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

Product Identifier

Material Name: Ketorolac Tromethamine Injection, USP (Hospira Inc.)

Trade Name: Not established
Synonyms: Ketorolac trometamol
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)

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A
Specific target organ systemic toxicity (repeated exposure): Category 2

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P314 - Get medical attention/advice if you feel unwell
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
International CHEMTREC (24 hours): +1-703-527-3887
Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketorolac tromethamine</td>
<td>74103-07-4</td>
<td>Not Listed</td>
<td>Acute Tox.3 (H301)</td>
<td>1.5-3.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE 2 (H373)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.1A (H360D)</td>
<td></td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>Flam. Liq. 2 (H225)</td>
<td>7 - 12</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>Press. Gas</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Corr.1A (H314)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.3 (H331)</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr.1A (H314)</td>
<td>**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary
** to adjust pH

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 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.
SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection, USP (Hospira Inc.)
Revision date: 03-Aug-2016

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

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

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 spill with absorbent material. 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
Avoid breathing vapor or mist. 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)
**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

Control Parameters

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

**Ethanol**

- ACGIH Threshold Limit Value (STEL) 1000 ppm
- Australia TWA 1000 ppm
- Austria OEL - MAKs 1000 ppm
  - 1900 mg/m³
- Belgium OEL - TWA 1000 ppm
  - 1900 mg/m³
- Bulgaria OEL - TWA 1000 mg/m³
- Czech Republic OEL - TWA 1000 mg/m³
- Denmark OEL - TWA 1000 ppm
  - 1900 mg/m³
- Estonia OEL - TWA 500 ppm
  - 1000 mg/m³
- Finland OEL - TWA 1000 ppm
  - 1900 mg/m³
- France OEL - TWA 1000 ppm
  - 1900 mg/m³
- Germany - TRGS 900 - TWAs 500 ppm
  - 960 mg/m³
- Germany (DFG) - MAK 500 ppm
  - 960 mg/m³
- Greece OEL - TWA 1000 ppm
  - 1900 mg/m³
- Hungary OEL - TWA 1900 mg/m³
- Latvia OEL - TWA 1000 mg/m³
- Lithuania OEL - TWA 500 ppm
  - 1000 mg/m³
- Netherlands OEL - TWA 260 mg/m³
- OSHA - Final PELS - TWAs: 1000 ppm
  - 1900 mg/m³
- Poland OEL - TWA 1900 mg/m³
- Portugal OEL - TWA 1000 ppm
- Romania OEL - TWA 1000 ppm
  - 1900 mg/m³
- Russia OEL - TWA 1000 mg/m³
- Slovakia OEL - TWA 500 ppm
- Slovenia OEL - TWA 1000 ppm
  - 1900 mg/m³
- Sweden OEL - TWAs 500 ppm
  - 1000 mg/m³
- Switzerland OEL - TWAs 500 ppm
  - 960 mg/m³
- Vietnam OEL - TWAs 1000 mg/m³

**Hydrochloric Acid**

- ACGIH Ceiling Threshold Limit: 2 ppm
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Limit Value 1</th>
<th>Limit Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia PEAK</td>
<td>5 ppm</td>
<td>7.5 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>5 ppm</td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>8 mg/m³</td>
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</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>2 ppm</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>5 ppm</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
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</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Italy OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>8 mg/m³</td>
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</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 mg/m³</td>
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<tr>
<td>Portugal OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
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<td>Romania OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>5 ppm</td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 ppm</td>
<td>7.6 mg/m³</td>
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<tr>
<td>Switzerland OEL - TWAs</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

Sodium hydroxide

- ACGIH Ceiling Threshold Limit: 2 mg/m³
- Australia PEAK: 2 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:
Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:
Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:
Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Solution</th>
<th>Color:</th>
<th>Clear to light yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>Alcohol Slight</td>
<td>Odor Threshold:</td>
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</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
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<td></td>
</tr>
<tr>
<td>Water Solubility:</td>
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<td></td>
</tr>
<tr>
<td>Solubility:</td>
<td>Soluble: Water</td>
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<td></td>
</tr>
<tr>
<td>pH:</td>
<td>6.9-7.9</td>
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<td></td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)
- Sodium chloride: No data available
- Ketorolac tromethamine: No data available
- Ethanol: No data available
- Water for injection: No data available
- Hydrochloric Acid: No data available
- Sodium hydroxide: 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
Specific Gravity: 0.991
Viscosity: No data available

