MATERIAL SAFETY DATA SHEET

SECTION 1 CHEMICAL PRODUCTS & COMPANY IDENTIFICATION

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Celebrex

CAS Number: 169590-42-5
RTECS: Not Assigned

SUBSTANCE: Celebrex Capsules

TRADE NAMES/SYNONYMS: 4-[5-(4-Methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide; Celecoxib; Celebra; Solexa; SC-58635; SC58635

CREATION DATE: 5/17/1994 REVISION DATE: 8/16/2002

SECTION 2 COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENT	CAS NUMBER	PERCENTAGE	EXPOSURE GUIDELINES
			Monsanto Work Place Permissible Exposure Guideline
SC-58635	169590-42-5	37.0 - 74.1%	2.0 mg/m3 (8 hr. TWA)

SECTION 3 HAZARDS IDENTIFICATION

NFPA RATINGS (Scale 0-4): Health=2 Fire=1 Reactivity=1
(U=Unknown)

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EMERGENCY OVERVIEW:

SC-58635 is a white solid material. SC-58635 is the active component of Celebrex. Celebrex is marketed as a nonsteroidal anti-inflammatory drug (NSAID). The dosage form may be a 100 mg, 200 mg or 400 mg capsule.

Celebrex may have a similar toxicity profile to other members of the NSAID class of medications. NSAIDs can cause allergic reaction or a syndrome of runny nose, skin rash and breathing

difficulties which can be severe. If these symptoms are noted, seek medical attention immediately.

CAUTION:

- Individuals with known hypersensitivity, or allergic reactions to celecoxib or sulfonamides should avoid exposure.
- Individuals with a history of pre-existing asthma, skin rash or other allergies after taking aspirin or other NSAIDs should avoid exposure.
- Pregnant/nursing women should avoid exposure.
- Individuals with a history of edema, fluid retention, high blood pressure or heart failure should consult a physician before exposure.
- Individuals taking anticoagulants (e.g. Warfarin, Coumadin, etc.), lithium, fluconazole, furosemide (Lasix, others) or angiotensin converting enzyme (ACE) inhibitors should discuss this with a physician before exposure.

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POTENTIAL HEALTH EFFECTS:

INHALATION:
SHORT TERM EXPOSURE: No information regarding inhalation hazards
LONG TERM EFFECTS: No information regarding inhalation hazards

SKIN CONTACT:
SHORT TERM EXPOSURE:
Based on animal studies, this material is not expected to cause skin irritation.
LONG TERM EFFECTS: No information regarding skin contact

EYE CONTACT:
SHORT TERM EXPOSURE:
Based on animal studies, this material may cause eye irritation.
LONG TERM EFFECTS: See Short Term Exposure

INGESTION:
SHORT TERM EXPOSURE:
See Long Term Effects.

LONG TERM EFFECTS:

Use of Celebrex has been associated with the following effects:

Allergies: Asthma, anaphylaxis with breathing difficulties which may require immediate emergency treatment.
Gastrointestinal: Nausea, upset stomach, diarrhea, abdominal discomfort, perforating ulcer, gas, pancreatitis, bleeding ulceration or perforation of the gastrointestinal lining, bloody or black stools, right upper abdominal tenderness, liver reactions including jaundice and severe hepatitis with symptoms of fatigue, nausea and itching skin.
Respiratory: Sore throat and sinuses, runny nose.
General: Generalized swelling, tender skin rash, allergic skin rash, flu-like symptoms, headache, dizziness, neuropathy

Clinical use of other nonsteroidal anti-inflammatory drugs (NSAIDs) has also been associated with the following effects:

Kidneys: Painful or frequent urination, fluid retention, blood or protein in the urine.
Blood: Prolonged bleeding.
Skin: Photosensitivity.
Other: Ringing in the ears.

CARCINOGEN STATUS:

Based on animal studies, there is no evidence that Celebrex is carcinogenic.

SECTION 4 FIRST AID MEASURES

INHALATION:

Remove to fresh air, monitor blood pressure, respiration, temperature and general condition. Get medical attention promptly.

SKIN CONTACT:

Remove contaminated clothing. Wash skin with soap and water. Get medical attention if irritation develops.

EYE CONTACT:
Immediately flush eyes with large amounts of water for 15 minutes. Get medical attention promptly.

INGESTION:
Provide general support and monitor blood pressure, respiration, temperature and general condition. Get medical attention promptly.

NOTE TO PHYSICIAN: See Section 11
ANTIDOTE: No antidote appropriate. Supportive care as indicated.

