



# SAFETY DATA SHEET

Revision date: 03-Nov-2017

Version: 4.7

Page 1 of 9

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

### Product Identifier

**Material Name:** Celecoxib Capsules

**Trade Name:** CELEBREX, CELEBRA, CELEBRA FEM, CELEBRA MAX, SOLEXA, CELORA, ACLARIX, ACLAREX, ARTILOG, ARTRID, CELECOX, VALDYNE, VALDYN, CAPSURE, CELATRIT, KUDEQ, SYRIBEX, DICOXIBE, IGEF

**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
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+00 44 (0)1304 616161

**Emergency telephone number:**  
CHEMTREC (24 hours): 1-800-424-9300

**Emergency telephone number:**  
1-212-573-2222  
**Hours of Operations - 24 Hours**

**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

### 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

## SAFETY DATA SHEET

Material Name: Celecoxib Capsules  
Revision date: 03-Nov-2017

Page 2 of 9  
Version: 4.7



**Other Hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (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<br>EINECS/ELINCS<br>List | GHS Classification   | %  |
|-----------------------|-------------|-----------------------------|--|----|
| Celecoxib             | 169590-42-5 | Not Listed                  | STOT RE 2 (H373)<br>Aquatic Chronic 1 (H410)<br>Repr. 1B (H360D) | 74 |
| Sodium Lauryl Sulfate | 151-21-3    | 205-788-1                   | Not Listed   | *  |
| Magnesium stearate    | 557-04-0    | 209-150-3                   | Not Listed   | *  |

| Ingredient              | CAS Number | EU<br>EINECS/ELINCS<br>List | GHS Classification | % |
|-------------------------|------------|-----------------------------|--------------------|---|
| Povidone                | 9003-39-8  | Not Listed                  | Not Listed         | * |
| Lactose NF, monohydrate | 64044-51-5 | Not Listed                  | Not Listed         | * |
| Croscarmellose sodium   | 74811-65-7 | Not Listed                  | Not Listed         | * |

**Additional Information:**

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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.

## SAFETY DATA SHEET

Material Name: Celecoxib Capsules  
Revision date: 03-Nov-2017

Page 3 of 9  
Version: 4.7

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

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

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

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

**Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**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

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 (see Section 8). 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

CELECOXIB CAPSULES

## SAFETY DATA SHEET

Material Name: Celecoxib Capsules  
Revision date: 03-Nov-2017

Page 4 of 9  
Version: 4.7

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

#### Celecoxib

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

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

Sweden OEL - TWAs 5 mg/m<sup>3</sup>

#### Exposure Controls

##### Engineering Controls:

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. Keep airborne contamination levels below the exposure limits listed above in this section.

##### 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:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

##### Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

##### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (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

|   |                    |                          |                               |
|---|--------------------|--------------------------|-------------------------------|
| <b>Physical State:</b>                                      | Capsule            | <b>Color:</b>            | White and blue, gold or green |
| <b>Odor:</b>  | No data available. | <b>Odor Threshold:</b>   | No data available.            |
| <b>Molecular Formula:</b>                                   | Mixture            | <b>Molecular Weight:</b> | Mixture                       |
| <b>Solvent Solubility:</b>                                  | No data available  |                          |                               |
| <b>Water Solubility:</b>                                    | No data available  |                          |                               |
| <b>pH:</b>  | No data available. |                          |                               |
| <b>Melting/Freezing Point (°C):</b>                         | No data available  |                          |                               |
| <b>Boiling Point (°C):</b>                                  | No data available. |                          |                               |
| <b>Partition Coefficient: (Method, pH, Endpoint, Value)</b> |                    |                          |                               |
| <b>Celecoxib</b>  |                    |                          |                               |
| Measured Log P  | 3.53               |                          |                               |
| <b>Povidone</b>   |                    |                          |                               |
| No data available   |                    |                          |                               |
| <b>Magnesium stearate</b>                                   |                    |                          |                               |
| No data available   |                    |                          |                               |

## SAFETY DATA SHEET

Material Name: Celecoxib Capsules  
Revision date: 03-Nov-2017

Page 5 of 9  
Version: 4.7

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Sodium Lauryl Sulfate

No data available

#### Lactose NF, monohydrate

No data available

#### Croscarmellose sodium

No data available

**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

**Viscosity:** No data available

#### Flammability:

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**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

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** 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. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**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 in sensitive 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.

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

## SAFETY DATA SHEET

Material Name: Celecoxib Capsules  
Revision date: 03-Nov-2017

Page 6 of 9  
Version: 4.7

### 11. TOXICOLOGICAL INFORMATION

#### Celecoxib

Rat Oral LD 50 > 2000 mg/kg  
Dog Oral LD 50 > 2000mg/kg

#### Povidone

Rat Oral LD50 100 g/kg

#### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

#### Sodium Lauryl Sulfate

Rat Oral LD 50 1288 mg/kg  
Rat Sub-tenon injection (eye) LD 50 210mg/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

|             |     |      |              |       |                                 |
|-------------|-----|------|--------------|-------|---------------------------------|
| 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         |

##### Sodium Lauryl Sulfate

3 Day(s) Rat Oral 75 mg/kg LOAEL Liver, Blood

#### 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 |

## SAFETY DATA SHEET

Material Name: Celecoxib Capsules  
Revision date: 03-Nov-2017

Page 7 of 9  
Version: 4.7

### 11. TOXICOLOGICAL INFORMATION

#### 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:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

##### **Povidone**

**IARC:** Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

#### **Toxicity:**

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

##### **Celecoxib**

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

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

##### **Celecoxib**

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

**Persistence and Degradability:** No data available

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

**Bio-accumulative Potential:** No data available

##### **Celecoxib**

Measured Log P 3.53

**Mobility in Soil:** No data available

## SAFETY DATA SHEET

Material Name: Celecoxib Capsules  
Revision date: 03-Nov-2017

Page 8 of 9  
Version: 4.7

### 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.

**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 Hazard(s):** Marine Pollutant

**5 kg/5L Exception:**

UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not regulated as dangerous goods for transport by any mode:

\* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

\* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

### 15. REGULATORY INFORMATION

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

**Celecoxib**

|  |            |
|--|------------|
| 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 |

**Povidone**

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting          | Not Listed |
| California Proposition 65                   | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present    |
| Australia (AICS):                           | Present    |
| EU EINECS/ELINCS List                       | Not Listed |



## SAFETY DATA SHEET

Material Name: Celecoxib Capsules  
Revision date: 03-Nov-2017

Page 9 of 9  
Version: 4.7

### 15. REGULATORY INFORMATION

#### Lactose NF, monohydrate

|                                    |            |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65          | Not Listed |
| Australia (AICS):                  | Present    |
| EU EINECS/ELINCS List              | Not Listed |

#### Sodium Lauryl Sulfate

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting                            | Not Listed |
| California Proposition 65                                     | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                   | Present    |
| Australia (AICS):   | Present    |
| Standard for the Uniform Scheduling<br>for Drugs and Poisons: | Schedule 6 |
| EU EINECS/ELINCS List   | 205-788-1  |

#### Croscarmellose sodium

|                                    |            |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65          | Not Listed |
| Australia (AICS):                  | Present    |
| EU EINECS/ELINCS List              | Not Listed |

#### Magnesium stearate

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting          | Not Listed |
| California Proposition 65                   | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present    |
| Australia (AICS):                           | Present    |
| EU EINECS/ELINCS List                       | 209-150-3  |

### 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

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. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

**Revision date:** 03-Nov-2017

Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**