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

Pfizer Inc
5 Giralda Farms
Madison, NJ 07940

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

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

Material Name: Advil Tablets/Caplets

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>ADVIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Family:</td>
<td>Not determined</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Consumer healthcare product used as non-steroidal, anti-inflammatory drug (nsaid)</td>
</tr>
</tbody>
</table>

2. HAZARDS IDENTIFICATION

Appearance: Pinkish brown caplet or tablet

Signal Word: WARNING

Statement of Hazard:
Harmful if swallowed.
Suspected of damaging the unborn child.

Additional Hazard Information:

**Short Term:** Accidental ingestion may cause effects similar to those seen in clinical use. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Acute overdosage and/or chronic abuse of ibuprofen may cause kidney effects.

**Long Term:** Animal studies have shown a potential to cause adverse effects on the fetus.

**Known Clinical Effects:**
Adverse effects associated with therapeutic use include gastrointestinal effects such as nausea, pain, heartburn, bleeding, ulceration, and perforation. It may also cause prolonged bleeding time. Drowsiness, fatigue, or headache are also possible. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

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

**EU Hazard Symbols:**

![Xn]

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

**Australian Hazard Classification (NOHSC):**
2. HAZARDS IDENTIFICATION

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
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<td>*</td>
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<tr>
<td>Sodium lauryl sulfate</td>
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<td>205-788-1</td>
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<tr>
<td>Starch, pregelatinized</td>
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<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
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<td>Ibuprofen</td>
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<td>Repr.Cat3;R62-63</td>
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<tr>
<td>Sulphur</td>
<td>57-50-1</td>
<td>200-334-9</td>
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</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 eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Due to the nature of this material first aid is not normally required. 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 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: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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). Wash hands and any exposed skin after removal of PPE. 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.

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.

Colloidal silicon dioxide

- Australia TWA 2 mg/m³
- Austria OEL - MAKs 4 mg/m³
- Czech Republic OEL - TWA 0.1 mg/m³
- 4.0 mg/m³
- Estonia OEL - TWA 2 mg/m³
- Germany - TRGS 900 - TWAs 4 mg/m³
- Germany (DFG) - MAK 4 mg/m³ inhalable fraction
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Ireland OEL - TWAs**
- 6 mg/m³
- 2.4 mg/m³

**Latvia OEL - TWA**
- 1 mg/m³

**OSHA - Final PELs - Table Z-3 Mineral D:**
- 20 mppcf
- Listed

**Slovakia OEL - TWA**
- 4.0 mg/m³

**Corn 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
  - 5 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

**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
- Spain OEL - TWA 10 mg/m³

**Sodium lauryl sulfate**
- Pfizer OEL TWA-8 Hr: 0.3 mg/m³

**Starch, pregelatinized**
- 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
  - 5 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
### Exposures Controls / Personal Protection

**Analytical Method:**
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. Engineering controls should be used as the primary means to control exposures.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

<table>
<thead>
<tr>
<th>Hands</th>
<th>Eyes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wear impervious gloves if skin contact is possible.</td>
<td>Wear safety glasses or goggles if eye contact is possible.</td>
</tr>
</tbody>
</table>

#### Hands:

<table>
<thead>
<tr>
<th>Material / Ingredient</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Titanium dioxide</td>
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<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
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<td>Australia OEL - MAKs</td>
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<td>Denmark OEL - TWA</td>
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<tr>
<td>Estonia OEL - TWA</td>
<td>5 mg/m³</td>
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<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Ireland OEL - TWAs</td>
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<tr>
<td>Latvia OEL - TWA</td>
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<tr>
<td>Lithuania OEL - TWA</td>
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<tr>
<td>OSHA - Final PEL - TWAs:</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>
<td>10 mg/m³</td>
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<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
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#### Eyes:

<table>
<thead>
<tr>
<th>Material / Ingredient</th>
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</thead>
<tbody>
<tr>
<td>Ibuprofen</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Pfizer OEL TWA-8 Hr:</td>
<td>3000µg/m³</td>
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</table>

#### Sucrose:

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<th>Material / Ingredient</th>
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</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia OEL - MAKs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
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<td>Bulgaria OEL - TWA</td>
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<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
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<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 or Caplets  
Molecular Formula: Mixture  
Color: Pinkish brown  
Molecular Weight: Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical 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

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)

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

Methylparaben  
Mouse  Oral  LD50 > 8000 mg/kg  
Rat  Oral  LD50  2280 mg/kg

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

Povidone  
Rat  Oral  LD50  100 g/kg

Propylparaben  
Mouse  Oral  LD 50  6332 mg/kg  
Mouse  Sub-tenon injection (eye)  LD 50  200 mg/kg

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

Sodium lauryl sulfate
11. TOXICOLOGICAL INFORMATION

**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)**

**Skin Irritation**
- **Rabbit** Non-irritating
- **10 Day(s)** Rat Oral 27370 mg/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