SECTION 5 FIRE FIGHTING MEASURES

FIRE AND EXPLOSION HAZARD: Will burn if involved in a fire

FLASH POINT: Not applicable

LOWER FLAMMABLE LIMIT: Not applicable

UPPER FLAMMABLE LIMIT: Not applicable

AUTOIGNITION: Not applicable

FLAMMABILITY CLASS (OSHA): Not known

HAZARDOUS COMBUSTION PRODUCTS:
Hydrogen fluoride, oxides of nitrogen and sulfur

EXTINGUISHING MEDIA:
Use dry chemical, carbon dioxide, water spray, regular foam or extinguishing agent suitable for surrounding fire.

FIREFIGHTING:
Evacuate area and fight fire from a safe distance. As in any fire, wear pressure demand self-contained breathing apparatus, and full protective gear.

SECTION 6 ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL SPILL:
Vacuum material with HEPA filter vacuum cleaner or wet sweep. Collect waste for proper disposal. Keep unnecessary people away. Do not flush spilled material into sewer.

SECTION 7 HANDLING AND STORAGE

Use with adequate ventilation. Avoid breathing dust. Avoid contact with eyes, skin or clothing. No special storage provisions necessary.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

MEASUREMENT METHOD: Not established

VENTILATION: Local exhaust ventilation

EYE PROTECTION: Safety glasses

CLOTHING: Long sleeves (if potential for skin contact) and disposable coveralls.

GLOVES:
Chemically resistent gloves should be used. This compound has not been specifically evaluated for glove suitability.

RESPIRATORY PROTECTION:
Choice of respirators can vary depending on individual circumstances. The specific application should be evaluated to determine if the following recommendations are appropriate.

HEPA air-purifying respirator for operations with adequate ventilation but with some potential for exposure (such as manual transfer operations).

Supplied-air respirator for operations without adequate ventilation.

FOR FIREFIGHTING AND OTHER IMMEDIATELY DANGEROUS TO LIFE OR HEALTH CONDITIONS WEAR: Self-contained breathing apparatus

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

DESCRIPTION: White solid
MOLECULAR WEIGHT: 381.38
MOLECULAR FORMULA: C17H14F3N3O2S
BOILING POINT: Not applicable
FREEZING/MELTING POINT: 156-157 C
VAPOR PRESSURE: Not applicable
VAPOR DENSITY: Not applicable
SPECIFIC GRAVITY: Not known
WATER SOLUBILITY: Not soluble in water
VOLATILITY: Not applicable
ODOR THRESHOLD: Not known
EVAPORATION RATE: Not applicable
VISCOSITY: Not applicable
SOLVENT SOLUBILITY:
Acetone, ethanol, DMSO, ethyl acetate and methylene chloride
PH: Not applicable

SECTION 10 STABILITY AND REACTIVITY

REACTIVITY: Stable under normal conditions of temperature and pressure.

CONDITIONS TO AVOID: Not known

INCOMPATIBILITIES: Not known

HAZARDOUS DECOMPOSITION: Not known

POLYMERIZATION: Not known

SECTION 11 TOXICOLOGY INFORMATION

EYE EFFECTS: Minimal irritant in rabbits

SKIN EFFECTS: Non-irritating in rabbits

ACUTE TOXICITY DATA:

Rat--Oral LD50: > 2000 mg/kg

Decreases in urinary chloride and sodium concentrations in rats after four days of oral dosing at 100 mg/kg/day.

MUTAGENICITY:

Negative in the Ames Assay and in mammalian cells. Negative for direct DNA damage in vitro and for potential to cause chromosomal aberrations in vitro (in Chinese Hamster Ovary cells) or to induce micronuclei in bone marrow in rats (dosages up to 600 mg/kg/day for three days.

CARCINOGENICITY:

Negative in two year oral bioassays in rats and mice.

CHRONIC EFFECTS:

In a six month oral toxicity study in rats, death occurred at 80 mg/kg/day and higher, and gastrointestinal and renal effects were seen at 80 mg/kg/day and 400 mg/kg/day respectively. The NOEL was 20 mg/kg/day.

A NOEL of 35 mg/kg/day was identified in a one year oral toxicity study in dogs.

SUBCHRONIC EFFECTS:

Gastrointestinal injury (300 mg/kg/day and higher) and renal effects (1000 mg/kg/day) have been observed in mice in a two week dietary study. The no-observed-effect-level (NOEL) was 100 mg/kg/day in males and 300 mg/kg/day in females.

Gastrointestinal injury and death were noted at 600 mg/kg/day and

liver weight increases at 400 mg/kg/day in a four week oral toxicity study in rats.

A NOEL of 20 mg/kg/day was reported in a 13 week oral dose study in rats. Renal effects were seen at 80 mg/kg/day and higher in this study and antinaturesis, a pharmacological consequence of prostaglandin inhibition, was seen at doses of 20 mg/kg/day and higher.

In a four week oral dog study, mortality/moribundity was seen at doses of 50 mg/kg/day and higher. Gastrointestinal injury and renal effects were noted at doses of 50 mg/kg/day and higher. The NOEL dose was 25 mg/kg/day.

A NOEL of 35 mg/kg/day was reported in a 13 week oral dose study in dogs.

The above mentioned target organ effects are consistent with those reported for NSAIDs.

REPRODUCTIVE:

Evidence of embryolethality was observed in rabbits at oral exposures greater than ten times the projected efficacious exposure (doses of 600 mg/kg/day). This effect is consistent with effects reported for non-steroidal anti-inflammatory drugs (NSAIDs).

No effects on fertility were observed in male and female rats at oral dosages up to 600 mg/kg/day.

Pre- and post implantation losses were seen at an oral dose of 300 mg/kg/day in rabbits and at 50 mg/kg/day and higher in rats.

TERATOGENICITY:

No evidence of malformations produced by SC-58635 was observed in studies in rabbits. Diaphramatic hernia was noted in rat fetuses at a maternal oral dose of 100 mg/kg/day and higher.

LOCAL EFFECTS:

Negative for antigenicity in studies with mice and guinea pigs.
Negative in a guinea pig maximization study for dermal sensitization.

TARGET EFFECTS:

Gastrointestinal tract and kidney.

AT INCREASED RISK FROM EXPOSURE:
See "CAUTION" under EMERGENCY OVERVIEW in Section 3.

ADDITIONAL DATA:
In addition to the symptoms described in Section 3, human use of Celebrex has been associated with the following:
General: Weight gain or loss, fluid retention, edema.
Gastrointestinal: Increases in some liver enzyme levels (notably ALT, AST), pancreatitis, fatal fulminant hepatitis, liver necrosis, fatal liver failure.
Hematological: Anemia, thrombocytopenia, leukopenia, ecchymoses, increased bleeding time, agranulocytosis, pancytopenia.
Renal: Albuminuria, hematuria, renal calculus, renal insufficiency, acute interstitial nephritis, nephrotic syndrome, papillary necrosis.
Skin: Severe skin reactions including erythema multiforme, toxic epidermal necrolysis, Sweet's syndrome.
Other: Hypoglycemia, hyperchloremia, hypophosphotemia, elevated BUN.

SECTION 12 ECOLOGICAL INFORMATION

ENVIRONMENTAL OVERVIEW:
The environmental and ecological aspects of this chemical have not been fully characterized. Care should be used in handling.

ACUTE AQUATIC TOXICITY:

Species	mg/L	NOEC (mg/L)
Daphnids (invertebrate)	48 hr. >1.5 (EC50)	48 hr. 1.5
Fathead Minnows (vertebrate)	96 hr. >1.2 (LC50)	96 hr. 1.2
Green Algae	12 days >0.11 (MIC)	12 days 0.11
Blue-Green Algae	14 days >1.5 (MIC)	14 days 1.5

DEGRADABILITY:
Aerobic biodegradation occurs slowly in loam soils with an estimated 6 month half-life. The metabolic profile indicates the degradation product is less toxic and less persistent in the environment than the parent compound.

LOG BIOCONCENTRATION FACTOR (BCF): Not known

LOG OCTANOL/WATER PARTITION COEFFICIENT: Not known

SECTION 13 DISPOSAL INFORMATION

Incinerate in approved facility. Observe all federal, state and local regulations when disposing of this substance.

SECTION 14 TRANSPORTATION INFORMATION

HAZARDOUS MATERIALS DESCRIPTION/PROPER SHIPPING NAME: IATA (air): Not Regulated; DOT (ground): Not regulated

HAZARD CLASS: Not applicable
IDENTIFICATION NUMBER: Not applicable

SECTION 15 REGULATORY INFORMATION

EINECS NUMBER: Not assigned
TSCA STATUS: Not applicable
CERCLA SECTION 103 (40CFR302.4): Not applicable
SARA SECTION 302 (40CFR355.30): Not applicable
SARA SECTION 304 (40CFR355.40): Not applicable
SARA SECTION 313 (40CFR372.65): Not applicable
OSHA PROCESS SAFETY (29CFR1910.119): Not applicable

CALIFORNIA PROPOSITION 65: Not applicable
RCRA: Not applicable

SARA HAZARD CATEGORIES, SARA SECTIONS 311/312 (40 CFR 370.21)
ACUTE HAZARD: Not applicable
CHRONIC HAZARD: Not applicable
FIRE HAZARD: Not applicable
REACTIVITY HAZARD: Not applicable
SUDDEN RELEASE HAZARD: Not applicable

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