



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 03-Aug-2016

Version: 1.0

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## 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)

### Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company  
275 North Field Drive  
Lake Forest, Illinois 60045  
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  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 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

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### 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

#### Hazardous

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

| Ingredient          | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|---------------------|------------|-----------------------|--------------------|---|
| Water for injection | 7732-18-5  | 231-791-2             | Not Listed         | * |
| Sodium chloride     | 7647-14-5  | 231-598-3             | Not Listed         | * |

#### 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.

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**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:** 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)

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### 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               |
|                                    | 1880 mg/m <sup>3</sup> |
| Austria OEL - MAKs                 | 1000 ppm               |
|                                    | 1900 mg/m <sup>3</sup> |
| Belgium OEL - TWA                  | 1000 ppm               |
|                                    | 1907 mg/m <sup>3</sup> |
| Bulgaria OEL - TWA                 | 1000 mg/m <sup>3</sup> |
| Czech Republic OEL - TWA           | 1000 mg/m <sup>3</sup> |
| Denmark OEL - TWA                  | 1000 ppm               |
|                                    | 1900 mg/m <sup>3</sup> |
| Estonia OEL - TWA                  | 500 ppm                |
|                                    | 1000 mg/m <sup>3</sup> |
| Finland OEL - TWA                  | 1000 ppm               |
|                                    | 1900 mg/m <sup>3</sup> |
| France OEL - TWA                   | 1000 ppm               |
|                                    | 1900 mg/m <sup>3</sup> |
| Germany - TRGS 900 - TWAs          | 500 ppm                |
|                                    | 960 mg/m <sup>3</sup>  |
| Germany (DFG) - MAK                | 500 ppm                |
|                                    | 960 mg/m <sup>3</sup>  |
| Greece OEL - TWA                   | 1000 ppm               |
|                                    | 1900 mg/m <sup>3</sup> |
| Hungary OEL - TWA                  | 1900 mg/m <sup>3</sup> |
| Latvia OEL - TWA                   | 1000 mg/m <sup>3</sup> |
| Lithuania OEL - TWA                | 500 ppm                |
|                                    | 1000 mg/m <sup>3</sup> |
| Netherlands OEL - TWA              | 260 mg/m <sup>3</sup>  |
| OSHA - Final PELs - TWAs:          | 1000 ppm               |
|                                    | 1900 mg/m <sup>3</sup> |
| Poland OEL - TWA                   | 1900 mg/m <sup>3</sup> |
| Portugal OEL - TWA                 | 1000 ppm               |
| Romania OEL - TWA                  | 1000 ppm               |
|                                    | 1900 mg/m <sup>3</sup> |
| Russia OEL - TWA                   | 1000 mg/m <sup>3</sup> |
| Slovakia OEL - TWA                 | 500 ppm                |
|                                    | 960 mg/m <sup>3</sup>  |
| Slovenia OEL - TWA                 | 1000 ppm               |
|                                    | 1900 mg/m <sup>3</sup> |
| Sweden OEL - TWAs                  | 500 ppm                |
|                                    | 1000 mg/m <sup>3</sup> |
| Switzerland OEL - TWAs             | 500 ppm                |
|                                    | 960 mg/m <sup>3</sup>  |
| Vietnam OEL - TWAs                 | 1000 mg/m <sup>3</sup> |

#### Hydrochloric Acid

ACGIH Ceiling Threshold Limit: 2 ppm

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|                                |                       |
|--------------------------------|-----------------------|
| Australia PEAK                 | 5 ppm                 |
|                                | 7.5 mg/m <sup>3</sup> |
| Austria OEL - MAKs             | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Belgium OEL - TWA              | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA             | 5 ppm                 |
|                                | 8.0 mg/m <sup>3</sup> |
| Cyprus OEL - TWA               | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Czech Republic OEL - TWA       | 8 mg/m <sup>3</sup>   |
| Estonia OEL - TWA              | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Germany - TRGS 900 - TWAs      | 2 ppm                 |
|                                | 3 mg/m <sup>3</sup>   |
| Germany (DFG) - MAK            | 2 ppm                 |
|                                | 3.0 mg/m <sup>3</sup> |
| Greece OEL - TWA               | 5 ppm                 |
|                                | 7 mg/m <sup>3</sup>   |
| Hungary OEL - TWA              | 8 mg/m <sup>3</sup>   |
| Ireland OEL - TWAs             | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Italy OEL - TWA                | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Japan - OELs - Ceilings        | 2 ppm                 |
|                                | 3.0 mg/m <sup>3</sup> |
| Latvia OEL - TWA               | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Lithuania OEL - TWA            | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Luxembourg OEL - TWA           | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Malta OEL - TWA                | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Netherlands OEL - TWA          | 8 mg/m <sup>3</sup>   |
| Poland OEL - TWA               | 5 mg/m <sup>3</sup>   |
| Portugal OEL - TWA             | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Romania OEL - TWA              | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Slovakia OEL - TWA             | 5 ppm                 |
|                                | 8.0 mg/m <sup>3</sup> |
| Slovenia OEL - TWA             | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Spain OEL - TWA                | 5 ppm                 |
|                                | 7.6 mg/m <sup>3</sup> |
| Switzerland OEL -TWAs          | 2 ppm                 |
|                                | 3.0 mg/m <sup>3</sup> |
| Vietnam OEL - TWAs             | 5 mg/m <sup>3</sup>   |
| <br>Sodium hydroxide           |                       |
| ACGIH Ceiling Threshold Limit: | 2 mg/m <sup>3</sup>   |
| Australia PEAK                 | 2 mg/m <sup>3</sup>   |

