SAFETY DATA SHEET

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

Product Identifier

Material Name: Mefenamic Acid Tablets

Trade Name: PONSTAN, PONSTYL, TANSTON, PARKEMED; RHEA MEFENAMIC ACID; Mefenamin Pfizer

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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:
International CHEMTREC (24 hours): +1-703-527-3887

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 4
Reproductive Toxicity: Category 2

EU Classification:

EU Indication of danger: Harmful
Toxic to Reproduction: Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

Label Elements

Signal Word: Warning
Hazard Statements:
H302 - Harmful if swallowed
H361d - Suspected of damaging the unborn child
Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash hands thoroughly after handling
P281 - Use personal protective equipment as required
P270 - Do not eat, drink or smoke when using this product
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P308+P313 - IF exposed or concerned: Get medical attention/advice
P330 - Rinse mouth
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
Australian Hazard Classification (NOHSC):

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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Silica colloidal, Ph. Eur.</td>
<td>112945-52-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium Lauryl Sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
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<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Mefenamic Acid</td>
<td>61-68-7</td>
<td>200-513-1</td>
<td>Repr. Cat.3;R63 Xn;R22</td>
<td>Acute Tox.4 (H302) Repr.2 (H361d)</td>
<td>70</td>
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<tr>
<td>Ferric oxide yellow</td>
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<td>257-098-5</td>
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<tr>
<td>Maize starch</td>
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<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
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<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylcellulose</td>
<td>9004-67-5</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Vanillin</td>
<td>121-33-5</td>
<td>204-465-2</td>
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<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
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</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Mefenamic Acid Tablets
Revision date: 01-Nov-2014

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Carbon dioxide, dry chemical, or foam

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.
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

Precautions for Safe 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). Wash thoroughly after handling. Releases to the environment should be avoided. 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Microcrystalline cellulose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³ 4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³ 5 mg/m³

Silica colloidal, Ph. Eur.
Austria OEL - MAKs 4 mg/m³

Titanium dioxide
ACGIH Threshold Limit Value (TWA) 10 mg/m³
ACGIH OELs - Notice of Intended Changes Listed
Australia TWA 10 mg/m³
Austria OEL - MAKs 5 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Denmark OEL - TWA 6 mg/m³
Estonia OEL - TWA 5 mg/m³
France OEL - TWA 10 mg/m³

PZ00585
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country or Region</th>
<th>TWAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>15 mg/m³</td>
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<tr>
<td>Poland OEL - TWA</td>
<td>10.0 mg/m³</td>
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<tr>
<td>Portugal OEL - TWA</td>
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<td>Romania OEL - TWA</td>
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<td>Russia OEL - TWA</td>
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<td>Sweden OEL - TWAs</td>
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<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
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<tr>
<td>Vietnam OEL - TWAs</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

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**Mefenamic Acid**

- Pfizer OEL TWA-8 Hr: 3000 µg/m³

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**Maize starch**

- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: 10 mg/m³
- Bulgaria OEL - TWA: 10.0 mg/m³
- Czech Republic OEL - TWA: 4.0 mg/m³
- Greece OEL - TWA: 10 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- 4 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Portugal OEL - TWA: 10 mg/m³
- Slovakia OEL - TWA: 4 mg/m³
- Spain OEL - TWA: 10 mg/m³
- Switzerland OEL - TWAs: 3 mg/m³

---

**Polyethylene glycol**

- Austria OEL - MAKs: 1000 mg/m³
- Germany - TRGS 900 - TWAs: 1000 mg/m³
- Germany (DFG) - MAK: 1000 mg/m³ average molecular weight 200-600
- Slovakia OEL - TWA: 1000 mg/m³
- Slovenia OEL - TWA: 1000 mg/m³
- Switzerland OEL - TWAs: 1000 ppm

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**Magnesium Stearate**

- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Lithuania OEL - TWA: 5 mg/m³
- Sweden OEL - TWAs: 5 mg/m³

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**Talc (non-asbestiform)**

- ACGIH Threshold Limit Value (TWA): 2 mg/m³
- Australia TWA: 2.5 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
<th>OEL - TWAs</th>
<th>OEL - MAKs</th>
<th>OEL - MAKs</th>
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<tbody>
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<td>2 mg/m³</td>
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<td>2 mg/m³</td>
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<tr>
<td>Belgium</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulgaria</td>
<td>1.0 fiber/cm³</td>
<td>6.0 mg/m³</td>
<td>3.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Czech Republic</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Denmark</td>
<td>0.5 fiber/cm³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greece</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hungary</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lithuania</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>0.25 mg/m³</td>
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<td></td>
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</tr>
<tr>
<td>OSHA - Final PELs</td>
<td>20 mppcf</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td>4.0 mg/m³</td>
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</tr>
<tr>
<td>Portugal</td>
<td>2 mg/m³</td>
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<td></td>
</tr>
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<td>Romania</td>
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<td>Slovakia</td>
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</tr>
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<td>Slovenia</td>
<td>2 mg/m³</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Spain</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>10 mg/m³</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>2 mg/m³</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Exposure Controls
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Tablets</td>
</tr>
<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color</td>
<td>Light yellow</td>
</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
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</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble: Water</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Methylcellulose
No data available
Maize starch
No data available
Sodium Lauryl Sulfate
No data available
Microcrystalline cellulose
No data available
Silica colloidal, Ph. Eur.
No data available
Magnesium Stearate
No data available
Talc (non-asbestiform)
No data available
Titanium dioxide
No data available
Hydroxypropyl methylcellulose
No data available
Ferric oxide yellow
No data available
Vanillin
No data available
Mefenamic Acid
No data available
Polyethylene glycol
No data available
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
10. STABILITY AND REACTIVITY

