



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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1-212-573-2222

Pfizer Ltd
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Sandwich, Kent
CT13 9NJ
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Meclofenamate Sodium Capsules

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Sodium Lauryl Sulfate	151-21-3	205-788-1	*
Magnesium stearate	557-04-0	209-150-3	*
Silica gel, amorphous	112926-00-8	Not listed	*
Meclofenamate Sodium	6385-02-0	228-983-3	27

Ingredient	CAS Number	EU EINECS List	%
E172 (colorant)	Not Assigned	Not listed	*
Lactose	63-42-3	200-559-2	*
Gelatin	9000-70-8	232-554-6	*
FD & C Red No. 3 (E 127)	16423-68-0	240-474-8	*
E 171 (colorant)	Not assigned	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: Tablets
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed or inhaled
Causes eye irritation.

Additional Hazard Information:

Short Term: Severe eye irritant, Mild skin irritant in experimental animals. Dust irritating to respiratory tract.
Known Clinical Effects: Clinical use has caused effects on the gastrointestinal system, including nausea, vomiting, flatulence, diarrhea, peptic ulcer, perforating ulcers.

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EU Indication of danger: Toxic
Irritant

EU Hazard Symbols:



EU Risk Phrases:
R25 - Toxic if swallowed.
R20 - Harmful by inhalation.
R36/37 - Irritating to eyes and respiratory system.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get 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. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.

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.

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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, skin, and clothing. Avoid generating airborne dust. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Silica gel, amorphous
Australia TWA = 10 mg/m³ TWA

Meclofenamate Sodium
Pfizer OEL TWA-8 Hr: 0.1 mg/m³, Skin
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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

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:	Tablets	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

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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)

Lactose

Rat Oral LD50 > 10 g/kg

Sodium Lauryl Sulfate

Rat Oral LD 50 1288 mg/kg

Rat Intraperitoneal LD 50 210 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

FD & C Red No. 3 (E 127)

Rat Oral LD50 1840 mg/kg

Mouse Oral LD50 1264 mg/kg

Meclufenamate Sodium

Rat Oral LD 50 87 mg/kg

Rabbit Dermal LD 50 > 2000 mg/kg

Rat Inhalation LC50 4h 2.8 mg/L

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)

Meclufenamate Sodium

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

Skin Sensitization - GPMT Guinea Pig Moderate

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

Sodium Lauryl Sulfate

3 Day(s) Rat Oral 75 mg/kg LOAEL Liver, Blood

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

Meclufenamate Sodium

Embryo / Fetal Development Rat No route specified 3.5 mg/kg/day NOEL Not teratogenic

Embryo / Fetal Development Rabbit No route specified 3.5 mg/kg/day NOEL Not Teratogenic

Fertility and Embryonic Development Rat Oral 9 mg/kg/day NOAL Not Teratogenic

Fertility and Embryonic Development Rat Oral 20 mg/kg/day LOEL Maternal Toxicity, Embryotoxicity

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Silica gel, amorphous

IARC: Group 3

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12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

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
Irritant

EU Risk Phrases:
R25 - Toxic if swallowed.
R20 - Harmful by inhalation.
R36/37 - Irritating to eyes and respiratory system.

EU Safety Phrases:
S22 - Do not breathe dust.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37 - Wear suitable protective clothing and gloves.
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).

OSHA Label:
WARNING
Harmful if swallowed or inhaled
Causes eye irritation.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 1, Subdivision B

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Sodium Lauryl Sulfate

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

Lactose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-559-2

Magnesium stearate

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

Gelatin

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6

FD & C Red No. 3 (E 127)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	240-474-8

Silica gel, amorphous

Australia (AICS):	Present
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Meclofenamate Sodium

EU EINECS List	228-983-3
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16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 13 - Disposal Considerations.

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet