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

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1-212-573-2222

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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: Meclofenamic Acid Suppositories

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meclofenamic acid</td>
<td>644-62-2</td>
<td>211-419-5</td>
<td>8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: Suppository
Signal Word: WARNING

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

Additional Hazard Information:
- Short Term: Moderate eye irritant in experimental animals. Active ingredient is not a skin irritant.
- Known Clinical Effects: Clinical use has caused effects on the gastrointestinal system, including nausea, vomiting, flatulence, diarrhea, peptic ulcer, perforating ulcers.
- EU Indication of danger: Harmful
- EU Hazard Symbols:
EU Risk Phrases:
R22 - Harmful 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 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.

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: Avoid contact with eyes. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Meclofenamic acid

Pfizer OEL TWA-8 Hr: 0.1 mg/m³

The exposure limit(s) listed for solid components are only relevant if dust may be generated.


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: Suppository
Molecular Formula: Mixture
Color: No data available.
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.

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)

Meclofenamic acid
Rat Oral LD50 87 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg
Rat Inhalation LC50 4h 2.8 mg/L
Material Name: Meclofenamic Acid Suppositories
Revision date: 15-Dec-2006
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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)

Meclofenamic acid
Eye irritation  Rabbit  Moderate
Skin irritation  Rabbit  Non-irritating
Skin sensitization - GPMT  Guinea Pig  Negative

Polyethylene glycol
Eye irritation  Rabbit  Mild
Skin irritation  Rabbit  Mild

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

Meclofenamic acid
Embryo / Fetal Development  Rat  3.5 mg/kg/day  NOEL  Not teratogenic
Embryo / Fetal Development  Rabbit  3.5 mg/kg/day  NOEL  Not Teratogenic
Fertility and Embryonic Development  Rat  Oral  9 mg/kg  NOAL  Not Teratogenic
Fertility and Embryonic Development  Rat  Oral  20 mg/kg  LOEL  Maternal Toxicity, Embryotoxicity

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

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: Xn
Material Name: Meclofenamic Acid Suppositories
Revision date: 15-Dec-2006

EU Indication of danger: Harmful

EU Risk Phrases: R22 - Harmful if swallowed.

EU Safety Phrases: S36/37 - Wear suitable protective clothing and gloves.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

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

Canada - WHMIS: Classifications

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

Polysorbate 80
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Polyethylene glycol
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Meclofenamic acid
Standard for the Uniform Scheduling for Drugs and Poisons:
Schedule 4
Schedule 5
EU EINECS List 211-419-5

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