

# Vioxx

sc-208486

## Material Safety Data Sheet



The Power is Question

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

## Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

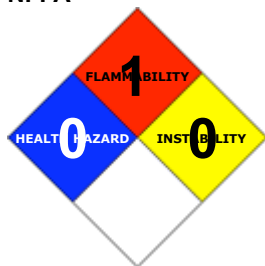
### PRODUCT NAME

Vioxx

### STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

### NFPA



### SUPPLIER

Santa Cruz Biotechnology, Inc.  
2145 Delaware Avenue  
Santa Cruz, California 95060  
800.457.3801 or 831.457.3800

### EMERGENCY

ChemWatch  
Within the US & Canada: 877-715-9305  
Outside the US & Canada: +800 2436 2255  
(1-800-CHEMCALL) or call +613 9573 3112

### SYNONYMS

C17-H14-O4-S, 4-[4-(methylsulfonyl)phenyl]-3-phenyl-2(5H)furanone, "L-748, 731-2, COX-2", MK0966, "MK 0966", Vioxx, "cyclooxygenase 2 inhibitor", "analgesic/ anti-inflammatory NSAID"

## Section 2 - HAZARDS IDENTIFICATION

### CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	2		
Reactivity:	1		
Chronic:	2		

Min/Nil=0  
Low=1  
Moderate=2  
High=3  
Extreme=4

### CANADIAN WHMIS SYMBOLS



### EMERGENCY OVERVIEW

## RISK

Harmful to aquatic organisms.

## POTENTIAL HEALTH EFFECTS

### ACUTE HEALTH EFFECTS

#### SWALLOWED

■ Although ingestion is not thought to produce harmful effects, the material may still be damaging to the health of the individual following ingestion, especially where pre-existing organ (e.g. liver, kidney) damage is evident.

■ Non-steroidal anti-inflammatory drug (NSAID) overdose may produce nausea, vomiting, indigestion and upper abdominal pain.

Other effects may include drowsiness, dizziness, confusion, disorientation, lethargy, "pins and needles", intense headache, blurred vision, ringing in the ears, muscle twitching, convulsions, stupor and coma.

#### EYE

■ Although the material is not thought to be an irritant, direct contact with the eye may produce transient discomfort characterized by tearing or conjunctival redness (as with windburn).

■ The material may be irritating to the eye, with prolonged contact causing inflammation.

Repeated or prolonged exposure to irritants may produce conjunctivitis.

#### SKIN

■ Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.

■ The material is not thought to be a skin irritant (as classified using animal models). Temporary discomfort, however, may result from prolonged dermal exposures.

■ Open cuts, abraded or irritated skin should not be exposed to this material.

■ Toxic effects may result from skin absorption.

#### INHALED

■ The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

### CHRONIC HEALTH EFFECTS

■ Principal routes of exposure are by accidental skin and eye contact and inhalation of generated dusts.

Prolonged use of non-steroidal analgesics damages the lining of the gastrointestinal tract, causing ulcers and bleeding. There may be diarrhea or constipation, perforations causing serious infection, and blood in the vomit or stools.

MK-0966 was negative in a battery of in vitro and in vivo genotoxicity assays. Several developmental toxicity studies have been performed in rats and rabbits. In an oral developmental study in rats given 1-30 mg/kg/day, treatment-related effects on fertility and embryo/ foetal survival were seen at maternally toxic doses (no-observed-effect-level (NOEL) = 25 mg/kg/day). In oral developmental studies in rabbits, there was a slight treatment-related increase in the number of foetuses with incomplete ossification of the metacarpal bones (NOAEL = 25 mg/kg/day) without evidence of other treatment related effects, such as skeletal malformations, decreased embryo/ foetal survival or decreased maternal weight. The NOAEL for maternal toxicity in rabbits is equal to 50 mg/kg/day. In a fostering/ cross fostering study in rats (25 mg/kg/day), there was a treatment related increase in the number of pup deaths which appears to be closely related to exposure during gestation and lactation. Developmental effects seen with other NSAIDs are similar; unlike other NSAIDs, MK-0966 did not cause a delay in parturition which is associated with increased pup deaths in rats.

■ Chronic ingestion of excessive amounts of non-narcotic analgesics can lead to nephropathy (kidney damage) in humans. A substantial number of health deficits are associated with this condition. These include reduced GFR (glomerular filtration rate), salt wastage, hyperkalaemia, metabolic acidosis, and a vasopressin-resistant concentration defect. More severe forms of analgesic nephropathy may lead to papillary necrosis with sloughing of the papilla. Although renal function may return to normal after discontinuation of treatment or abuse, complete anuria (absence of urine formation) may result following continued abuse.

Most patients who develop analgesic nephropathy consume analgesics for up to 3 years, consuming between 2 and 5 mg daily.

## Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
rofecoxib	162011-90-7	>98

## Section 4 - FIRST AID MEASURES

#### SWALLOWED

■ If poisoning occurs, contact a doctor or Poisons Information Center. ■ Poison Information Centers in each State capital city can provide additional assistance.

#### EYE

■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

#### **SKIN**

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

#### **INHALED**

· If dust is inhaled, remove from contaminated area. · Encourage patient to blow nose to ensure clear passage of breathing. · If irritation or discomfort persists seek medical attention.

#### **NOTES TO PHYSICIAN**

■ Treat symptomatically.

### **Section 5 - FIRE FIGHTING MEASURES**

Upper Explosive Limit (%):	Not available
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available
Relative Vapor Density (air=1):	Not available

#### **EXTINGUISHING MEDIA**

· Water spray or fog.  
· Foam.

#### **FIRE FIGHTING**

· Alert Emergency Responders and tell them location and nature of hazard.  
· Wear breathing apparatus plus protective gloves for fire only.

#### **GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS**

· Solid which exhibits difficult combustion or is difficult to ignite.  
· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.  
Combustion products include: carbon monoxide (CO) and sulfur oxides (SO<sub>x</sub>).

Dust explosivity information: Kst 286

MIE >3mJ

MIT 460 deg C-470 deg C

LOC 8%

#### **FIRE INCOMPATIBILITY**

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

#### **PERSONAL PROTECTION**

Glasses:

Safety Glasses.

Chemical goggles.

Gloves:

Respirator:

Particulate

### **Section 6 - ACCIDENTAL RELEASE MEASURES**

#### **MINOR SPILLS**

· Remove all ignition sources.  
· Clean up all spills immediately.  
· Avoid contact with skin and eyes.  
· Control personal contact by using protective equipment.  
· Use dry clean up procedures and avoid generating dust.  
· Place in a suitable, labelled container for waste disposal.

#### **MAJOR SPILLS**

· Clean up all spills immediately.  
· Wear protective clothing, safety glasses, dust mask, gloves.

### **Section 7 - HANDLING AND STORAGE**

#### **PROCEDURE FOR HANDLING**

· Avoid generating and breathing dust  
· Avoid contact with skin and eyes.  
· Wear nominated personal protective equipment when handling.  
· Use in a well-ventilated area.  
· Use good occupational work practices.  
· Observe manufacturer's storing and handling recommendations.

## RECOMMENDED STORAGE METHODS

- Packaging as recommended by manufacturer.
- Check that containers are clearly labelled.
- Tamper-proof containers.
- Polyethylene or polypropylene containers.
- Metal drum with sealed plastic liner.

## STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.

## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE CONTROLS

The following materials had no OELs on our records

- rofecoxib: CAS:162011-90-7

### PERSONAL PROTECTION



#### RESPIRATOR

Particulate

Consult your EHS staff for recommendations

##### ■ EYE

No special equipment needed when handling small quantities of substance.

For bulk handling wear:

Chemical goggles or

Face shield.

#### HANDS/FEET

Rubber gloves

PVC gloves

Protective shoe covers

Head covering.

#### OTHER

No special equipment when handling small quantities of substance otherwise:

Coveralls

For Emergencies:

Vinyl suit

Safety shower

### ENGINEERING CONTROLS

- Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

## Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

### PHYSICAL PROPERTIES

Solid.

Does not mix with water.

State	Divided solid	Molecular Weight	314.36
Melting Range (°F)	411.8	Boiling Range (°F)	Not available
Solubility in water (g/L)	Partly miscible	Flash Point (°F)	Not available
pH (1% solution)	Not available	Decomposition Temp (°F)	Not available
pH (as supplied)	Not applicable	Autoignition Temp (°F)	Not available
Vapour Pressure (mmHG)	Negligible	Upper Explosive Limit (%)	Not available
Specific Gravity (water=1)	Not available	Lower Explosive Limit (%)	Not available
Relative Vapor Density (air=1)	Not available	Volatile Component (%vol)	Negligible
Evaporation Rate	Not available		

## APPEARANCE

Yellow crystalline powder; does not mix well with water (4.6 mg/l). Light sensitive and degrades on contact with air.

log Kow 1.45

Material	Value
----------	-------

## Section 10 - CHEMICAL STABILITY

### CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.

### STORAGE INCOMPATIBILITY

- Be sure container is tightly closed when not in use.

For incompatible materials - refer to Section 7 - Handling and Storage.

## Section 11 - TOXICOLOGICAL INFORMATION

ROFECOXIB

### TOXICITY AND IRRITATION

ROFECOXIB:

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (rat) LD50: >2000 mg/kg *	Eye (rabbit): slight-Mild *
	Skin (rabbit): non-irritating *

ADI: 1 mg/day

\* [Mercke, Sharp and Dohme]

## Section 12 - ECOLOGICAL INFORMATION

Harmful to aquatic organisms.

## Section 13 - DISPOSAL CONSIDERATIONS

### Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

- Recycle wherever possible. Special hazard may exist - specialist advice may be required.

## Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

## Section 15 - REGULATORY INFORMATION

No data for rofecoxib (CAS: , 162011-90-7)

## Section 16 - OTHER INFORMATION

*Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no representations and assumes no liability for any direct, incidental or consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.*

- Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:

[www.chemwatch.net/references](http://www.chemwatch.net/references).

- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

*This document is copyright. Apart from any fair dealing for the purposes of private study, research, review or criticism, as permitted under the Copyright Act, no part may be reproduced by any process without written permission from CHEMWATCH. TEL (+61 3) 9572 4700.*

Issue Date: Dec-6-2007

Print Date: Jan-28-2011