

ARTIFICIAL TEARS SAFETY DATA SHEET (SDS)

Revision Date: 05/26/15

Page 1 of 6

Section 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Artificial Tears, Formula Number 008	For Information:	(909) 598-9499, (Customer Service) Ext.10
		For Emergency:	800-424-9300 (CHEMTREC) (USA)
Synonyms	Murine Tears		
CAS Number:	N / A		
RTECS Number	N / A		
Product Code(s):	N / A		
Therapeutic Category:	Ophthalmic		
Manufacturer:	K.C. Pharmaceuticals, Inc.		
Address:	3201 Producer Way Pomona, CA 91768		

Notes: **CAS:** Chemical Abstracts Service. **RTECS:** Registry of Toxic Effects of Chemical Substances.

Section 2: HAZARDS IDENTIFICATION

PRECAUTIONS:

This product is intended as an eye drop. If any discomfort develops, immediately discontinue use of this product. If discomfort persists, contact your eye care professional. Use in accordance with instructions on product packaging.

If you are allergic to any ingredient in this product, DO NOT USE.

POTENTIAL HEALTH EFFECTS

EYE:

Non-irritating to the eyes when used as directed.

SKIN:

Non-irritating to skin or mucous membranes when used as directed.

INGESTION:

Small amounts (a tablespoonful) swallowed are not likely to cause injury; swallowing amounts larger than that may cause gastrointestinal irritation.

INHALATION:

No hazard when used as directed.

CHRONIC HEALTH EFFECTS

No known chronic hazards.

CARCINOGENICITY:

NTP (National Toxicology Program): No ingredients listed. **IARC (International Agency for Research on Cancer):** No ingredients listed. **OSHA:** No ingredients listed.

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

Material Name	CAS #	OSHA TWA (mg/m ³)	OSHA STEL (mg/m ³)	% Content, Weight/Volume
Benzalkonium Chloride, NF	8001-54-5	N/E	N/A	0.012

**ARTIFICIAL TEARS
SAFETY DATA SHEET (SDS)**

Revision Date: 05/26/15

Page 2 of 6

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

<i>Material Name</i>	<i>CAS #</i>	<i>OSHA TWA (mg/m³)</i>	<i>OSHA STEL (mg/m³)</i>	<i>% Content, Weight/Volume</i>
Dextrose, USP	50-99-7	N/A	N/A	< 1
Disodium Edetate•2H ₂ O, USP	6381-92-6	N/A	N/A	< 0.1
Polyvinyl Alcohol, USP	9002-89-5	N/A	N/A	0.5
Potassium Chloride, USP	7447-40-7	N/A	N/A	< 1
Povidone, USP	9003-39-8	N/A	N/A	0.6
Sodium Bicarbonate, USP	144-55-8	N/A	N/A	< 1
Sodium Chloride, USP	7647-14-5	N/A	N/A	< 1
Sodium Citrate•2H ₂ O, USP	6132-04-3	N/A	N/A	< 1
Sodium Phosphate Dibasic, Anhydrous, USP	7558-79-4	N/A	N/A	< 1
Sodium Phosphate Monobasic, Monohydrate, USP	10049-21-5	N/A	N/A	< 1
Purified Water, USP	7732-18-5	N/A	N/A	Quantity Sufficient

Notes: For acronyms:

N/E: Not Established.

N/A: Not Available.

OSHA: Occupational Safety & Health Administration.

TWA: 8-Hour Time-Weighted Average.

STEL: Short-Term Exposure Limit.

This product (ARTE) is regulated as a drug product. Polyvinyl Alcohol, and Povidone are the active ingredients, and Benzalkonium Chloride is the preservative.

Other inactive ingredients: Dextrose, Sodium Chloride, Potassium Chloride, Sodium Phosphate Monobasic, Sodium Phosphate Dibasic, Sodium Bicarbonate, Sodium Citrate, Disodium Edetate, and Purified Water.

Section 4: FIRST AID MEASURES

EYES:

If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional.

SKIN:

No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

INGESTION:

No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

INHALATION:

No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention if cough or other symptoms develop.

Section 5: FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES:

Flash Point: Non-Combustible

Method: NA

EXTINGUISHING MEDIA:

**ARTIFICIAL TEARS
SAFETY DATA SHEET (SDS)**

Revision Date: 05/26/15

Page 3 of 6

Section 5: FIRE FIGHTING MEASURES

Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

HAZARDOUS COMBUSTION PRODUCTS:

None identified.