**Eye Irritation**
- **Rabbit** Non-irritating
- **3 Week(s)** Rat Oral 27.1 g/kg LOAEL Endocrine system
- **4 Week(s)** Rat Oral 347.2 mg/kg LOAEL Male reproductive system

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

**Sodium lauryl sulfate**
- Eye Irritation Rabbit Moderate
- Skin Irritation Rabbit Mild Moderate
- Skin Sensitization - GPMT Guinea Pig Negative
- Skin Sensitization - LLNA Mouse Negative

**Stearic acid**
- Skin Irritation Rabbit Moderate
- Eye Irritation Rabbit Mild

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

**Propylparaben**
- 3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
- 4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

**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

**Stearic acid**
- 30 Week(s) Rat Oral 300 ppm LOAEL Adipose tissue

**Ibuprofen**
- 4 Day(s) Rat Oral 200 mg/kg Gastrointestinal System
- 30 Day(s) Dog Oral 480 mg/kg Gastrointestinal system
- 2 Week(s) Rat Oral 1300 mg/kg Liver

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

**Sodium benzoate**
- Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity
11. TOXICOLOGICAL INFORMATION

Ibuprofen
Fertility and Embryonic Development  Rat rectal 100 mg/kg/day  Fertility
Fertility and Embryonic Development  Rat rectal 200 mg/kg/day  Fetotoxicity
Embryo / Fetal Development  Rabbit Oral 60 mg/kg/day  Not Teratogenic
Embryo / Fetal Development  Rat Oral 180 mg/kg/day  Not Teratogenic

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

Sodium lauryl sulfate
Bacterial Mutagenicity (Ames)  Salmonella  Negative

Stearic acid
In Vitro Bacterial Mutagenicity (Ames)  Salmonella  Negative
Unscheduled DNA Synthesis  E. coli  Negative

Ibuprofen
Bacterial Mutagenicity (Ames)  Salmonella  Negative

Sucrose
Bacterial Mutagenicity (Ames)  Salmonella  Negative

Stearic acid
26 Week(s)  Rat Subcutaneous 0.5 mg/kg/week  NOAEL  Not carcinogenic
52 Week(s)  Mouse Subcutaneous 0.05 mg/kg/week  LOAEL  Tumors

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

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

Colloidal silicon dioxide
IARC:  Group 3 (Not Classifiable)

Povidone
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:
Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

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

Sodium lauryl sulfate
Onchorhynchus mykiss (Rainbow Trout)  LC50  96 Hours  3.6 mg/L

Ibuprofen
Daphnia magna (Water Flea)  EC50  48 Hours  108 mg/L
Desmodesmus subcapitata (Green Alga)  EC50  72 Hours  315 mg/L
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

EU Symbol: Xn
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.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
Harmful if swallowed.
Suspected of damaging the unborn child.

Canada - WHMIS: Classifications

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

Colloidal silicon dioxide
### 15. REGULATORY INFORMATION

**Material Name:** Advil Tablets/Caplets  
**Revision date:** 14-Dec-2011  
**Version:** 1.2  

<table>
<thead>
<tr>
<th>Material Name</th>
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<th>Status</th>
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<td><strong>Australia (AICS):</strong></td>
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<td><strong>EU EINECS/ELINCS List</strong></td>
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<td></td>
<td><strong>Australia (AICS):</strong></td>
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<td><strong>Standard for the Uniform Scheduling for Drugs and Poisons:</strong></td>
<td>Schedule 6</td>
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<tr>
<td></td>
<td><strong>EU EINECS/ELINCS List</strong></td>
<td>232-679-6</td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

Stearic acid
   Inventory - United States TSCA - Sect. 8(b) Present
   Australia (AICS): Present
   EU EINECS/ELINCS List 200-313-4

Synthetic iron oxide
   Inventory - United States TSCA - Sect. 8(b) Present

Titanium dioxide
   Inventory - United States TSCA - Sect. 8(b) Present
   Australia (AICS): Present
   EU EINECS/ELINCS List 236-675-5

Ibuprofen
   Inventory - United States TSCA - Sect. 8(b) Present
   Australia (AICS): Present
   Standard for the Uniform Scheduling for Drugs and Poisons:
   Schedule 2
   Schedule 3
   Schedule 4
   EU EINECS/ELINCS List 239-784-6

Sucrose
   Inventory - United States TSCA - Sect. 8(b) Present
   Australia (AICS): Present
   REACH - Annex IV - Exemptions from the obligations of Register:
   EU EINECS/ELINCS List 200-334-9

Beeswax
   Inventory - United States TSCA - Sect. 8(b) Present
   Australia (AICS): Present
   EU EINECS/ELINCS List 232-383-7

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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

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

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients.

Prepared by: Product Stewardship Hazard Communication
             Pfizer Global Environment, Health, and Safety Operations

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