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause allergic reactions in susceptible individuals. May be harmful if swallowed. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on gastrointestinal system, liver, kidneys, heart.

Known Clinical Effects: Adverse effects associated with therapeutic use of mefenamic acid include serious gastrointestinal toxicity such as bleeding, ulceration, and perforation and kidney toxicity. Dizziness, headaches, anemia, increased bleeding time, rashes, and liver effects have also been reported. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

Acute Toxicity: (Species, Route, End Point, Dose)

Sodium Lauryl Sulfate
Rat Oral LD50 1288 mg/kg
Rat Sub-tenon injection (eye) LD50 210mg/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Talc (non-asbestiform)
Rat Oral LD50 > 1600 mg/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD50 50 mg/kg

Hydroxypropyl methylcellulose
Rat Oral LD50 > 10,000 mg/kg

Vanillin
Rat Oral LD 50 1580 mg/kg

Mefenamic Acid
Mouse Oral LD50 525 mg/kg
Rat Oral LD50 740mg/kg
Mouse IV LD50 96mg/kg
Rat IV LD50 112mg/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)
11. TOXICOLOGICAL INFORMATION

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

Polyethylene glycol
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

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

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

Mefenamic Acid
78 Week(s)  Rat  Oral  25 mg/kg/day  NOEL  Kidney, Gastrointestinal System
1 Year(s)  Dog  Oral  200 mg/kg/day  LOAEL  Kidney, Liver
2 Year(s)  Monkey  No route specified  200 mg/kg/day  NOAEL  Kidney, Liver, Gastrointestinal system, Heart

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

Mefenamic Acid
Embryo / Fetal Development  Mouse  No route specified  <3500 mg/day  LOEL  Teratogenic
Reproductive & Fertility  Rat  No route specified  8.75-17.5 g/day  NOEL  No effects at maximum dose
Embryo / Fetal Development  Rat  No route specified  Not Teratogenic
Embryo / Fetal Development  Rabbit  No route specified  Not Teratogenic

Carcinogen Status:
See below

Silica colloidal, Ph. Eur.
IARC:  Group 3 (Not Classifiable)

Talc (non-asbestiform)
IARC:  Group 3 (Not Classifiable)

Titanium dioxide
IARC:  Group 2B (Possibly Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

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

Toxicity:
No data available

Persistence and Degradability:
No data available

Bio-accumulative Potential:
No data available
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

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

Microcrystalline cellulose

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex XVII - Restrictions on Certain Dangerous Substances: Use restricted. See item 9[f]. powder
- EU EINECS/ELINCS List: 232-674-9

Silica colloidal, Ph. Eur.

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Lauryl Sulfate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>205-788-1</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>carcinogen initial date 9/2/11 airborne, unbound particles of respirable size</td>
<td>Present</td>
<td>236-675-5</td>
</tr>
<tr>
<td>Mefenamic Acid</td>
<td>Not Listed</td>
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<td>Present</td>
<td>Present</td>
<td>200-513-1</td>
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<tr>
<td>Ferric oxide yellow</td>
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<td>Present</td>
<td>Present</td>
<td>257-098-5</td>
</tr>
<tr>
<td>Methylcellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Maize starch</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>232-679-6</td>
</tr>
<tr>
<td>Vanillin</td>
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<td></td>
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<td>232-679-6</td>
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</tbody>
</table>
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>Australian Safety Standard</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Not Listed</td>
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<td>Present</td>
<td>Present</td>
<td>204-465-2</td>
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<tr>
<td>Polyethylene glycol</td>
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<tr>
<td>Magnesium Stearate</td>
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<td>Present</td>
<td>Present</td>
<td>209-150-3</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>238-877-9</td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

**Text of R phrases and GHS Classification abbreviations mentioned in Section 3**

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child  

Toxic to Reproduction: Category 3  
Xn - Harmful  

R22 - Harmful if swallowed.  
R63 - Possible risk of harm to the unborn child.

**Data Sources:** Safety data sheets for individual ingredients. Pfizer proprietary drug development information.
SAFETY DATA SHEET

Material Name: Mefenamic Acid Tablets
Revision date: 01-Nov-2014

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 01-Nov-2014
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet