MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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

Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
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+00 44 (0)1304 616161
Emergency telephone number:
1-212-573-2222
Hours of Operations - 24 Hours

Material Name: Celecoxib Capsules

Trade Name: CELEBREX®; CELEBRA®; SOLEXA®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

2. HAZARDS IDENTIFICATION

Appearance: White and blue , gold or green capsules
Signal Word: WARNING

Statement of Hazard: May damage the unborn child.
May cause damage to gastrointestinal system, kidneys through prolonged or repeated exposure.

Additional Hazard Information:

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.

EU Indication of danger: Toxic to reproduction, Category 2
Harmful

EU Hazard Symbols:

T

2. HAZARDS IDENTIFICATION

EU Risk Phrases:

R61 - May cause harm to the unborn child.
R53 - May cause long-term adverse effects in the aquatic environment.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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	EU Classification	%
Celecoxib	169590-42-5	Not Listed	Rep. Cat.2;R61 Xn;R48/22 R53	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	EU 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.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

6. ACCIDENTAL RELEASE MEASURES

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

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.

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

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

General 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.

Storage Conditions: Store as directed by product packaging.

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

Analytical Method: Analytical method available for Celecoxib. Contact Pfizer Inc for further information.

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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

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

Povidone
Rat Oral LD50 100 g/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

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

11. TOXICOLOGICAL INFORMATION

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)

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:

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

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.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction, Category 2
Harmful

EU Risk Phrases:

R61 - May cause harm to the unborn child.
R53 - May cause long-term adverse effects in the aquatic environment.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

15. REGULATORY INFORMATION

EU Safety Phrases:

S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May damage the unborn child.
May cause damage to gastrointestinal system, kidneys through prolonged or repeated exposure.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A
Class D, Division 2, Subdivision B

Celecoxib

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Povidone

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

Lactose NF, monohydrate

Australia (AICS):	Present

Sodium Lauryl Sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	205-788-1

Croscarmellose sodium

Australia (AICS):	Present

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 14 - Transport Information. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communication
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