SAFETY DATA SHEET

Ketorolac Tromethamine Injection, USP

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, Australian WorkSafe, Japanese Industrial Standard JIS Z 7250:2000, and European Directives

1. PRODUCT IDENTIFICATION

1.1 TRADE NAME (AS LABELED):	**Ketorolac Tromethamine Injection, USP**
SYNONYMS:	±-5-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxyli acid, Compound with 2-amino-2-(hydroxymethyl)-1,3- propanediol (1:1)
CAS#:	Mixture
1.2 PRODUCT USE:	Pharmaceutical, Injectable
PRODUCT CODE:	72611-719-25 (15 mg/mL), 72611-722-25 (30 mg/mL), 72611-725-25 (60 mg/2mL)
1.3 MANUFACTURER'S NAME:	**Almaject, Inc.**
ADDRESS:	44 Whippany Road, Suite 300, Morristown, NJ 07960
BUSINESS PHONE:	1-833-256-2532
FAX NUMBER:	1-973-807-1625
1.4 EMERGENCY PHONE NUMBER:	
EMERGENCY PHONE #:	1-833-256-2532
COMPANY WEB SITE INFORMATION:	www.almaject.com
1.5 PREPARATION INFORMATION:	
DATE OF CURRENT REVISION:	May 21, 2019
DATE OF LAST REVISION:	New

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW:
Product Description: This product is a clear, colorless to slightly yellow liquid with no odor.
Health Hazards: Common adverse effects to excessive exposure include nausea, vomiting, gastrointestinal irritation, diarrhea, fatigue, insomnia, headache and dizziness.
Flammability Hazards: This product is combustible with a flash point of 106ºF.
Reactivity Hazards: None known
Environmental Hazards: The Environmental effects of this product have not been investigated. Release of this product is not expected to have significant adverse effects in the aquatic environment.

US DOT SYMBOLS	CANADA (WHMIS) SYMBOLS	EUROPEAN and (GHS) Hazard Symbols
Non-Regulated Material See Section 14 for Details	Complies with WHMIS 2015	 Signal Word: **Danger!**

2.1 CLASSIFICATION OF SUBSTANCE OR MIXTURE IN ACCORDANCE WITH 29 CFR 1200 (OSHA HCS) AND THE EUROPEAN UNION DIRECTIVES:

This product does meet the definition of a hazardous substance or preparation as defined by 29 CFR 1910. 1200 AND the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

EU HAZARD CLASSIFICATION OF INGREDIENTS PER DIRECTIVE 1272/2008/EC:
EC# 231-791-2 This substance is not classified in the Annex VI
EC# 200-578-6 This substance is classified in the Annex VI, Index# 603-002-00-5
EC# 620-545-3 This substance is not classified in the Annex VI
EC# 231-132-9 This substance is not classified in the Annex VI
Substances not listed either individually or in group entries must be self classified.

Component(s) Contributing to Classification(s)
All Ingredients

2.2 LABEL ELEMENTS:

GHS Hazard Classification(s):
Flammable Liquid Category 2
Skin Irritant Category 2
Eye Irritant Category 2

Hazard Statement(s):

H225 Flammable liquid and vapor
H315: Causes skin irritation
H319: Causes Eye irritation

Precautionary Statement(s):

P210: Keep away from flames and hot surfaces. No Smoking
P264: Wash skin after handling.

Response Statement(s):

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing

Storage Statement(s):

P403+P235: Store in a well ventilated place. Keep cool

Disposal Statement(s):

P501: Dispose of contents/container in accordance with local/regional/national/international regulations

Other Known Hazard(s):

This mixture has not been tested to the criteria for PBT or vPvB in accordance with Annex VII.
No other hazards known

2.3 HEALTH HAZARDS OR RISKS FROM EXPOSURE:

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The most significant routes of exposure for this product are by injection, ingestion, inhalation and skin or eye contact.

ACUTE:

Common adverse effects to excessive exposure include nausea, vomiting, gastrointestinal irritation, diarrhea, fatigue, insomnia, headache and dizziness.

CHRONIC: Chronic toxicity will result only on excessive repetitive exposure. Chronic Toxicity effects may be seen at the digestive system.

