



# SAFETY DATA SHEET

Revision date 18-Mar-2023

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Ketorolac Tromethamine Injection, USP (Hospira Inc.)  
**Product Code(s)** PZ03100  
**Synonyms** Ketorolac trometamol  
**Trade Name:** Not applicable  
**Chemical Family:** Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as Non-steroidal, anti-inflammatory drug (NSAID)

### 1.3. 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

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Acute toxicity - Oral** Category 5 - (H303)  
**Reproductive toxicity** Category 1A - (H360D)  
**Specific target organ toxicity (repeated exposure)** Category 2 - (H373)

### 2.2. Label elements

**Signal word** Danger

**Hazard statements**  
H303 - May be harmful if swallowed  
H360D - May damage the unborn child  
H373 - May cause damage to organs through prolonged or repeated exposure: kidneys, gastrointestinal system.

**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  
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel

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unwell  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations



## 2.3. 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.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Ethyl alcohol (ethanol) (CAS #: 64-17-5)	7 - 12	-	200-578-6	Flam. Liq. 2 (H225)	Not Listed	No data available	No data available
Ketorolac tromethamine (CAS #: 74103-07-4)	1.5-3.0		Not Listed	Acute Tox.3 (H301) STOT RE 2 (H373) Repr.1A (H360D)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 ::	No data available	No data available

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					10%≤C<25% STOT SE 3 :: C>=10%	
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NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

Acute Toxicity Estimate

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Ethyl alcohol (ethanol) 64-17-5	7060	No data available	116.9 133.8	No data available	No data available
Ketorolac tromethamine 74103-07-4	112	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

**Additional information**

\* Proprietary  
 \*\* to adjust pH  
 + Substance with a Union workplace exposure limit  
 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. Non-hazardous ingredients provided for completeness.

**Section 4: FIRST AID MEASURES**

**4.1. Description of first aid measures**

- Inhalation**                      Remove to fresh air. Seek immediate medical attention/advice.
- Eye contact**                      Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
- 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.

### 4.2. Most important symptoms and effects, both acute and delayed

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** None.

## **Section 5: FIRE-FIGHTING MEASURES**

### 5.1. Extinguishing media

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

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Fine particles (such as mists) may fuel fires/explosions.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

### 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## **Section 6: ACCIDENTAL RELEASE MEASURES**

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

**Advice on safe handling**

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

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

## 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

## 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical product used as. Non-steroidal, anti-inflammatory drug (NSAID).

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

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

#### **Ketorolac tromethamine**

Pfizer OEL TWA-8 Hr: 30 µg/m<sup>3</sup>

#### **Ethyl alcohol (ethanol)**

ACGIH TLV

Austria

STEL: 1000 ppm

1000 ppm

1900 mg/m<sup>3</sup>

STEL 2000 ppm

STEL 3800 mg/m<sup>3</sup>

Bulgaria

1000 mg/m<sup>3</sup>

Czech Republic

1000 mg/m<sup>3</sup>

Ceiling: 3000 mg/m<sup>3</sup>

Denmark

1000 ppm

1900 mg/m<sup>3</sup>

Estonia

500 ppm

1000 mg/m<sup>3</sup>

STEL: 1000 ppm

STEL: 1900 mg/m<sup>3</sup>

Finland

1000 ppm

1900 mg/m<sup>3</sup>

STEL: 1300 ppm

STEL: 2500 mg/m<sup>3</sup>

France

1900 mg/m<sup>3</sup>

Germany

200 ppm

380 mg/m<sup>3</sup>

Ceiling / Peak: 800 ppm

Ceiling / Peak: 1520 mg/m<sup>3</sup>

Germany

200 ppm

380 mg/m<sup>3</sup>

Hungary

1900 mg/m<sup>3</sup>

STEL: 3800 mg/m<sup>3</sup>

Ireland

STEL: 1000 ppm

Latvia

1000 mg/m<sup>3</sup>

Netherlands

260 mg/m<sup>3</sup>

STEL: 1900 mg/m<sup>3</sup>

H\*

Poland

1900 mg/m<sup>3</sup>

Romania

1000 ppm

1900 mg/m<sup>3</sup>

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Russia	STEL: 5000 ppm STEL: 9500 mg/m <sup>3</sup> TWA: 1000 mg/m <sup>3</sup> MAC: 2000 mg/m <sup>3</sup>
Slovakia	500 ppm 960 mg/m <sup>3</sup>
Spain	STEL: 1000 ppm STEL: 1910 mg/m <sup>3</sup>
Switzerland	500 ppm 960 mg/m <sup>3</sup> STEL: 1000 ppm STEL: 1920 mg/m <sup>3</sup>
OSHA PEL	1000 ppm 1900 mg/m <sup>3</sup> (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m <sup>3</sup>
United Kingdom	TWA: 1000 ppm TWA: 1920 mg/m <sup>3</sup> STEL: 3000 ppm STEL: 5760 mg/m <sup>3</sup>

