



MATERIAL SAFETY DATA SHEET

Revision date: 20-Dec-2005

Version: 1.0

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

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Emergency telephone number:
CHEMTREC (24 hours): 1-800-262-8200

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

Material Name: Celecoxib

Trade Name: Not determined
Synonyms: SC-58635, YM-177
Chemical Family: COX-2
Intended Use: Pharmaceutical active: non-steroidal, anti-inflammatory drug (nsaid)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Celecoxib	169590-42-5	Not listed	100

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

3. HAZARDS IDENTIFICATION

Appearance: White solid
Signal Word: DANGER

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

Additional Hazard Information:
Short Term:

Minimal eye irritant in experimental animals . Not a skin irritant , Not acutely toxic (based on components) . An Occupational Exposure Limit has been established for this substance; see Section 8.

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on 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, 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.

EU Indication of danger:

Toxic to reproduction, Category 2
Harmful

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EU Hazard Symbols:



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.

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.

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. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

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 include oxides of nitrogen, sulfur, carbon. May include products of fluorine.

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

Fire / Explosion Hazards: Dust can form an explosive mixture in air. 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 the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. **Avoid use of a filtered vacuum to clean spills of dry solids, due to the potential for electrostatic discharge and very high sensitivity to ignition.**

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.

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7. HANDLING AND STORAGE

General Handling: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. All plant and equipment must be earthed (grounded) to ensure that no isolated conductors are present. Consider earthing operators dealing with dusty operations. Minimise the use of plastics when handling this material. This material should be handled in conductive or anti-static liners (bags). At ambient humidity, this material is relatively conductive and has a very short charge decay. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

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

Engineering Controls: Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protective Equipment:

Hands: Chemical protective gloves
Eyes: Safety glasses or goggles
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
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:	Solid	Color:	White
Molecular Formula:	C17H14F3N3O2S	Molecular Weight:	381.38
Solvent Solubility:	Soluble: Acetone, Ethanol, Dimethylsulfoxide, Ethyl acetate		
Solubility:	Insoluble: Water		
Melting/Freezing Point (°C):	156-157		
Particle Size (um):	4.0		

10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions

Conditions to Avoid: Incompatible with electrostatic discharge in situations where a dust cloud may be produced. Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Dust Explosivity:

Min. Ignition Energy (mJ): 3 - 10

Electrostatic Risk:

Powder Resistivity:

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Ambient Humidity: > 70 Tera ohm-m
Low Humidity: > 40 Tera ohm-m

11. TOXICOLOGICAL INFORMATION

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

Celecoxib

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

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)	NOAEL	Not carcinogenic
2 Year(s)	Mouse	Oral	25 (M), 50 (F)	NOAEL	Not carcinogenic

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

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12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

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.

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: Incineration is the recommended method of disposal for this material. 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 Labeling:	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:

DANGER

May cause allergic reaction in aspirin-sensitive individuals

Causes damage to gastrointestinal system, heart, liver, kidneys through prolonged or repeated exposure.

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Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B



16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet