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

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

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

Material Name: Valdecoxib Tablets

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

2. HAZARDS IDENTIFICATION

Appearance: White or yellow tablets
Signal Word: DANGER

Statement of Hazard:
May cause allergic reaction in aspirin-sensitive individuals
Causes damage to gastrointestinal system, cardiovascular system through prolonged or repeated exposure.
Suspected of damaging the unborn child.
Harmful to aquatic life with long lasting effects.

Additional Hazard Information:
Short Term: Minimal eye irritant in experimental animals
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, kidneys, endocrine system, 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 . Clinical use may cause Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis). Clinical use has caused effects on the cardiovascular system, including heart attack (myocardial infarction), stroke, blood clots, blood clot in the lung (pulmonary embolism).

EU Indication of danger: Toxic to Reproduction; Category 3

EU Hazard Symbols:

EU Risk Phrases:
R63 - Possible risk of harm to the unborn child.

2. HAZARDS IDENTIFICATION

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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	Classification	%
Valdecoxib	181695-72-7	Not listed	Xn;R48/22 Repr.Cat3;R63 N;R51/53	4.9-9.7
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Opadry Yellow	NOT ASSIGNED	Not listed	Xn;R22	*
Lactose Monohydrate	64044-51-5	Not listed	Not Listed	*
Opadry white	NOT ASSIGNED	Not listed	Xn;R22	*
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.

5. FIRE FIGHTING MEASURES

5. FIRE FIGHTING MEASURES

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

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

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: 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). Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Valdecoxib

Pfizer OEL TWA-8 Hr:	100 µg/m^3	

Starch, pregelatinized

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	
Belgium OEL - TWA	Listed	
Bulgaria OEL - TWA	Listed	
Czech Republic OEL - TWA	Listed	
Greece OEL - TWA	Listed	
Ireland OEL - TWAs	= 10 mg/m^3 TWA = 4 mg/m^3 TWA	
OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA = 5 mg/m^3 TWA	total
Portugal OEL - TWA	Listed	
Spain OEL - TWA	Listed	

Magnesium Stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA	
Belgium OEL - TWA	Listed	
Ireland OEL - TWAs	= 10 mg/m^3 TWA	except lead stearate
Lithuania OEL - TWA	Listed	
Portugal OEL - TWA	Listed	
Spain OEL - TWA	Listed	
Sweden OEL - TWAs	= 5 mg/m^3 LLV	

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	
Belgium OEL - TWA	Listed	
Estonia OEL - TWA	Listed	
France OEL - TWA	Listed	
Ireland OEL - TWAs	= 10 mg/m^3 TWA = 4 mg/m^3 TWA	
Latvia OEL - TWA	Listed	
OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA = 5 mg/m^3 TWA	total
Portugal OEL - TWA	Listed	
Romania OEL - TWA	Listed	
Spain OEL - TWA	Listed	

The exposure limit(s) listed for solid components are only relevant if dust may be generated. Refer to available public information for specific member state Occupational Exposure Limits.

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

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:	Tablets	**Color:**	White or yellow
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability:	Stable at normal conditions
Conditions to Avoid:	None known
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)

Valdecoxib
Rat (F) Oral LD 50 > 800 mg/kg
Rat (M) Oral LD 50 > 1600 mg/kg
Rat Dermal LD 50 > 2000 mg/kg

Lactose Monohydrate
Rat Oral LD 50 29700 mg/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 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)

Valdecoxib
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Minimal
Skin Sensitization - GPMT Guinea Pig Negative

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Valdecoxib
4 Week(s) Dog Oral 1 mg/kg/day NOEL Kidney
4 Week(s) Rat Oral 5 (F), 25 (M) mg/kg/day NOEL Gastrointestinal system, Liver, Kidney, Adrenal gland
13 Week(s) Rat Oral 5 (M), 2.5 (F) mg/kg/day NOEL Gastrointestinal system, Liver, Kidney, Adrenal gland
26 Week(s) Dog Oral 3 mg/kg/day NOEL Kidney, Skin
2 Year(s) Rat Oral 0.5 (F), 2.5 (M) mg/kg/day LOAEL Gastrointestinal system

Magnesium Stearate
13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Valdecoxib
Reproductive & Fertility Rat Oral 6 (F), 9 (M) mg/kg/day NOEL Negative
Reproductive & Fertility - Females Rat Oral 0.2 mg/kg/day NOEL Fertility
Reproductive & Fertility-Males Rat Oral 3 mg/kg/day NOAEL Negative
Embryo / Fetal Development Rabbit Oral 40 mg/kg/day LOAEL Fetotoxicity, Teratogenic
Embryo / Fetal Development Rat Oral 10 mg/kg/day NOAEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

11. TOXICOLOGICAL INFORMATION

Valdecoxib
Bacterial Mutagenicity (Ames) *Salmonella* Negative
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
In Vitro HGPRT Chinese Hamster Ovary (CHO) cells Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Valdecoxib
2 Year(s) Male Rat Oral <= 7.5 mg/kg/day NOAEL Not carcinogenic
2 Year(s) Female Rat Oral <= 1.5 mg/kg/day NOAEL Not carcinogenic
2 Year(s) Male Mouse Oral <= 25 mg/kg/day NOAEL Not carcinogenic
2 Year(s) Female Mouse Oral <= 50 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.

12. ECOLOGICAL INFORMATION

Environmental Overview: Harmful to aquatic life with long lasting effects. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Valdecoxib
Pseudokirchneriella subcapitata (Green Alga) TAD LC50 72 Hours 4.5 mg/L
Daphnia magna (Water Flea) EPA EC50 48 Hours 7.7 mg/L
Pimephales promelas (Fathead Minnow) TAD LC50 96 Hours > 9.3 mg/L
Pimephales promelas (Fathead Minnow) OECD NOEC 32 Days 0.98 mg/L
Daphnia magna (Water Flea) OECD NOEC 21 Days 0.055 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.
The (21) day (Daphnia magna) study above is a reproductive/survival study.

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

Valdecoxib
Activated sludge OECD EC50 3 Hours >1000 mg/L
Photobacterium Phosphoreum EC-50 0.25 Hours > 100 mg/L
Aspergillus niger (Fungus) FDA MIC 4 Days >1000 mg/L
Clostridium perfingens (Bacterium) FDA MIC 1 Days >1000 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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

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

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Toxic to Reproduction; Category 3

EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

EU Safety Phrases:

S36/37 - Wear suitable protective clothing and gloves.
S61 - Avoid release to the environment. Refer to special instructions/Safety data sheets.

OSHA Label:
DANGER
May cause allergic reaction in aspirin-sensitive individuals
Causes damage to gastrointestinal system, cardiovascular system through prolonged or repeated exposure.
Suspected of damaging the unborn child.
Harmful to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

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

Valdecoxib

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

Lactose Monohydrate

Australia (AICS):	Present

Starch, pregelatinized

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

Magnesium Stearate

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

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

Croscarmellose sodium

Australia (AICS):	Present

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R63 - Possible risk of harm to the unborn child.
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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