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

Material Name: Mefenamic Acid Oral Suspension

| Trade Name: | Ponstan; Ponstyl |
| Chemical Family: | Not determined |
| Intended Use: | Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid) |

2. HAZARDS IDENTIFICATION

Appearance: Off-white creamy suspension

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
- **Short Term:** May be harmful if swallowed. May cause allergic reactions in susceptible individuals. 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 the 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.

EU Indication of danger: Not classified


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>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mefenamic Acid</td>
<td>61-68-7</td>
<td>200-513-1</td>
<td>Repr. Cat.3; R63 Xn; R22</td>
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<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C; R35</td>
<td>&lt;1</td>
<td></td>
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<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>C; R35 T; R23</td>
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<td></td>
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<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</td>
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<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>F; R11</td>
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</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
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<td>Not Listed</td>
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<tr>
<td>Gluconolactone</td>
<td>90-80-2</td>
<td>202-016-5</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Magnesium aluminum silicate</td>
<td>1327-43-1</td>
<td>215-478-8</td>
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<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
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<tr>
<td>Sodium saccharin</td>
<td>128-44-9</td>
<td>204-886-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>9004-32-4</td>
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<tr>
<td>Sorbitol solution</td>
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<td>200-061-5</td>
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<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
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<td>*</td>
</tr>
<tr>
<td>Flavor</td>
<td>NOT ASSIGNED</td>
<td>Not listed</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.

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.

**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.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:**  
Carbon dioxide, dry chemical, or foam
Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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 spill with absorbent material. 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 breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Mefenamic Acid

Pfizer OEL TWA-8 Hr: 3000 µg/m³

Sodium hydroxide

ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling
Australia PEAK = 2 mg/m³ Peak
Austria OEL - MAKs = 2 mg/m³ MAK
Belgium OEL - TWA = 2 mg/m³ TWA
Bulgaria OEL - TWA = 2.0 mg/m³ TWA
Czech Republic OEL - TWA = 1 mg/m³ TWA
Finland OEL - TWA = 2 mg/m³ TWA
France OEL - TWA = 2 mg/m³ VME
Greece OEL - TWA = 2 mg/m³ TWA
Hungary OEL - TWA = 2 mg/m³ TWA
Latvia OEL - TWA = 0.5 mg/m³ TWA
OSHA - Final PELS - TWAs: 2 mg/m³
Poland OEL - TWA = 0.5 mg/m³ NDS
Slovakia OEL - TWA = 2 mg/m³ TWA
Slovenia OEL - TWA = 2 mg/m³ TWA
Sweden OEL - TWAs = 1 mg/m³ LLV

Hydrochloric Acid
ACGIH Ceiling Threshold Limit:

