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

Product Identifier

Material Name: Tranexamic Acid Tablets
Trade Name: CYKLOKAPRON®
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product used as blood clotting agent

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
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
Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Hazard Statements:
Not classified in accordance with international standards for workplace safety.

Other Hazards
No data available

Australian Hazard Classification (NOHSC):

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

Hazardous

PZ00139
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>
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<tbody>
<tr>
<td>Tranexamic Acid</td>
<td>1197-18-8</td>
<td>214-818-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>500 mg***</td>
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<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
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<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>231-545-4</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>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<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>
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<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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:**
Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Carbon monoxide, carbon dioxide, and oxides of nitrogen may be generated in a fire.

**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.

Tranexamic Acid
Pfizer OEL TWA-8 Hr: 1500µg/m³

Talc (non-asbestiform)
ACGIH Threshold Limit Value (TWA) 2 mg/m³
Australia TWA 2.5 mg/m³
Austria OEL - MAKs 2 mg/m³
Belgium OEL - TWA 2 mg/m³
Bulgaria OEL - TWA 1.0 fiber/cm³
6.0 mg/m³
3.0 mg/m³
Czech Republic OEL - TWA 2.0 mg/m³
Denmark OEL - TWA 0.3 fiber/cm³
Finland OEL - TWA 0.5 fiber/cm³
Greece OEL - TWA 10 mg/m³
2 mg/m³
Hungary OEL - TWA 2 mg/m³
Ireland OEL - TWAs 10 mg/m³
0.8 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Exposure Level</th>
</tr>
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<tbody>
<tr>
<td>Lithuania OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>0.25 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>20 mppcf</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1.0 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
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<tr>
<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>2 mg/m³</td>
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<tr>
<td>Sweden OEL - TWAs</td>
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<tr>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>2 mg/m³</td>
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</table>

**Silicon dioxide, NF**

<table>
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<tr>
<th>Country</th>
<th>Exposure Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td></td>
<td>0.3 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>0.1 mg/m³</td>
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<tr>
<td></td>
<td>4.0 mg/m³</td>
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<tr>
<td>Estonia OEL - TWA</td>
<td>2 mg/m³</td>
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<tr>
<td>Finland OEL - TWA</td>
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<td>Germany - TRGS 900 - TWAs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
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<tr>
<td>Ireland OEL - TWAs</td>
<td>6 mg/m³</td>
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<td></td>
<td>2.4 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
<td>1 mg/m³</td>
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<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>20 mppcf</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td></td>
<td>0.3 mg/m³</td>
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</table>

**Magnesium stearate**

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<tr>
<th>Country</th>
<th>Exposure Level</th>
</tr>
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<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
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**Microcrystalline cellulose**

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<th>Country</th>
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<tbody>
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<td>ACGIH Threshold Limit Value (TWA)</td>
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<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<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>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>2 mg/m³</td>
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<td>OSHA - Final PELs - TWAs:</td>
<td>15 mg/m³</td>
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<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>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Exposure Controls</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Engineering Controls:</strong></td>
<td>Engineering controls should be used as the primary means to control exposures.</td>
</tr>
<tr>
<td><strong>Personal Protective Equipment:</strong></td>
<td>Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).</td>
</tr>
</tbody>
</table>

- **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:** Round tablet
- **Color:** White
- **Odor:** No data available.
- **Odor Threshold:** No data available.
- **Molecular Formula:** Mixture
- **Molecular Weight:** Mixture

- **Solvent Solubility:** No data available
- **Water Solubility:** No data available
- **pH:** No data available.
- **Melting/Freezing Point (°C):** No data available
- **Boiling Point (°C):** No data available
- **Partition Coefficient (Method, pH, Endpoint, Value):** No data available
- **Microcrystalline cellulose:** No data available
- **Talc (non-asbestiform):** No data available
- **Magnesium stearate:** No data available
- **Povidone:** No data available
- **Tranexamic Acid:** No data available
- **Silicon dioxide, NF:** 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:** No data available
- **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

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.
  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 eye irritation. Not acutely toxic (based on animal data). May produce allergic reactions after systemic administration.
Known Clinical Effects: Adverse effects most commonly reported in clinical use include skin rash and gastrointestinal disturbances. Effects on blood and blood-forming organs have also occurred. Effects on vision have been seen during clinical use.

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

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

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

Magnesium stearate
  Rat Oral LD50 > 2000 mg/kg
  Rat Inhalation LC50 > 2000 mg/m³

Tranexamic Acid
  Rat Oral LD50 > 10,000 mg/kg
  Mouse Oral LD50 > 10,000mg/kg
  Rat Intravenous LD50 1,330mg/kg
  Mouse Intravenous LD50 1,350mg/kg
  Rat Subcutaneous LD50 4,620mg/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)

Microcrystalline cellulose
  Skin Irritation Rabbit Non-irritating
  Eye Irritation Rabbit Non-irritating
11. TOXICOLOGICAL INFORMATION

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

**Tranexamic Acid**
- 6 Month(s)  
  - Rat  
  - Oral  
  - 4,000 mg/kg/day  
  - LOAEL  
  - Gastrointestinal system, Spleen

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

**Tranexamic Acid**
- Embryo / Fetal Development  
  - Rat  
  - Oral  
  - 300 mg/kg/day  
  - NOAEL  
  - Not teratogenic
- Embryo / Fetal Development  
  - Mouse  
  - Oral  
  - 300 mg/kg/day  
  - NOAEL  
  - Not Teratogenic
- Reproductive & Fertility  
  - Rat  
  - Rabbit  
  - Mouse  
  - No route specified  
  - No effects at maximum dose

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

**Tranexamic Acid**
- *In Vivo*  
  - Not specified  
  - Negative
- *In Vitro*  
  - Not specified  
  - Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

**Tranexamic Acid**
- Not specified  
  - Mouse  
  - Oral  
  - 5 g/kg/day  
  - LOAEL  
  - Immune system, Bone marrow

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

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

**Povidone**
- 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.

**Toxicity:**
No data available

**Persistence and Degradability:**
No data available

**Bio-accumulative Potential:**
No data available

**Mobility in Soil:**
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: None required

Tranexamic Acid

<table>
<thead>
<tr>
<th>Classification</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
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</tr>
<tr>
<td>California Proposition 65</td>
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</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 4</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>214-818-2</td>
</tr>
</tbody>
</table>

Povidone

<table>
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<tr>
<th>Classification</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Talc (non-asbestiform)
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Component</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>
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</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>231-674-9</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>209-150-3</td>
</tr>
<tr>
<td>Silicon dioxide, NF</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

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

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 4 - First Aid Measures. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

**Revision date:** 16-Jul-2014

**Prepared by:** Product Stewardship Hazard Communication

**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**