SPECIAL FIRE FIGHTING INSTRUCTIONS:

As in any fire, wear self-contained breathing apparatus and full protective gear.

Section 6: ACCIDENTAL RELEASE MEASURES

General Information:

Contain spill and absorb with a suitable inert material, then place in a chemical waste container. Dispose of in accordance with Section 13.

For large spill, recover product, and place in an appropriate container for disposal in accordance with Section 13.

Section 7: HANDLING AND STORAGE

HANDLING:

No special handling is required. Use in accordance with printed instructions on label and carton.

STORAGE:

Store according to printed instructions on label and carton.

Keep cap tightly closed.

Use before expiration date marked on the carton and bottle.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION:

No special controls or personal protection required under conditions of intended use.

SKIN PROTECTION:

No special controls or personal protection required under conditions of intended use.

EYE PROTECTION:

No special controls or personal protection required under conditions of intended use.

ADDITIONAL PROTECTIVE CLOTHING & EQUIPMENT:

Not Applicable

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES:

Appearance / Physical State: Clear, Water-Like Liquid

Odor: Odorless

CHEMICAL PROPERTIES:

Boiling Point: Not Determined

Melting Point: Not Applicable

Vapor Pressure: Not Determined

Vapor Density: Not Determined

Solubility In Water: Highly Soluble

Specific Gravity (H₂O = 1): 1 (Approx.)

pH: Approx. 7.0

Freezing Point: Not Determined

Molecular Weight: Mixture, Not Applicable

ARTIFICIAL TEARS SAFETY DATA SHEET (SDS)

Revision Date: 05/26/15

Page 4 of 6

Section 10: STABILITY AND REACTIVITY

GENERAL:

Stable under recommended storage conditions.

INCOMPATIBLE MATERIALS AND CONDITIONS TO AVOID:

No data available.

HAZARDOUS POLYMERIZATION:

No data available.

HAZARDOUS DECOMPOSITION PRODUCTS:

No data available.

Section 11: TOXICOLOGICAL INFORMATION

Material Name	CAS #	Toxicity Data	Irritation Data	RTECS
Benzalkonium Chloride, NF	8001-54-5	Oral-Rat LD50: 240 mg/kg. Oral-Mouse LD50: 150 mg/kg Inhalation: No data available Dermal-Rat LD50: 1,420 mg/kg	May cause eye irritation, skin irritation, and respiratory irritation	BO3150000
Dextrose, USP	50-99-7	Oral-Rat LD50: 25,800 mg/kg <i>Remarks: Behavioral: Coma. Cyanosis Diarrhoea</i> Inhalation: no data available Dermal: no data available	Not available	LZ6600000
Disodium Edetate•2H ₂ O, USP	6381-92-6	Oral-Rat LD50: 2,000 mg/kg Inhalation: no data available Dermal: no data available	Not available	AH4375000
Polyvinyl Alcohol, USP	9002-89-5	Oral-Rat LD50: 20,000 mg/kg Oral-Mouse LD50: 14,700 mg/kg <i>Remarks: Behavioral: Altered sleep time (including change in righting reflex). Behavioral: Somnolence (general depressed activity). Behavioral: Muscle weakness.</i> Inhalation: No data available Dermal: No data available	Not available	TR8100000
Potassium Chloride, USP	7447-40-7	Oral-Guinea Pig LD50: 2,500 mg/kg Oral-Rat LD50: 2,600 mg/kg Oral-Mouse LD50: 1,500 mg/kg	Not available	TS8050000
Povidone, USP	9003-39-8	Oral-Mouse LD50: 40,000 mg/kg. Oral-Rat LD50: 100,000 mg/kg Oral-Guinea Pig LD50: 100,000 mg/kg Inhalation: no data available Dermal: no data available	Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.	TR8370000
Sodium Bicarbonate, USP	144-55-8	Oral-Rat LD50: 4,220 mg/kg Inhalation: no data available Dermal: no data available	Not available	VZ0950000
Sodium Chloride, USP	7647-14-5	Oral-Rat LD50: 3,550 mg/kg Oral-Mouse LD50: 4 g/kg Inhalation-Rat LC50 1 hr: 42,000 mg/m ³ Dermal-Rabbit LD50: 10,000 mg/kg	Not available	VZ4725000
Sodium Citrate•2H ₂ O, USP	6132-04-3	Acute toxicity: no data available Inhalation: no data available Dermal: no data available	Not available	TZ8595800 (Dihydrate) GE8300000 (Anhydrous)