- = 2 ppm Ceiling
- = 5 ppm Peak
- = 7.5 mg/m³ Peak

Austria OEL - MAKs
- = 5 ppm MAK
- = 8 mg/m³ MAK

Belgium OEL - TWA
- = 5 ppm TWA
- = 8 mg/m³ TWA

Bulgaria OEL - TWA
- = 8.0 mg/m³ TWA

Cyprus OEL - TWA
- = 5.0 ppm TWA
- = 8.0 mg/m³ TWA

Czech Republic OEL - TWA
- = 8 mg/m³ TWA

Estonia OEL - TWA
- = 5 ppm TWA
- = 8 mg/m³ TWA

Germany - TRGS 900 - TWAs
- = 2 ppm TWA
- = 3 mg/m³ TWA

Greece OEL - TWA
- = 5 ppm TWA
- = 7 mg/m³ TWA

Hungary OEL - TWA
- = 8 mg/m³ TWA

Ireland OEL - TWAs
- = 5 ppm TWA
- = 7 mg/m³ TWA

Italy OEL - TWA
- = 5 ppm TWA
- = 8 mg/m³ TWA

Latvia OEL - TWA
- = 5 ppm TWA
- = 8 mg/m³ TWA

Lithuania OEL - TWA
- = 5 ppm IPRV
- = 8 mg/m³ IPRV

Luxembourg OEL - TWA
- = 5 ppm TWA
- = 8 mg/m³ TWA

Malta OEL - TWA
- = 5 ppm TWA
- = 8 mg/m³ TWA

Netherlands OEL - TWA
- = 5 ppm MAC
- = 8 mg/m³ MAC

Poland OEL - TWA
- = 5 mg/m³ NDS

Romania OEL - TWA
- = 5 ppm TWA
- = 8 mg/m³ TWA

Slovakia OEL - TWA
- = 5 ppm TWA
- = 8.0 mg/m³ TWA

Slovenia OEL - TWA
- = 5 ppm TWA  anhydrous
- = 8 mg/m³ TWA  anhydrous

Spain OEL - TWA
- = 5 ppm VLA-ED
- = 7.6 mg/m³ VLA-ED

Magnesium aluminum silicate

- Bulgaria OEL - TWA
  - = 1.5 mg/m³ TWA
  - = 10.0 mg/m³ TWA

- Czech Republic OEL - TWA
  - = 10.0 mg/m³ TWA  except for gamma Al₂O₃

- Slovakia OEL - TWA
  - = 6 mg/m³ TWA  except γ-Al₂O₃

Sucrose

ACGIH Threshold Limit Value (TWA)

- = 10 mg/m³ TWA

- Austria TWA
- = 10 mg/m³ TWA

- Belgium OEL - TWA
- = 10 mg/m³ TWA

- Bulgaria OEL - TWA
- = 10.0 mg/m³ TWA

- Estonia OEL - TWA
- = 10 mg/m³ TWA

- France OEL - TWA
- = 10 mg/m³ VME
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:

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>Physical State:</th>
<th>Creamy suspension</th>
<th>Color:</th>
<th>Off-white</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

Solubility: Soluble: Water
pH: 4.9-5.1
Specific Gravity: 1.12-1.14(25 °C)

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Polymerization: Will not occur

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)

Mefenamic Acid
Mouse Oral LD50 525 mg/kg
Rat Oral LD50 740 mg/kg
Mouse IV LD50 96 mg/kg
Rat IV LD50 112 mg/kg

Sucrose
Rat Oral LD50 29.7 g/kg

Sodium benzoate
Rat Oral LD50 4,070 mg/kg
Mouse Oral LD50 1600 mg/kg

Alcohol

PZ00586
**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)**

**Alcohol**
Eye Irritation Rabbit Severe

**Sodium hydroxide**
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

**Hydrochloric Acid**
Skin Irritation Severe
Eye Irritation Severe

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

**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

**Sodium benzoate**
- 10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood
- 10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

**Sodium saccharin**
- 36 Week(s) Rat Oral 756 g/kg LOAEL Kidney, Ureter, Bladder
- 54 Day(s) Rat Oral 32400 mg/kg LOAEL Immune system

**Carboxymethylcellulose sodium**
- 13 Week(s) Rat Oral 227 g/kg LOAEL Liver, Kidney, Ureter, Bladder
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  Rat  No route specified  Not Teratogenic

Sodium benzoate
Embryo / Fetal Development  Rat  Oral  44 g/kg  LOEL  Developmental toxicity

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

Povidone
IARC:  Group 3 (Not Classifiable)

Hydrochloric Acid
IARC:  Group 3 (Not Classifiable)

Sodium saccharin
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this mixture 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. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger:  Not classified
OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

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

Mefenamic Acid
  Australia (AICS): Present
  Standard for the Uniform Scheduling for Drugs and Poisons:
    Schedule 2
  EU EINECS/ELINCS List
    200-513-1

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

Sodium hydroxide
  CERCLA/SARA Hazardous Substances and their Reportable Quantities:
    = 1000 lb final RQ
    = 454 kg final RQ
  Inventory - United States TSCA - Sect. 8(b)
    Present
  Australia (AICS):
    Present
  Standard for the Uniform Scheduling for Drugs and Poisons:
    Schedule 5
  EU EINECS/ELINCS List
    215-185-5

Gluconolactone
  Inventory - United States TSCA - Sect. 8(b)
    Present
  Australia (AICS):
    Present
  EU EINECS/ELINCS List
    202-016-5

Hydrochloric Acid
  CERCLA/SARA 313 Emission reporting
    = 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
  CERCLA/SARA Hazardous Substances and their Reportable Quantities:
    = 2270 kg final RQ
    = 5000 lb final RQ
  CERCLA/SARA - Section 302 Extremely Hazardous TPQs
    = 500 lb TPQ gas only
  CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs
    = 5000 lb EPCRA RQ gas only
  Inventory - United States TSCA - Sect. 8(b)
    T
  Australia (AICS):
    Present
  Standard for the Uniform Scheduling for Drugs and Poisons:
    Schedule 5
    Schedule 6
  EU EINECS/ELINCS List
    231-595-7
16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R11 - Highly flammable.
R22 - Harmful if swallowed.
R23 - Toxic by inhalation.
R35 - Causes severe burns.
R63 - Possible risk of harm to the unborn child.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

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

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End of Safety Data Sheet