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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+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

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. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celecoxib</td>
<td>169590-42-5</td>
<td>Not listed</td>
<td>74</td>
</tr>
<tr>
<td>Sodium Lauryl Sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

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

Statement of Hazard: Suspected of damaging the unborn child.
May cause damage to gastrointestinal system, heart, liver, kidneys, through prolonged or repeated exposure.
May cause allergic reaction in aspirin-sensitive individuals

Additional Hazard Information:
Short Term: May cause minimal eye irritation (based on animal data). Not a skin irritant, Not acutely toxic (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 the developing fetus.
4. FIRST AID MEASURES

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: May burn emitting oxides of: nitrogen sulfur carbon and products of

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

Fire / Explosion Hazards: Not applicable

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Celecoxib

Pfizer OEL TWA-8 Hr: 1.0 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. 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
Stability: Stable at normal conditions
Conditions to Avoid: Not determined
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, Endpoint, 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/m³

Sodium Lauryl Sulfate
- Rat Oral LD50 1288 mg/kg
- Rat Intraperitoneal 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.

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, Endpoint, 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, Endpoint, 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)
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

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 OECD EC-50 48 Hours > 1.5 mg/L
Fathead minnow OECD LC-50 96 Hours >1.2 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: (Species, Method, End Point, Duration, Result)

Celecoxib
Green Algae MIC 12 Days >0.11 mg/L
Blue-green Algae MIC 14 Days >1.5 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
Suspected of damaging the unborn child.
May cause damage to gastrointestinal system, heart, liver, kidneys, through prolonged or repeated exposure.
May cause allergic reaction in aspirin-sensitive individuals

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) XU
Australia (AICS): Present

Lactose NF, monohydrate
Australia (AICS): Present

Croskemillose sodium
Australia (AICS): Present

Sodium Lauryl Sulfate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 205-788-1

Magnesium stearate
Inventory - United States TSCA - Sect. 8(b) Present
16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - 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.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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End of Safety Data Sheet