson syndrome. Gastrointestinal bleeding. Kidney damage.

Cross sensitivity

Individuals sensitive to sulfonamides may be sensitive to this material also. Persons sensitive to aspirin or any of the other nonsteroidal anti-inflammatory agents may be sensitive to this material also. This material may cause bronchoconstriction or anaphylaxis in aspirin-sensitive asthmatics, especially those with aspirin-induced nasal polyps, allergies, or asthma.

Medical conditions aggravated by exposure

Cardiovascular disease. Cerebrovascular disease. High blood pressure. Peptic ulcer. Asthma. Allergy to aspirin or other NSAIDs. Liver impairment. Kidney impairment. Fluid retention.

Acute toxicity**Product****Species****Test Results**

CELECOXIB (CAS 169590-42-5)

Oral

Rat

> 2000 mg/kg

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation

Due to lack of data the classification is not possible.

Local effects**Irritancy**

Result: Minimal irritant effects.

Species: Rabbit

Organ: Eye

Irritancy

Result: Negative

Species: Rabbit

Organ: Skin

Respiratory sensitization

Due to lack of data the classification is not possible.

Skin sensitization

Due to lack of data the classification is not possible.

Germ cell mutagenicity

Data from germ cell mutagenicity tests were not found. Due to lack of data the classification is not possible.

Mutagenicity

Ames Salmonella/microsome assay

Result: Negative

In vitro cytogenetics assay in Chinese hamster ovary cells

Result: Negative

In vitro direct DNA interaction

Result: Negative

In vivo micronucleus assay in rat bone marrow

Result: Negative

Mammalian cell HGPRT

Result: Negative

Carcinogenicity Based on available data, the classification criteria are not met. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

10 mg/kg/day Oral carcinogenicity study, Female
Result: Negative
Species: Rat
200 mg/kg/day Oral carcinogenicity study, Male
Result: Negative
Species: Rat
25 mg/kg/day Oral carcinogenicity study, Male
Result: Negative
Species: Mouse
50 mg/kg/day Oral carcinogenicity study, Female
Result: Negative
Species: Mouse

Reproductive toxicity May damage fertility or the unborn child.
Therapeutic use of NSAIDs during the second half of pregnancy may cause adverse effects on the fetus, such as premature closure of the ductus arteriosus which may lead to persistent pulmonary hypertension in the newborn. Animal studies have shown that administration of NSAIDs in late pregnancy may prolong gestation and cause difficult labor.

Reproductivity

100 mg/kg/day Embryo-fetal development
Result: Fetotoxic.
Species: Rabbit
30 mg/kg/day Embryo-fetal development
Result: Dose dependent increase in diaphragmatic hernias.
Species: Rat
50 mg/kg/day Embryo-fetal development
Result: Pre-implantation loss and resorption as well as reduced embryo/fetal survival rates.
Species: Rat
> 150 mg/kg/day Embryo-fetal development
Result: Fused ribs, fused and misshapen sternbrae, and increased incidence of cardiovascular defects.
Species: Rabbit

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure May cause damage to organs (gastrointestinal tract, cardiovascular system) through prolonged or repeated exposure.

Aspiration hazard Based on available data, the classification criteria are not met.

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

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations Not available.
Hazardous waste code Not available.
Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
Not regulated as a hazardous material by DOT.

IATA
Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date 01-31-2014

Revision date 01-31-2014

Version # 02

Further information Not available.

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Revision Information This document has undergone significant changes and should be reviewed in its entirety.