



# SAFETY DATA SHEET

Revision date: 17-Apr-2018

Version: 4.1

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Celecoxib

**Trade Name:** Not applicable  
**Compound Number:** SC-58635  
**Synonyms:** YM-177, CJ-016377, CP-598107, PF-00345549, PHA-00846533  
**Chemical Family:** COX-2 inhibitor  
  
**CAS Number** 169590-42-5

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical active

### Details of the Supplier of the Safety Data Sheet

**Pfizer Global Supply**  
**Pfizer Inc**  
235 East 42nd Street  
New York, NY 10017  
1-800-879-3477

**Pfizer Ltd**  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161  
**Emergency telephone number:**  
**ChemSafe (24 hours): +44 (0)208 762 8322**

**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Reproductive Toxicity: Category 1B  
Specific target organ systemic toxicity (repeated exposure): Category 2  
Chronic aquatic toxicity: Category 1

#### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H360D - May damage the unborn child  
H373 - May cause damage to organs through prolonged or repeated exposure if swallowed  
H410 - Very toxic to aquatic life with long lasting effects  
May form combustible dust concentrations in air

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### 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  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
P314 - Get medical attention/advice if you feel unwell  
P405 - Store locked up  
P391 - Collect spillage  
P273 - Avoid release to the environment  
P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

An Occupational Exposure Value has been established for this substance ( see Section 8 ).

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Celecoxib	169590-42-5	Not Listed	STOT RE 2 (H373) Aquatic Chronic 1 (H410) Repr. 1B (H360D)	100

### Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

## 4. FIRST AID MEASURES

### Description of First Aid Measures

#### Eye Contact:

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

#### Skin Contact:

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

#### 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.

#### Inhalation:

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

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### Most Important Symptoms and Effects, Both Acute and Delayed

<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	None known

### Indication of the Immediate Medical Attention and Special Treatment Needed

<b>Notes to Physician:</b>	None
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## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** May include oxides of nitrogen, sulfur, carbon. May include products of fluorine.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

**Specific end use(s):** Pharmaceutical active

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

##### Celecoxib

Pfizer OEL TWA-8 Hr: 1000µg/m<sup>3</sup>

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

##### Hands:

Wear impervious gloves (e.g. Nitrile, etc.) as minimum protection. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

##### Eyes:

Wear safety glasses as minimum protection. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

##### Skin:

Wear impervious protective clothing when handling this compound. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

##### Respiratory protection:

Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Solid

#### Color:

White

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

C17H14F3N3O2S

#### Molecular Weight:

381.38

#### Solvent Solubility:

Soluble: Acetone, Ethanol, Dimethylsulfoxide, Ethyl acetate

#### Water Solubility:

5.0 mg/L (20 °C)

#### pH:

No data available.

#### pKa:

11.1

#### Melting/Freezing Point (°C):

156-157

#### Boiling Point (°C):

No data available.

#### Partition Coefficient: (Method, pH, Endpoint, Value)

##### Celecoxib

Measured Log P 3.53

#### Decomposition Temperature (°C):

No data available.

#### Evaporation Rate (Gram/s):

No data available

#### Vapor Pressure (kPa):

No data available

#### Vapor Density (g/ml):

No data available

#### Relative Density:

No data available

#### Particle Size (µm):

4.0

#### Viscosity:

No data available

#### Flammability:

##### Autoignition Temperature (Solid) (°C):

No data available

##### Flammability (Solids):

No data available

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Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available
Dust Explosivity:	
Min. Ignition Energy (mJ):	100-300
Electrostatic Risk:	
Resistivity (ohm-m):	
Powder:	Ambient: > 4e13 Low: > 4e13

### 10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable at normal conditions
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. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

Short Term:	Minimal eye irritant in experimental animals .
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus. May have long-term effects on the aquatic environment.
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, headache, dizziness, insomnia, increase in blood pressure (hypertension), respiratory infection, heart attack (myocardial infarction), stroke, congestive heart failure, kidney effects, changes in blood cell levels, Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis). It may also cause prolonged bleeding time.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Celecoxib

Rat Oral LD 50 > 2000 mg/kg

Dog Oral LD 50 > 2000mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Celecoxib

Skin Irritation Rabbit No effect

Eye Irritation Rabbit Minimal

Skin Sensitization - GPMT Guinea Pig No effect

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Celecoxib

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### 11. TOXICOLOGICAL INFORMATION

13 Week(s)	Rat	Oral	20 mg/kg/day	NOAEL	Kidney, Gastrointestinal System
13 Week(s)	Dog	Oral	35 mg/kg/day	NOAEL	Gastrointestinal system
6 Month(s)	Rat	Oral	20 mg/kg/day	NOAEL	Gastrointestinal system, Kidney
12 Month(s)	Dog	Oral	35 mg/kg/day	NOAEL	Gastrointestinal system

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Celecoxib**

Embryo / Fetal Development	Rat	Oral	50 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral	100 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Oral	30 mg/kg/day	LOAEL	Teratogenic
Embryo / Fetal Development	Rabbit	Oral	60 mg/kg/day	NOAEL	Teratogenic

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Celecoxib**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	HGPRT	Negative
Direct DNA Interaction	Not applicable	Negative
<i>In Vitro</i> Cytogenetics	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vivo</i> Micronucleus	Not applicable	Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Celecoxib**

2 Year(s)	Rat	Oral	200 (M), 10 (F) mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Mouse	Oral	25 (M), 50 (F) mg/kg/day	NOAEL	Not carcinogenic

**Carcinogen Status:** Not listed as a carcinogen by IARC, NTP or US OSHA.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** May have long-term effects on the aquatic environment. Releases to the environment should be avoided. See aquatic toxicity data, below:

#### **Toxicity:**

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### **Celecoxib**

<i>Daphnia magna</i> (Water Flea)	TAD	EC50	48 Hours	> 1.5 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	TAD	LC50	96 Hours	>1.2 mg/L
<i>Selenastrum capricornutum</i> (Green Alga)	TAD	NOEC	12 Days	0.11 mg/L
<i>Microcystis aeruginosa</i> (Blue-green Alga)	TAD	NOEC	14 Days	0.089 mg/L
<i>Ceriodaphnia dubia</i> (Daphnids)	TAD	NOEC	7 Days	0.17 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	OECD	NOEC	33 Days	0.23 mg/L
<i>Daphnia magna</i> (Water Flea)	EPA	NOEC	21 Days	0.06 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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### Bacterial Inhibition: (Inoculum, Method, End Point, Result)

#### Celecoxib

*Trichoderma viride* (Fungus) TAD MIC > 1000 mg/L

### Persistence and Degradability:

#### Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Celecoxib Ready 53.2% After 28 Day(s) Not Ready

### Bio-accumulative Potential:

#### Partition Coefficient: (Method, pH, Endpoint, Value)

#### Celecoxib

Measured Log P 3.53

**Mobility in Soil:** No data available

## 13. DISPOSAL CONSIDERATIONS

### **Waste Treatment Methods:**

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.

## 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.

<b>UN number:</b>	UN 3077
<b>UN proper shipping name:</b>	Environmentally Hazardous Substance, Solid, n.o.s (celecoxib)
<b>Transport hazard class(es):</b>	9
<b>Packing group:</b>	III
<b>Environmental Hazard(s):</b>	Marine Pollutant

## 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Celecoxib

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### 15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure if swallowed

Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

**Data Sources:** Pfizer proprietary drug development information.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.  
Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

**Revision date:** 17-Apr-2018

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**