SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	:	Ketorolac Tromethamine Injection, USP (Caplin Steriles Ltd.)
Chemical Family	:	A pyrrolizine carboxylic acid derivative
Synonyms	:	Ketorolac trometamol
Manufacturer or supplier's details		
Details of the Supplier of the Safety Data Sheet	:	Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.
Emergency Telephone Number	:	+91-4467901901/02/03

Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid).
Restrictions on use	:	Not applicable

SECTION 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



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 INGREDIENT

Hazardous

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

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium Chloride	7647-14-5	231-598-3	Not Listed	0.4-0.7
Water for injection	7732-18-5	231-791-2	Not Listed	Qs to 100%

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

SECTION 4: FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure:	None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:	None

SECTION 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 firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 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.

SECTION 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 thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:	Store as directed by product packaging.
Specific end use(s):	Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Control Parameters

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

Ketorolac Tromethamine

Caplin OEL TWA-8 Hr:	30 µg/m^3

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 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
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
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
Russia OEL - TWA	1000 mg/m^3
Slovakia OEL - TWA	500 ppm
	960 mg/m^3
Slovenia OEL - TWA	1000 ppm
	1900 mg/m^3
Sweden OEL - TWAs	500 ppm
	1000 mg/m^3
Switzerland OEL -TWAs	500 ppm
	960 mg/m^3
Vietnam OEL - TWAs	1000 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
Switzerland OEL -TWAs	2 mg/m^3
Sodium chloride	
Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
Hydrochloric Acid	
ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	5 ppm 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	2 ppm 3.0 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
Portugal OEL - TWA	5 ppm 8 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
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

Sodium Chloride

Caplin Occupational Exposure Band (OEB): **OEB** 1 (control exposure to the range of 1000ug/m^3 to 3000ug/m^3)

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). 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.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are 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 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 half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

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

Partition Coefficient: (Method, pH, Endpoint, Value)

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

Flammablity:

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

SECTION 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

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effect

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.
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^3
Rat Oral LD50 7,060mg/kg
Mouse Inhalation LC50 4h 39g/m^3
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 & 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		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

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 IARC. The IARC monograph examining the carcinogenic potential of ethanol only alcoholic beverages. See below

Ethanol
IARC: Group 1 (Carcinogenic to Humans)

Hydrochloric Acid
IARC: Group 3 (Not Classifiable)

SECTION 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

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

Ethanol

Fathead Minnow	NPDES	LC-50	24 Hours	11,200 mg/L
Oncorhynchus mykiss (Rainbow Trout)	NPDES	LC-50	96 Hours	12,900 mg/L
Pimephales promelas (Fathead Minnow)	NPDES	LC-50	96 Hours	14,200 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

SECTION 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.

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.

SECTION 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
Australia (AICS):	Not Listed
Standard for the Uniform Scheduling	Schedule 4

for Drugs and Poisons:	
EU EINECS/ELINCS List	Not Listed

ETHANOL

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 4/29/2011 in alcoholic beverages 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

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

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 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 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 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
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 Schedule 6
EU EINECS/ELINCS List	231-595-7

SECTION 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

Prepared by : Caplin Steriles Limited

General Disclaimer The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

---End of Safety Data Sheet---