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): 55 (ethanol)
- 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 mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
- 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: 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.
11. TOXICOLOGICAL INFORMATION

Known Clinical Effects: Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation. Ingestion of this material may cause effects similar to those seen in clinical use including serious gastrointestinal toxicity such as bleeding, ulceration, and perforation and kidney toxicity. Clinical use of this drug has caused headache, dizziness, blurred vision, ringing of the ears, skin rash, itching, swelling, and liver effects.

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

**Sodium chloride**
- Rat Oral LD50 3000 mg/kg
- Mouse Oral LD50 4000 mg/kg

**Ketorolac tromethamine**
- Rat Oral LD50 189 mg/kg
- Mouse Oral LD50 293mg/kg

**Ethanol**
- Mouse Oral LD50 3,450 g/m³
- Rat Oral LD50 7,060mg/kg
- Mouse Inhalation LC50 4h 39g/m³
- Rat Inhalation LC50 10h 20,000ppm

**Sodium hydroxide**
- Mouse IP LD50 40 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

**Sodium chloride**
- Eye Irritation Rabbit Moderate
- Skin Irritation Rabbit Mild

**Ethanol**
- Eye Irritation Rabbit Severe

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

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

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

**Ketorolac tromethamine**
- Reproductive & Fertility-Females Rat Oral 16 mg/kg/day NOAEL Negative
- Reproductive & Fertility-Males Rat Oral 9 mg/kg/day NOAEL Negative
- Prenatal & Postnatal Development Rabbit Oral 3.6 mg/kg/day NOAEL Negative
- Prenatal & Postnatal Development Rat Oral 10 mg/kg/day NOAEL Negative
11. TOXICOLOGICAL INFORMATION

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

Ketorolac tromethamine
Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
Unscheduled DNA Synthesis Not specified Negative
In Vivo Micronucleus Mouse Negative

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

Ketorolac tromethamine
24 Month(s) Rat Oral 5 mg/kg/day NOAEL Not carcinogenic
18 Month(s) Mouse Oral 2 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: Carcinogenicity of the mixture has not been determined. Alcohol is listed as a carcinogen by IARC. The IARC monograph examining the carcinogenic potential of ethanol examined only alcoholic beverages. See below

Ethanol
IARC: Group 1 (Carcinogenic to Humans)

Hydrochloric Acid
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:

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

Ethanol
Fingerling Trout NPDES LC50 24 Hours 11,200 mg/L
Oncorhynchus mykiss (Rainbow Trout) NPDES LC50 96 Hours 12,900 mg/L
Pimephales promelas (Fathead Minnow) NPDES LC50 96 Hours 14,200 mg/L

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

Ketorolac tromethamine

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: Not Listed

Ethanol

- CERCLA/SARA 313 Emission reporting: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-578-6

Hydrochloric Acid

- CERCLA/SARA 313 Emission reporting: 1.0 %
- CERCLA/SARA Hazardous Substances and their Reportable Quantities: 5000 lb, 2270 kg
- CERCLA/SARA - Section 302 Extremely Hazardous TPQs: 500 lb
- CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs: 5000 lb
- California Proposition 65: Not Listed
15. REGULATORY INFORMATION

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 231-595-7

Sodium hydroxide
- CERCLA/SARA 313 Emission reporting Not Listed
- CERCLA/SARA Hazardous Substances 1000 lb
- and their Reportable Quantities: 454 kg
- California Proposition 65 Not Listed
- 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

Water for injection
- 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 IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List 231-791-2

Sodium chloride
- CERCLA/SARA 313 Emission reporting Not Listed
- California Proposition 65 Not Listed
- Inventory - United States TSCA - Sect. 8(b) Present
- Australia (AICS): Present
- EU EINECS/ELINCS List 231-598-3

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.
Revision date: 03-Aug-2016
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