



MATERIAL SAFETY DATA SHEET

Revision date: 13-Jul-2012

Version: 2.0

Page 1 of 10

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Ketorolac Tromethamine Injection

Trade Name:	Not applicable
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

2. HAZARDS IDENTIFICATION

Appearance: Clear to light yellow solution
Signal Word: DANGER

Statement of Hazard: May damage the unborn child.
May cause damage to gastrointestinal system through prolonged or repeated exposure.

Additional Hazard Information:
Short Term: Accidental ingestion may cause effects similar to those seen in clinical use. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

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, liver effects.

EU Indication of danger: Toxic to reproduction: Category 1
Harmful

EU Hazard Symbols:



EU Risk Phrases:

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R61 - May cause harm to the unborn child.
Hazardous Substance. Dangerous Goods.

Australian Hazard Classification (NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection
Revision date: 13-Jul-2012

Page 2 of 10
Version: 2.0

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the 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	EU Classification	%
Ethanol	64-17-5	200-578-6	F;R11	10
Ketorolac tromethamine	74103-07-4	Not Listed	T,R22-R48/25; Repr. Cat.1,R61	1.5-3.0
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**
Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	80-85

Additional Information: * Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush 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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

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

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

MATERIAL SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection
Revision date: 13-Jul-2012

Page 3 of 10
Version: 2.0

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of the spill or leak. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly. Prevent discharge to

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

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Ethanol

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m ³
Austria OEL - MAKs	1000 ppm
	1900 mg/m ³
Belgium OEL - TWA	1000 ppm
	1907 mg/m ³
Bulgaria OEL - TWA	1000.0 mg/m ³
Czech Republic OEL - TWA	1000 mg/m ³
Denmark OEL - TWA	1000 ppm
	1900 mg/m ³
Estonia OEL - TWA	500 ppm
	1000 mg/m ³
Finland OEL - TWA	1000 ppm
	1900 mg/m ³
France OEL - TWA	1000 ppm
	1900 mg/m ³
Germany - TRGS 900 - TWAs	500 ppm
	960 mg/m ³

MATERIAL SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection
Revision date: 13-Jul-2012

Page 4 of 10
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany (DFG) - MAK	500 ppm
	960 mg/m ³
Greece OEL - TWA	1000 ppm
	1900 mg/m ³
Hungary OEL - TWA	1900 mg/m ³
Ireland OEL - TWAs	1000 ppm
	1900 mg/m ³
Latvia OEL - TWA	1000 mg/m ³
Lithuania OEL - TWA	500 ppm
	1000 mg/m ³
Netherlands OEL - TWA	260 mg/m ³
OSHA - Final PELs - TWAs:	1000 ppm
	1900 mg/m ³
Poland OEL - TWA	1900 mg/m ³
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm
	1900 mg/m ³
Slovakia OEL - TWA	500 ppm
	960 mg/m ³
Slovenia OEL - TWA	1000 ppm
	1900 mg/m ³
Spain OEL - TWA	1000 ppm
	1910 mg/m ³
Sweden OEL - TWAs	500 ppm
	1000 mg/m ³
Sodium chloride	
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sodium hydroxide	
ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Hydrochloric Acid	
ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³

MATERIAL SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection
Revision date: 13-Jul-2012

Page 5 of 10
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	5 ppm 8 mg/m ³
Belgium OEL - TWA	5 ppm 8 mg/m ³
Bulgaria OEL - TWA	8.0 mg/m ³
Cyprus OEL - TWA	5 ppm 8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm 8 mg/m ³
Italy OEL - TWA	5 ppm 8 mg/m ³
Japan - OELs - Ceilings	5 ppm 7.5 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³

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:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

MATERIAL SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection
Revision date: 13-Jul-2012

Page 6 of 10
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Clear to light yellow
Odor:	Alcohol Slight	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

Solubility:	Soluble: Water
pH:	6.9-7.9
Specific Gravity:	0.991

Flammability:	
Flash Point (Liquid) (°C):	55 (ethanol)
Polymerization:	Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Ethanol

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

Sodium hydroxide

Mouse	IP	LD50	40 mg/kg
-------	----	------	----------

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	293 mg/kg

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

Ethanol

MATERIAL SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection
Revision date: 13-Jul-2012

Page 7 of 10
Version: 2.0

11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Severe

Hydrochloric Acid

Skin Irritation Severe

Eye Irritation Severe

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Sodium chloride

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild

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

Ketorolac tromethamine

Reproductive & Fertility-Females Rat Oral 16 mg/kg/day NOEL Negative

Reproductive & Fertility-Males Rat Oral 9 mg/kg/day NOEL Negative

Prenatal & Postnatal Development Rabbit Oral 3.6 mg/kg/day NOEL Negative

Prenatal & Postnatal Development Rat Oral 10 mg/kg/day NOEL Negative

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 NOEL Not carcinogenic

18 Month(s) Mouse Oral 2 mg/kg/day NOEL Not carcinogenic

Carcinogen Status:

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

Ethanol

IARC: Group 1 (Carcinogenic to Humans)

OSHA: Listed

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.

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

Ethanol

Fingerling Trout NPDES LC50 24 Hours 11,200 mg/L

MATERIAL SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection
Revision date: 13-Jul-2012

Page 8 of 10
Version: 2.0

12. ECOLOGICAL INFORMATION

<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

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction: Category 1
Harmful

EU Risk Phrases:
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R61 - May cause harm to the unborn child.

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

OSHA Label:
DANGER
May damage the unborn child.
May cause damage to gastrointestinal system through prolonged or repeated exposure.

Canada - WHMIS: Classifications

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

MATERIAL SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection
Revision date: 13-Jul-2012

Page 9 of 10
Version: 2.0

15. REGULATORY INFORMATION



Ethanol

California Proposition 65	developmental toxicity initial date 10/1/87
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

Ketorolac tromethamine

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
---	------------

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Water for injection

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

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
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

MATERIAL SAFETY DATA SHEET

Material Name: Ketorolac Tromethamine Injection
Revision date: 13-Jul-2012

Page 10 of 10
Version: 2.0

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.

R22 - Harmful if swallowed.

R11 - Highly flammable.

R20/22 - Harmful by inhalation and if swallowed.

R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 9 - Physical and Chemical Properties. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information.

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

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet