

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** 000042**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 plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525

E-mail address SDS@Allergan.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



Appearance Liquid	Physical state Liquid	Odor No information available
Chemical Name Memantine Hydrochloride	Symptoms Most common are dizziness, headache, confusion and constipation	
Chemical Name Memantine Hydrochloride	Medical Conditions Aggravated by Exposure Contraindication include hypersensitivity to any component of this product hepatic impairment	

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	74103-06-3	N/A	0.1 - 1*
Octoxynol 40	9081-99-6	N/A	<0.1*
EDETATE DISODIUM USP	6381-92-6	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
Memantine Hydrochloride

Note to physicians

Conditions that raise urine pH may decrease urinary elimination of Memantine, resulting in increased plasma levels of memantine.

Benzalkonium Chloride

Treat symptomatically.

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 (ug/m ³)
Ketorolac Tromethamine 74103-06-3	N/A	N/A	N/A	5

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

Physical state	Liquid	Appearance	Liquid
Color	No information available	Odor	No information available
Odor threshold	No information available		

Property

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

Values

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 ³ (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	Not mutagenic in the standard battery of tests. With the exception of high doses.	An 18-month study in mice with oral doses of ketorolac tromethamine at 2 mg/kg/day (0.9 times the human systemic exposure at the recommended IM or IV dose of 30 mg qid, based on area-under-the-plasma-concentration curve [AUC]), and a 24-month study in rats at 5 mg/kg/day (0.5 times the human AUC) showed no evidence of tumorigenicity.	Impairment of fertility did not occur in male or female rats at oral doses of 9 mg/kg (0.9 times the human AUC) and 16 mg/kg (1.6 times the human AUC) of ketorolac tromethamine, respectively. Reproduction studies have been performed during organogenesis using daily oral doses of ketorolac tromethamine at 3.6 mg/kg (0.37 times the human AUC) in rabbits and at 10 mg/kg (1.0 times the human AUC) in rats. Results of these studies did not reveal evidence of teratogenicity to the fetus. Because of the known effects of nonsteroidal anti-inflammatory drugs on the fetal cardiovascular system (closure of ductus arteriosus), use during pregnancy (particularly late pregnancy) should be avoided. Oral doses of ketorolac tromethamine at 1.5 mg/kg (0.14 times the	No information available

			human AUC), administered after gestation Day 17, caused dystocia and higher pup mortality in rats. The use of ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive. In women who have difficulty conceiving or are undergoing investigation of infertility, withdrawal of ketorolac tromethamine should be considered.	
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

Chemical Name	STOT - single exposure	STOT - repeated exposure
Ketorolac Tromethamine	No information available.	Gastrointestinal tract (GI).

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	4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 7050: 96 h Pimephales promelas mg/L LC50 semi-static 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static	340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static 1000: 48 h Daphnia magna mg/L EC50

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

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>ICAO (air)</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	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

Acute health hazard	Yes
Chronic Health Hazard	Yes
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	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 02-Oct-2018
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