SAFETY DATA SHEET

Section 1: Identification	
Material	Ketorolac Tromethamine Injection, USP
Recommended use	Pharmaceutical product used as non-steroidal, anti-inflammatory drug (NSAID)
Manufacturer	Aspiro Pharma Limited
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Classification of the substance or mixture	Reproductive Toxicity: Category 1A Specific target organ systemic toxicity (repeated exposure): Category 2
Hazard Statements	May damage the unborn child. May cause damage to organs through prolonged or repeated exposure
Precautionary Statements	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection. IF exposed or concerned: Get medical attention/advice. Get medical attention/advice if you feel unwell.
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	
Ingredient	**CAS No.**
Ketorolac Tromethamine	74103-07-4
Ethanol	64-17-5
Sodium hydroxide	1310-73-2

Hydrochloric Acid	7647-01-0
Sodium chloride	7647-14-5
Water for injection	7732-18-5
Citric acid anhydrous	77-92-9
Section 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.
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
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.
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	
Suitable 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. Cleanup 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 hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Conditions for Safe Storage, Including any incompatibilities Storage Conditions	Store as directed by product packaging.
Specific end use(s)	Pharmaceutical product used as non-steroidal, anti-inflammatory drug (NSAID)
8. Exposure controls / personal protection	
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 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.)

Section 9: Physical and Chemical Properties	
Physical State	Solution
Description	Ketorolac tromethamine injection, USP is a sterile, clear and slightly yellow color solution and is supplied as follows: **15 mg / mL - NDC** 31722-305-25 Tray of 25 1 mL fill in a 2 mL single-dose glass fliptop vial **30 mg / mL - NDC** 31722-306-25 Tray of 25 1 mL fill in a 2 mL single-dose glass **60 mg / mL - NDC** 31722-307-25 Tray of 25 2 mL fill in a 2 mL single-dose glass fliptop vial
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 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.

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

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

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Ketorolac tromethamine

Rat Oral LD50 189 mg/kg
Mouse Oral LD50 293mg/kg

Ethanol

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

Sodium hydroxide

Mouse IP LD50 40 mg/kg

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

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Ethanol

Eye Irritation Rabbit Severe

Hydrochloric Acid

Skin Irritation Severe
Eye Irritation Severe

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

Ketorolac tromethamine

Reproductive & Fertility- Females Rat Oral16 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

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)

Section 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

Ketorolac tromethamine

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

Persistence and Degradability : No data available
Bio-accumulative Potential : No data available
Mobility in Soil : No data available

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 California Proposition 65 Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS/ELINCS List	 Not Listed Not Listed Schedule 4 Not Listed
Ethanol CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory-United States TSCA-Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List	 Not Listed carcinogen 4/29/2011 in alcoholic beverages developmental toxicity 10/1/1987 in alcoholic beverages Present Present 200-578-6
Sodium hydroxide CERCLA/SARA 313 Emission reporting CERCLA/SARA Hazardous Substances and their Reportable Quantities: California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	 Not Listed 1000 lb 454 kg Not Listed Present

Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS/ELINCS List	Present Schedule 5 Schedule 6 215-185-5
Water for injection CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory-United States TSCA-Sect. 8(b) Australia (AICS): REACH-Annex IV-Exemptions from the obligations of Register: EU EINECS/ELINCS List	 Not Listed Not Listed Present Present Present 231-791-2
Sodium chloride CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List	 Not Listed Not Listed Present Present 231-598-3
Hydrochloric Acid CERCLA/SARA 313 Emission reporting CERCLA/SARA Hazardous Substances and their Reportable Quantities: CERCLA/SARA - Section 302 Extremely Hazardous TPQs CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs California Proposition 65 Inventory-United States TSCA-Sect.8(b) Inventory- United States TSCA- Sect.8(b) Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS/ELINCS List	 1.0 % 5000 lb 2270 kg 500 lb 500 lb Not Listed Present Present Schedule 5 Schedule 6 231-595-7

Section 16: Other Information, including date of preparation or last revision

Issue Date: 29-08-2023

Version: 00

Further information

Revision date: NA

Revision note: NA

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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