

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

**Product identifier****Product Name** Ketorolac 0.4% 5mL**Other means of identification****Product Code** FG056**Synonyms** Acular, Acuvail**Recommended use of the chemical and restrictions on use****Recommended Use** Non Steroidal Anti-Inflammatory

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Details of the supplier of the safety data sheet****Manufacturer**

ALLERGAN  
400 Interpace Parkway, Morris Corporate Center III  
Parsippany, NJ 07054, USA  
+1-800-272-5525

**E-mail address** SDS@Actavis.com**Emergency telephone number****Emergency Telephone**

Call CHEMTREC Day or Night  
Within USA or Canada: 1-800-424-9300  
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

## 2. HAZARDS IDENTIFICATION

**Classification****OSHA Regulatory Status**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity

Category 2

**Label elements****Emergency Overview****Warning****Hazard statements**

H361 - Suspected of damaging fertility or the unborn child



<b>Appearance</b> Liquid	<b>Physical state</b> Liquid	<b>Odor</b> No information available
<b>Chemical Name</b> Ketorolac Tromethamine	<b>Symptoms</b> The most frequent adverse reactions reported by up to 40% of patients participating in clinical trials have been transient stinging and burning on instillation. NSAIDs, including TORADOL, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. severe complications of treatment with TORADOL, such as GI ulceration, bleeding and perforation, postoperative bleeding, acute renal failure, anaphylactic and anaphylactoid reactions and liver failure.	
<b>Benzalkonium Chloride</b>	Common adverse reactions of this medication are dry, burning, or stinging sensation in the eye. Exposure may include nausea, vomiting, cough, shortness of breath, headache.	
<b>Chemical Name</b> Ketorolac Tromethamine	<b>Medical Conditions Aggravated by Exposure</b> Contraindication include hypersensitivity to any component of this product Renal impairment, cerebrovascular bleeding, cardiovascular disease, active peptic ulcer disease, in patients with recent gastrointestinal bleeding or perforation, and in patients with a history of peptic ulcer disease or gastrointestinal bleeding.	

**Precautionary statements**

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P281 - Use personal protective equipment as required
- P308 + P313 - IF exposed or concerned: Get medical advice/attention
- P405 - Store locked up
- P501 - Dispose of contents/ container to an approved waste disposal plant
- P280 - Wear protective gloves/protective clothing/eye protection/face protection

**Other Information**

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS No.	EINECS	Weight-%
Water	7732-18-5	231-791-2	60 - 100*
SODIUM CHLORIDE USP	7647-14-5	231-598-3	0.1 - 1*
Ketorolac Tromethamine	41100-52-1	255-219-6	0.1 - 1*
Octoxynol 40	9081-99-6	N/A	<0.1*
Benzalkonium Chloride	63449-41-2	264-151-6	<0.1*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

**4. FIRST AID MEASURES**

**First aid measures**

- General advice** Immediate medical attention is required.
- Eye contact** Keep eye wide open while rinsing. Immediate medical attention is required. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Do not rub affected area.
- Skin Contact** Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
- Inhalation** Remove to fresh air. Call a physician or poison control center immediately. If not breathing,

give artificial respiration. If breathing is difficult, give oxygen.

**Ingestion**

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Drink plenty of water. Immediate medical attention is required. Remove from exposure, lie down. Clean mouth with water and drink afterwards plenty of water. Call a physician or poison control center immediately.

**Chemical Name**

Ketorolac Tromethamine

**Note to physicians**

Delayed healing; Cross-sensitivity or hypersensitivity; Increased bleeding time due to interference with thrombocyte aggregation; Corneal effects including keratitis.  
Treat symptomatically.

Benzalkonium Chloride

## 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable extinguishing media**

None known.

**Specific hazards arising from the chemical**

The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating and toxic gases and vapors. In the event of fire and/or explosion do not breathe fumes.

**Explosion data****Sensitivity to Mechanical Impact**

Not impact sensitive.

**Sensitivity to Static Discharge**

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

**Protective equipment and precautions for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions**

Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing. Keep people away from and upwind of spill/leak.

**Environmental precautions**

Do not allow into any sewer, on the ground or into any body of water. Should not be released into the environment. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional ecological information.

**Methods for containment**

Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.

**Methods for cleaning up**

Dike far ahead of liquid spill for later disposal. Soak up with inert absorbent material. Take up mechanically, placing in appropriate containers for disposal. Clean contaminated surface thoroughly. Prevent product from entering drains. Dam up. After cleaning, flush away traces with water.

## 7. HANDLING AND STORAGE

**Advice on safe handling**

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Ensure adequate ventilation, especially in confined areas. In case of insufficient ventilation, wear suitable respiratory equipment. Use only with adequate ventilation and in closed systems.

**Storage Conditions**

Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep in properly labeled containers.

**Incompatible materials** Incompatible with strong acids and bases. Incompatible with oxidizing agents.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

Control parameters

**Exposure Guidelines**

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL
Ketorolac Tromethamine 41100-52-1	N/A	N/A	N/A	5.00

*NIOSH IDLH Immediately Dangerous to Life or Health*

**Other Information** Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

**Engineering Controls** The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

**Eye/face protection** No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

**Skin and body protection** During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

**Respiratory protection** Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Information on basic physical and chemical properties

<b>Physical state</b>	Liquid	<b>Appearance</b>	Liquid
<b>Color</b>	No information available	<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available		

<u>Property</u>	<u>Values</u>
pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	No information available

Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

**Other Information**

Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

**10. STABILITY AND REACTIVITY**

**Reactivity**

Not defined As Reactive substance

**Chemical stability**

Stable under normal conditions.

