SAFETY DATA SHEET

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

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

Pfizer Ltd
Ramsgate Road
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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

Other Hazards No data available
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)	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 EINECS/ELINCS 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.

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 fire fighting 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. Clean up 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

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^3

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	5 mg/m^3

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).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Capsule	**Color:**	White and blue, gold or green
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

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

Celecoxib
Measured Log P 3.53

Povidone
No data available

Magnesium stearate
No data available

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

Flammablity:
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)

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^3

11. TOXICOLOGICAL INFORMATION

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) *Salmonella* Negative
Mammalian Cell Mutagenicity HGPRT Negative
Direct DNA Interaction Not applicable Negative
In Vitro Cytogenetics Chinese Hamster Ovary (CHO) cells Negative
In Vivo 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: 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)

11. TOXICOLOGICAL INFORMATION

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

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:
Effective January 1, 2015, 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

Lactose NF, monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	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

15. REGULATORY INFORMATION

Standard for the Uniform Scheduling 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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 16 - Other Information.
Revision date:	13-May-2016
	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