TARGET ORGANS: Acute: Skin, Eyes, Digestive System **Chronic:** Digestive System

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Ingredients:	WT (mg/mL)	CAS#	EINECS #	GHS Hazard Classification(s)
Water for Injection	87.8%	7732-18-5	231-791-2	Not Classified
Ethanol	10.0%	64-17-5	200-578-6	H225: Flammable Liq. Cat 2, H319: Eye Irritant Cat 2
Ketorolac Tromethamine	1.5%	74103-07-4	620-545-3	Not Classified
Sodium Chloride	0.7%	7440-23-5	231-132-9	H31: Skin Irritation Cat
Balance of other ingredients is less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).				

NOTE: This product has been classified in accordance with the hazard criteria of the 29CFR1200 and the SDS contains all the information required by the CFR, EU Directives and the Japanese Industrial Standard *JIS Z 7250: 2000*.

4. FIRST-AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES:

EYE CONTACT: If product enters the eyes, open eyes while under gentle running water for at least 15 minutes. Seek medical attention if irritation continues or blurred vision occurs.

SKIN CONTACT: If product contacts skin, wash skin thoroughly with soap and water after handling. Seek medical attention if irritation develops and persists.

INHALATION: If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

INGESTION: If product is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Allergies to non-steroidal, anti-inflammatory drugs such as aspirin.

4.2 SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

Common adverse effects to excessive exposure include nausea, vomiting, gastrointestinal irritation, diarrhea, fatigue, insomnia, headache and dizziness.

Ketorolac affects the central nervous system and has relatively low acute toxicity. Chronic toxicity will result only on excessive repetitive exposure. Chronic Toxicity effects may be seen at the digestive system.

4.3 RECOMMENDATIONS TO PHYSICIANS: Treat symptoms and eliminate overexposure.

5. FIRE-FIGHTING MEASURES

5.1 FIRE EXTINGUISHING MATERIALS:

Use fire extinguishing methods below:

Water Spray: Yes	Carbon Dioxide: Yes
Foam: Yes	Dry Chemical: Yes
Halon: Yes	Other: Any "C" Class

5.2 UNUSUAL FIRE AND EXPLOSION HAZARDS:

This product contains a flammable ingredient and should be kept away from ignition sources.

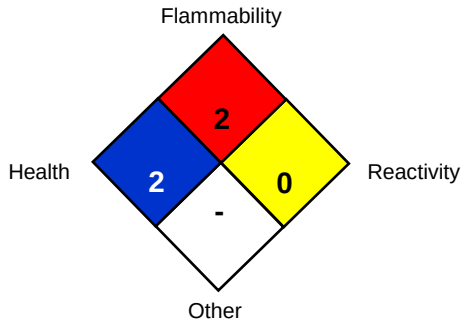
Explosion Sensitivity to Mechanical Impact: No

Explosion Sensitivity to Static Discharge: No

5.3 SPECIAL FIRE-FIGHTING PROCEDURES:

Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING SYSTEM



HMIS RATING SYSTEM

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD (BLUE)	2
FLAMMABILITY HAZARD (RED)	2
PHYSICAL HAZARD (YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	See Sect 8		See Sect 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe * = Chronic hazard

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:

See section 8.2 for Exposure Controls.

6.2 ENVIRONMENTAL PRECAUTIONS:

None known

6.3 SPILL AND LEAK RESPONSE:

Absorb spill with absorbent material and place in an impervious container. Wash the contaminated area. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

7. HANDLING and STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING:

Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment Wash thoroughly after handling.

7.2 STORAGE AND HANDLING PRACTICES:

Keep in cool, dry environment. Store away from heat and ignition sources. Protect containers from physical damage.

7.3 SPECIFIC USES:

Pharmaceutical product, injectable

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

8.1 EXPOSURE PARAMETERS:

Chemical Name	CAS#	ACGIH TLV	OSHA TWA
Water for Injection	7732-18-5	Not Listed	Not Listed
Ethanol	64-17-5	1000 ppm	1000 ppm
Ketorolac Tromethamine	74103-07-4	Not Listed	Not Listed
Sodium Chloride	7440-23-5	Not Listed	Not Listed

8.2 EXPOSURE CONTROLS:

VENTILATION AND ENGINEERING CONTROLS: Not Applicable

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standard of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: Not normally required when using this product. If necessary, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

EYE PROTECTION Safety glasses should be worn when handling this product. If necessary, refer to U.S. OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

SKIN PROTECTION: Gloves should be worn to prevent skin contact. If necessary, refer to U.S. OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate Standards of Canada, Australian Standards, or relevant Japanese Standards.