**Possibility of Hazardous Reactions**

None under normal processing.

**Conditions to avoid**

Exposure to air or moisture over prolonged periods.

**Incompatible materials**

Incompatible with strong acids and bases. Incompatible with oxidizing agents.

**Hazardous Decomposition Products**

Thermal decomposition can lead to release of irritating and toxic gases and vapors.

**11. TOXICOLOGICAL INFORMATION**

**Information on likely routes of exposure**

**Acute toxicity**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	N/A	N/A
SODIUM CHLORIDE USP	= 3000 mg/kg ( Rat )	> 10 g/kg ( Rabbit )	> 42 g/m <sup>3</sup> ( Rat ) 1 h
Ketorolac Tromethamine	189 mg/kg (rat)	N/A	N/A
Benzalkonium Chloride	N/A	= 1420 mg/kg ( Rat )	N/A

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Ketorolac Tromethamine	Ketorolac tromethamine was not mutagenic in vitro in the Ames assay or in forward mutation assays. Similarly, it did not result in an in vitro increase in unscheduled DNA synthesis or an in vivo increase in chromosome breakage in mice. However, ketorolac tromethamine did result in an increased incidence in chromosomal aberrations in Chinese hamster ovary cells.	Ketorolac tromethamine was not carcinogenic in either rats given up to 5 mg/kg/day orally for 24 months or in mice given 2 mg/kg/day orally for 18 months. These doses are approximately 125 times and 50 times higher respectively than the maximum recommended human topical ophthalmic daily dose given as QID for itching to affected eyes on a mg/kg basis.	Teratogenic Effects. Pregnancy Category C - Ketorolac tromethamine, administered during organogenesis, was not teratogenic in rabbits and rats at oral doses of 3.6 mg/kg/day and 10 mg/kg/day, respectively. These doses are approximately 100 times and 250 times higher respectively than the maximum recommended human topical ophthalmic daily dose of 2 mg (5 mg/mL x 0.05 mL/drop, x 4 drops x	It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to nursing mothers.

			2 eyes) to affected eyes on a mg/kg basis. Additionally, when administered to rats after Day 17 of gestation at oral doses up to 1.5 mg/kg/day (approximately 40 times the typical human topical ophthalmic daily dose), ketorolac tromethamine resulted in dystocia and increased pup mortality. There are no adequate and well-controlled studies in pregnant women. ACULAR® solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nonteratogenic Effects: Because of the known effects of prostaglandin-inhibiting drugs on the fetal cardiovascular system (closure of the ductus arteriosus), the use of ACULAR® solution during late pregnancy should be avoided.	
Benzalkonium Chloride	Not Suspected of being a Mutagen.	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	No information available.	No information available

**Chronic toxicity**

Chronic exposure to corrosive fumes/gases may cause erosion of the teeth followed by jaw necrosis. Bronchial irritation with chronic cough and frequent attacks of pneumonia are common. Gastrointestinal disturbances may also be seen. Avoid repeated exposure. Possible risk of irreversible effects.

**Target Organ Effects**

Eyes, Gastrointestinal tract (GI), kidney, Respiratory system, Skin.

**Numerical measures of toxicity - Product Information**

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral)	577
ATEmix (dermal)	5677

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

Toxic to aquatic life with long lasting effects

0.44% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
SODIUM CHLORIDE USP 7647-14-5	N/A	5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 7050: 96 h Pimephales promelas mg/L LC50 semi-static	1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static

**Other adverse effects** No information available

**13. DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Disposal of wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Do not reuse container.

This product contains one or more substances that are listed with the State of California as a hazardous waste.

**14. TRANSPORT INFORMATION**

**DOT** Not regulated

**TDG** Not regulated

**ICAO (air)** Not regulated

**IATA** Not regulated

**IMDG** Not regulated

**ADR** Not regulated

**ADN** Not regulated

**15. REGULATORY INFORMATION**

**International Inventories**

**TSCA** Not Listed

**DSL/NDSL** Not Listed

**EINECS/ELINCS** Not Listed

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**US Federal Regulations**

**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

**SARA 311/312 Hazard Categories**

<b>Acute health hazard</b>	Yes
<b>Chronic Health Hazard</b>	Yes
<b>Fire hazard</b>	No
<b>Sudden release of pressure hazard</b>	No
<b>Reactive Hazard</b>	No

**CWA (Clean Water Act)**

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21

and 40 CFR 122.42)

**CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

**US State Regulations****California Proposition 65**

This product does not contain any Proposition 65 chemicals

**U.S. State Right-to-Know Regulations****16. OTHER INFORMATION**

**Revision Date** 06-May-2016  
**Revision Note** No information available

**Disclaimer**

The information provided in this Material Safety Data Sheet 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 guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered 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 materials or in any process, unless specified in the text.

**End of Safety Data Sheet**