ARTIFICIAL TEARS SAFETY DATA SHEET (SDS)

Revision Date: 05/26/15

Page 5 of 6

Section 11: TOXICOLOGICAL INFORMATION

Material Name	CAS #	Toxicity Data	Irritation Data	RTECS
Sodium Phosphate Dibasic, Anhydrous, USP	7558-79-4	Oral-Rat LD50: 17,000 mg/kg Inhalation: No data available Dermal: No data available	Not available	WC4500000
Sodium Phosphate Monobasic, Monohydrate, USP	10049-21-5	Acute toxicity: No data available Inhalation: No data available	Not available	WA1900000

Section 12: ECOLOGICAL INFORMATION

No data available on the environmental impact of this product.

Section 13: DISPOSAL CONSIDERATIONS

All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the sole responsibility of the waste generator.

Section 14: TRANSPORT INFORMATION

United Nations Dangerous Goods (UNDG) number: Not applicable
United Nations Shipping Name: Not applicable
Transport Hazard Class: Not applicable
Packing Group: Not applicable
Department of Transportation (DOT): Not regulated as a hazardous material.
International Air Transport Association (IATA): Not regulated as a dangerous good
International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good
 There are no unreasonable risks (health, safety, or property), that this product would have when transported in commerce. Hazard class definitions (49 CFR, Part 172.101) are not applicable to this product.

Section 15: REGULATORY INFORMATION

OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):
 Artificial Tears is considered non-hazardous under the Occupational Safety & Health Administration Hazard Communication Standard.
Information on other relevant regulations are tabulated below.

Material Name	SARA 302	SARA 313	SARA 311/312 Hazards	Prop 65	TSCA
Benzalkonium Chloride, NF	No	No	Acute	No	TSCA 8(b) inventory: No
Dextrose, USP	No	No	No	No	TSCA 8(b) inventory: Yes (D-Glucose)
Disodium Edetate.2H ₂ O, USP	No	No	No	No	TSCA 8(b) inventory: No
Polyvinyl Alcohol, USP	No	No	No	No	TSCA 8(b) inventory: Yes (Ethenol, homopolymer)
Potassium Chloride, USP	No	No	No	No	TSCA 8(b) inventory: Yes
Povidone, USP	No	No	No	No	TSCA 8(b) inventory: Yes (2-Pyrrolidinone, 1-ethenyl-, homopolymer)
Sodium Bicarbonate, USP	No	No	No	No	TSCA 8(b) inventory: Yes (Carbonic acid sodium salt)

ARTIFICIAL TEARS SAFETY DATA SHEET (SDS)

Revision Date: 05/26/15

Page 6 of 6

Material Name	SARA 302	SARA 313	SARA 311/312 Hazards	Prop 65	TSCA
					(1:1))
Sodium Chloride, USP	No	No	No	No	TSCA 8(b) inventory: Yes
Sodium Citrate•2H ₂ O, USP	No	No	No	No	TSCA 8(b) inventory: No
Sodium Phosphate Dibasic, Anhydrous, USP	No	No	No	No	TSCA 8(b) inventory: Yes (Phosphoric acid, sodium salt (1:2))
Sodium Phosphate Monobasic, Monohydrate, USP	No	No	No	No	TSCA 8(b) inventory: No

Notes on used acronyms and terms:

TSCA: Toxic Substance Control Act.

SARA TITLE III (Superfund Amendments and Reauthorization Act)

SARA 302: SARA TITLE III, SECTION 302 (Extremely Hazardous Substances)

SARA 311, 312: SARA TITLE III, SECTION 311, 312 (Hazard Categories)

SARA 313: SARA TITLE III, SECTION 313 (Toxic Chemicals).

Prop 65: California Proposition 65. Regulations regarding substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels that would require a warning under the statute.

Immediate (Acute) Health Hazards includes highly toxic materials, toxic materials, corrosives, irritants, sensitizers and other hazardous materials which exhibit an adverse effect with short term exposure.

Delayed (Chronic) Health Hazard includes carcinogens and other hazardous chemicals with an adverse effect with long term exposure.

Section 16: OTHER INFORMATION

To the best of our knowledge, the information contained herein is accurate. However, *KC Pharmaceuticals Inc.* does not assume any liability whatsoever for the accuracy or completeness of the information contained in this document.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall *KC Pharmaceuticals Inc.* be liable for any special, incidental or consequential damages.