9. PHYSICAL and CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

APPEARANCE (Physical State) and COLOR: This product is a clear, slightly yellow colorless liquid with no odor.
ODOR: None
ODOR THRESHOLD: Not Available
pH: 6.9 - 7.9
MELTING/FREEZING POINT: Not Available
BOILING POINT: 91ºC
FLASH POINT: 108ºF Ethanol
EVAPORATION RATE (n-BuAc=1): Not Available
FLAMMABILITY (SOLID, GAS): Not Applicable
UPPER/LOWER FLAMMABILITY OR EXPLOSION LIMITS: 3.3% - 19%
VAPOR PRESSURE (mm Hg @ 20°C (68°F): Not Available
VAPOR DENSITY: Not Available
RELATIVE DENSITY: Not Available
DENSITY: Not Available
SPECIFIC GRAVITY: Approximately 1.0
SOLUBILITY IN WATER: Water, ethyl alcohol
WEIGHT PER GALLON: Not Available
PARTITION COEFFICENT (n-octanol/water): Not Available
AUTO-IGNITION TEMPERATURE: Not Available
DECOMPOSITION TEMPERATURE: Not Available
VISCOSITY: Not Available
VOC g/l / Lb/gal: Not Available

9.2 OTHER INFORMATION:

No additional information available.

10. STABILITY and REACTIVITY

10.1 REACTIVITY:

This product is not reactive.

10.2 STABILITY:

Stable under conditions of normal storage and use.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS:
Will not occur

10.4 CONDITIONS TO AVOID:
Incompatible materials

10.5 MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:
Strong oxidizers

10.6 HAZARDOUS DECOMPOSITION PRODUCTS:
May emit toxic fumes.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

TOXICITY DATA:

Chemical Name	CAS#	Oral LD50	Dermal LD50	Inhalation LC50
Water for Injection	7732-18-5	No Data Available	No Data Available	No Data Available
Ethanol	64-17-5	7060 mg/kg	20 gm/kg	20000 ppm
Ketorolac Tromethamine	74103-07-4	189 mg/kg	No Data Available	No Data Available
Sodium Chloride	7440-23-5	No Data Available	No Data Available	No Data Available

Acute Oral Toxicity	**Based on available data, the classification criteria are not met**
Skin Corrosion / Irritation	**Skin Irritant Category 2**
Serious Eye Damage / Irritation	**Eye Irritant Category 2**
Respiratory or Skin Sensitization	**Based on available data, the classification criteria are not met**
Germ Cell Mutagenicity	**Based on available data, the classification criteria are not met**
Carcinogenicity	**Based on available data, the classification criteria are not met**
Reproductive Toxicity	**Based on available data, the classification criteria are not met**
STOT – Single Exposure	**Based on available data, the classification criteria are not met**
STOT – Repeated Exposure	**Based on available data, the classification criteria are not met**
Aspiration Hazard	**Based on available data, the classification criteria are not met**

SUSPECTED CANCER AGENT: None of the ingredients within this product are found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, or CAL/OSHA and therefore are not considered to be, or suspected to be, cancer-causing olam by these agencies.

IRRITANCY OF PRODUCT: This product may be irritating to eyes.

SENSITIZATION TO THE PRODUCT: This product is not expected to cause sensitization

REPRODUCTIVE TOXICITY INFORMATION: No data available

SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE: Eyes, Skin and Digestive System

SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE: Nervous System

ASPIRATION HAZARD: None

12. ECOLOGICAL INFORMATION

12.1 TOXICITY:
No toxicity data available.

12.2 PERSISTENCE AND DEGRADABILITY:
No specific data available on this product.

12.3 BIOACCUMULATIVE POTENTIAL:
No specific data available on this product.

12.4 MOBILITY IN SOIL:
No specific data available on this product.

12.5 RESULTS OF PBT ANDvPvB ASSESSMENT:
No specific data available on this product.

12.6 OTHER ADVERSE EFFECTS:
No specific data available on this product.
ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

12.7 WATER ENDANGERMENT CLASS:
Water endangering in accordance with EU Guideline 91/155-EWG. Not determined

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS:

Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, those of Canada, Australia, EU Member States and Japan.

13.2 EU Waste Code:

Not determined

14. TRANSPORTATION INFORMATION

US DOT, IATA, IMO, ADR:

U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS: This product is classified (per 49 CFR 172.101) by the U.S. Department of Transportation, as follows.

NOTE: 49 CFR173.150 Allows medicines, medical screening solutions, and concentrates containing ethyl alcohol classed as a flammable liquid containing not more than 70% ethyl alcohol by volume for liquids are excepted from the Hazardous Material Requirements provided the following requirements are met:

For non-glass inner packaging: The volume does not exceed 16 fluid ounces in capacity for liquids; or For volumes greater than 16 fluid ounces but not exceeding 1 gallon the company name and the words “Contains Ethyl Alcohol” are marked on the package; For weight greater than one pound up to 8 pounds the company name and the words “Contains Ethyl Alcohol” are marked on the package.

For glass inner packaging: The volume does not exceed 8 fluid ounces in capacity; or For volumes greater than 8 fluid ounces to 16 fluid ounces the company name and the words “Contains Ethyl Alcohol” are marked on the package; For weight greater than 1/2 pound up to 1 pound the company name and the words “Contains Ethyl Alcohol” are marked on the package. The net liquid contents of all inner packagings in any single outer packaging may not exceed 192 fluid ounces. The net solid contents of all inner packagings in any single outer packaging may not exceed 32 pounds. The gross weight of any single outer package shipped may not exceed 65 pounds; Inner packagings must secured and cushioned within the outer package to prevent breakage, leakage, and movement

14.1 PROPER SHIPPING NAME: Non-Regulated Material (see above)
14.2 HAZARD CLASS NUMBER and DESCRIPTION: None
14.3 UN IDENTIFICATION NUMBER: None
14.4 PACKING GROUP: None
14.5 DOT LABEL(S) REQUIRED: None
NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER: None
RQ QUANTITY: None

14.6 MARINE POLLUTANT: None of the components of this product are designated by the Department of Transportation to be Marine Pollutants (49 CFR 172.101, Appendix B).

14.7 SPECIAL PRECAUTIONS FOR USER:

Avoid exposure

14.8 INTERNATIONAL TRANSPORTION:

INTERNATIONAL AIR TRANSPORT ASSOCIATION SHIPPING INFORMATION (IATA): This product is considered as dangerous goods.

INTERNATIONAL MARITIME ORGANIZATION SHIPPING INFORMATION (IMO): This product is considered as dangerous goods.

14.9 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND IBC CODE:

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is considered by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

15.1 UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: None of the components of this product are subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

SARA 302: None

SARA 313 Reporting: None

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for the components of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lbs (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITY (RQ): None

U.S. TSCA INVENTORY STATUS: The components of this product are listed on the TSCA Inventory or are exempted form listing. Commercial use of this material is regulated by the FDA.

OTHER U.S. FEDERAL REGULATIONS: None

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): Ingredients within this product are not on the Proposition 65 Lists.

15.2 CANADIAN REGULATIONS:

CANADIAN DSL/NDSL INVENTORY STATUS: The components of this product are on the DSL Inventory, or are exempted from listing.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS:

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: Complies with WHMIS 2015

15.3 EUROPEAN ECONOMIC COMMUNITY INFORMATION:

This product does meet the definition of a hazardous substance or preparation as defined by the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

See Section 2 for full Details.

15.4 AUSTRALIAN INFORMATION FOR PRODUCT:

The components of this product are listed on the International Chemical Inventory list.

15.5 JAPANESE INFORMATION FOR PRODUCT:

JAPANESE MINISTER OF INTERNATIONAL TRADE AND INDUSTRY (MITI) STATUS:

The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

JAPANESE ENCS INVENTORY:

The components of this product are on the ENCS Inventory as indicated in the section on International Chemical Inventories, below.

POISONOUS AND DELETERIOUS SUBSTANCES CONTROL LAW:

No component of this product is a listed Specified Poisonous Substance under the Poisonous and Deleterious Substances Control Law.

16. OTHER INFORMATION

PREPARED BY: Paul Eigbrett – (**GHS MSDS Compliance PLUS)**

DATE OF PRINTING: May 21, 2019

The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of the need that information is current, applicable and suited to the circumstances of use. Almaject, Inc. assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are no adhered to as stipulated in the data sheet. Furthermore, Almaject, Inc. assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed.

END OF SDS SHEET