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|                           |                       |
|---------------------------|-----------------------|
| Austria OEL - MAKs        | 2 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA        | 2.0 mg/m <sup>3</sup> |
| Czech Republic OEL - TWA  | 1 mg/m <sup>3</sup>   |
| Estonia OEL - TWA         | 1 mg/m <sup>3</sup>   |
| France OEL - TWA          | 2 mg/m <sup>3</sup>   |
| Greece OEL - TWA          | 2 mg/m <sup>3</sup>   |
| Hungary OEL - TWA         | 2 mg/m <sup>3</sup>   |
| Japan - OELs - Ceilings   | 2 mg/m <sup>3</sup>   |
| Latvia OEL - TWA          | 0.5 mg/m <sup>3</sup> |
| OSHA - Final PELs - TWAs: | 2 mg/m <sup>3</sup>   |
| Poland OEL - TWA          | 0.5 mg/m <sup>3</sup> |
| Slovakia OEL - TWA        | 2 mg/m <sup>3</sup>   |
| Slovenia OEL - TWA        | 2 mg/m <sup>3</sup>   |
| Sweden OEL - TWAs         | 1 mg/m <sup>3</sup>   |
| Switzerland OEL - TWAs    | 2 mg/m <sup>3</sup>   |

**Sodium chloride**

|                     |                     |
|---------------------|---------------------|
| Latvia OEL - TWA    | 5 mg/m <sup>3</sup> |
| Lithuania OEL - TWA | 5 mg/m <sup>3</sup> |

**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

|                                     |                    |                          |                       |
|-------------------------------------|--------------------|--------------------------|-----------------------|
| <b>Physical State:</b>              | Solution           | <b>Color:</b>            | Clear to light yellow |
| <b>Odor:</b>                        | Alcohol Slight     | <b>Odor Threshold:</b>   | No data available.    |
| <b>Molecular Formula:</b>           | Mixture            | <b>Molecular Weight:</b> | Mixture               |
| <b>Solvent Solubility:</b>          | No data available  |                          |                       |
| <b>Water Solubility:</b>            | No data available  |                          |                       |
| <b>Solubility:</b>                  | Soluble: Water     |                          |                       |
| <b>pH:</b>                          | 6.9-7.9            |                          |                       |
| <b>Melting/Freezing Point (°C):</b> | No data available  |                          |                       |
| <b>Boiling Point (°C):</b>          | No data available. |                          |                       |

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### 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.

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### 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/m<sup>3</sup>  
Rat Oral LD50 7,060mg/kg  
Mouse Inhalation LC50 4h 39g/m<sup>3</sup>  
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

#### Reproduction & 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



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### 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 |  |
| <i>Oncorhynchus mykiss</i> (Rainbow Trout)  | NPDES | LC50 | 96 Hours | 12,900 mg/L |  |
| <i>Pimephales promelas</i> (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

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### 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   |
| California Proposition 65                   | carcinogen 4/29/2011 in alcoholic beverages<br>developmental toxicity 10/1/1987 in alcoholic beverages |
| 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<br>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         |

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|   |            |
|---|------------|
| Inventory - United States TSCA - Sect. 8(b) | Present    |
| Australia (AICS):                           | Present    |
| Standard for the Uniform Scheduling         | Schedule 5 |
| for Drugs and Poisons:                      | Schedule 6 |
| 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         | Schedule 5 |
| for Drugs and Poisons:                      | Schedule 6 |
| 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      | Present    |
| obligations of Register:                    |            |
| 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  
 Product Stewardship Hazard Communication  
**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

## SAFETY DATA SHEET

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

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**Version: 1.0**

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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**