## SODIUM CHLORIDE

Latvia	5 mg/m <sup>3</sup>
Russia	MAC: 5 mg/m <sup>3</sup>

## Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m <sup>3</sup>
ACGIH TLV	Ceiling: 2 mg/m <sup>3</sup>
Austria	2 mg/m <sup>3</sup> STEL 4 mg/m <sup>3</sup>
Bulgaria	2.0 mg/m <sup>3</sup>
Czech Republic	1 mg/m <sup>3</sup> Ceiling: 2 mg/m <sup>3</sup>
Denmark	Ceiling: 2 mg/m <sup>3</sup>
Estonia	1 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
Finland	Ceiling: 2 mg/m <sup>3</sup>
France	2 mg/m <sup>3</sup>
Hungary	1 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
Ireland	STEL: 2 mg/m <sup>3</sup>
Ceiling Limit Value	2 mg/m <sup>3</sup>
Latvia	0.5 mg/m <sup>3</sup>
Poland	STEL: 1 mg/m <sup>3</sup> 0.5 mg/m <sup>3</sup>
Romania	1 mg/m <sup>3</sup> STEL: 3 mg/m <sup>3</sup>
Slovakia	2 mg/m <sup>3</sup>
Spain	STEL: 2 mg/m <sup>3</sup>
Switzerland	2 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
OSHA PEL	2 mg/m <sup>3</sup> (vacated) Ceiling: 2 mg/m <sup>3</sup>
United Kingdom	STEL: 2 mg/m <sup>3</sup>

## + Hydrochloric Acid

ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	5 ppm 8 mg/m <sup>3</sup> STEL 10 ppm STEL 15 mg/m <sup>3</sup>
Bulgaria	STEL: 10 ppm

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	STEL: 15.0 mg/m <sup>3</sup>
	5 ppm
	8.0 mg/m <sup>3</sup>
Czech Republic	8 mg/m <sup>3</sup>
	Ceiling: 15 mg/m <sup>3</sup>
Estonia	5 ppm
	8 mg/m <sup>3</sup>
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
European Union	TWA: 5 ppm
	TWA: 8 mg/m <sup>3</sup>
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
Finland	STEL: 5 ppm
	STEL: 7.6 mg/m <sup>3</sup>
Germany	2 ppm
	3.0 mg/m <sup>3</sup>
	Ceiling / Peak: 4 ppm
	Ceiling / Peak: 6 mg/m <sup>3</sup>
Germany	2 ppm
	3 mg/m <sup>3</sup>
Hungary	8 mg/m <sup>3</sup>
	STEL: 16 mg/m <sup>3</sup>
Ireland	8 mg/m <sup>3</sup>
	5 ppm
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
Italy	5 ppm
	8 mg/m <sup>3</sup>
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
Ceiling Limit Value	2 ppm
	3.0 mg/m <sup>3</sup>
Latvia	5 ppm
	8 mg/m <sup>3</sup>
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
Netherlands	8 mg/m <sup>3</sup>
	STEL: 15 mg/m <sup>3</sup>
Poland	STEL: 10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Romania	5 ppm
	8 mg/m <sup>3</sup>
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
Russia	MAC: 5 mg/m <sup>3</sup>
Slovakia	5 ppm
	8.0 mg/m <sup>3</sup>
Spain	5 ppm
	7.6 mg/m <sup>3</sup>
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
Switzerland	2 ppm
	3 mg/m <sup>3</sup>
	STEL: 4 ppm
	STEL: 6 mg/m <sup>3</sup>
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm
	7 mg/m <sup>3</sup>
OSHA PEL	(vacated) Ceiling: 5 ppm
	(vacated) Ceiling: 7 mg/m <sup>3</sup>

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United Kingdom

Ceiling: 5 ppm  
Ceiling: 7 mg/m<sup>3</sup>  
TWA: 1 ppm  
TWA: 2 mg/m<sup>3</sup>  
STEL: 5 ppm  
STEL: 8 mg/m<sup>3</sup>

## Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

## 8.2. 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.

### Environmental exposure controls

No information available.

### Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

### Eye/face protection

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.).

### Hand protection

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.).

### Skin and body protection

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.).

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Physical state

Solution

Color

Clear to Light yellow

Odor

Alcohol. Slight.

Odor threshold

No information available

Molecular formula

Mixture

Molecular weight

Mixture

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<u>Property</u>	<u>Values</u>
<b>pH</b>	6.9-7.9
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	55 (ethanol)
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	0.991
<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	Soluble Water
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## **9.2. Other information**

No information available

### **9.2.1. Information with regard to physical hazard classes**

No information available

### **9.2.2. Other safety characteristics**

No information available

## **Section 10: STABILITY AND REACTIVITY**

### **10.1. Reactivity**

**Reactivity** No data available.

### **10.2. Chemical stability**

**Stability** Stable under normal conditions.

#### **Explosion data**

**Sensitivity to Mechanical Impact** No data available.

**Sensitivity to Static Discharge** No data available.

### **10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** No information available.

**Hazardous polymerization** Will not occur.

### **10.4. Conditions to avoid**

**Conditions to avoid** Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

### **10.5. Incompatible materials**

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

### **10.6. Hazardous decomposition products**

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**Hazardous decomposition products** No data available.

## Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients
<b>Short term</b>	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.
<b>Known Clinical Effects:</b>	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.
<b>Acute toxicity</b>	Classification is based on mixture calculation methods based on component data
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Classification is based on mixture calculation methods based on component data.
<b>Reproductive toxicity</b>	Classification is based on mixture calculation methods based on component data.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

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

#### Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg  
Rat Oral LD50 7060 mg/kg  
Rat Inhalation LC50 10h 20,000 ppm

#### Ketorolac tromethamine

Rat Oral LD50 112 mg/kg  
Mouse Oral LD50 400 mg/kg

#### SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>  
Rat Oral LD 50 3 g/kg  
Mouse Oral LD 50 4 g/kg  
Rabbit Dermal LD 50 > 10 g/kg

#### Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Ethyl alcohol (ethanol)	= 7060 mg/kg ( Rat )	-	= 116.9 mg/L ( Rat ) 4 h = 133.8 mg/L ( Rat ) 4 h
Ketorolac tromethamine	= 189 mg/kg ( Rat )	-	-
SODIUM CHLORIDE	= 3 g/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-
+ Hydrochloric Acid	238 - 277 mg/kg ( Rat )	> 5010 mg/kg ( Rabbit )	= 1.68 mg/L ( Rat ) 1 h

**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.

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

### Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

### Ketorolac tromethamine

Skin Sensitization - GPMT Guinea Pig Negative

### SODIUM CHLORIDE

Skin irritation Rabbit Mild  
Eye irritation Rabbit Mild

### Sodium hydroxide

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

### + Hydrochloric Acid

Skin irritation Severe  
Eye irritation Severe

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

### Ketorolac tromethamine

3 Month(s) Monkey Intramuscular 4.5 mg/kg/day LOAEL None identified  
6 Month(s) Mouse Oral 3.3 mg/kg/day LOAEL Gastrointestinal system  
6 Month(s) Monkey Oral 0.75 mg/kg/day LOAEL None identified  
12 Month(s) Monkey Oral 0.75 mg/kg/day LOAEL Kidney

## Reproduction & Development Toxicity: (Duration, 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  
Embryo / Fetal Development Rat Oral 3.6 mg/kg/day NOAEL No effects at maximum dose  
Embryo / Fetal Development Rabbit Oral 3.6 mg/kg/day NOAEL No effects at maximum dose

## 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

### + Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vivo* Micronucleus Rat 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

### Carcinogenicity

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

### + Hydrochloric Acid

IARC Group 3 (Not Classifiable)

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

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## 11.2.2. Other information

**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

### 12.1. Toxicity

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

##### Ethyl alcohol (ethanol)

*Oncorhynchus mykiss* (Rainbow Trout) NPDES LC50 96 Hours 12,900 mg/L  
Fingerling Trout NPDES LC50 24 Hours 11200 mg/L  
*Pimephales promelas* (Fathead Minnow) NPDES LC50 96 Hours 14200 mg/L

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

### 12.4. Mobility in soil

**Mobility in soil** No information available.

### 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** No information available.

Chemical name	PBT and vPvB assessment
Ethyl alcohol (ethanol)	The substance is not PBT / vPvB PBT assessment does not apply
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
+ Hydrochloric Acid	The substance is not PBT / vPvB PBT assessment does not apply

### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 12.7. Other adverse effects

No information available.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific

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provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater 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.

## Section 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.

**UN number:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable  
  
**Special precautions for user:** Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

Ethyl alcohol (ethanol)

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	carcinogen 7/1/1988 when associated with alcohol abuse carcinogen 4/29/2011 developmental toxicity 10/1/1987
<b>TSCA</b>	Present
<b>EINECS</b>	200-578-6
<b>AICS</b>	Present

Ketorolac tromethamine

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4

SODIUM CHLORIDE

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-598-3
<b>AICS</b>	Present

Sodium hydroxide

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present

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<b>EINECS</b>	215-185-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5
+ Hydrochloric Acid	Schedule 6
<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-595-7
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5
	Schedule 6

Chemical name	French RG number	Title
Ethyl alcohol (ethanol) 64-17-5	RG 84	-
SODIUM CHLORIDE 7647-14-5	RG 78	-

### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

### Persistent Organic Pollutants

Not applicable

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid - 7647-01-0	25	250

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

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## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### **Full text of H-Statements referred to under 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

<b>Data Sources:</b>	Pfizer proprietary drug development information. Safety data sheets for individual ingredients.
<b>Reason for revision</b>	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.
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<b>Prepared By</b>	Pfizer Global Environment, Health, and Safety

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