



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name – Flurbiprofen Sodium Ophthalmic Solution

Product Code – NDC 69292-0722-25

Relevant identified uses of the substance or mixture and uses advised against

Recommended use – Finished Pharmaceutical Product; Flurbiprofen sodium ophthalmic solution is indicated for the inhibition of intraoperative miosis.

Restrictions on use – Use in accordance with product literature. Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer – Amici Pharmaceuticals LLC
425 Broadhollow Road Suite 115
Melville, NY 11747
United States

Telephone (General) 631 – 396 - 0111

Emergency telephone number

Manufacturer – 631 – 396 - 0111

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 consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS Eye Mild Irritation 2B

Label elements

UN GHS

WARNING

Hazard statements May cause eye irritation

Precautionary statements

Prevention: Use personal protective equipment as required.
Wash thoroughly after handling.

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

Storage/Disposal: Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

Other hazards

UN GHS

No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Citric acid	CAS:77-92-9 EINECS:201-069-1	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Edetate Disodium Dihydrate	CAS:139-33-3 EINECS:205-358-3	< 1%	UN GHS: NDA
Flurbiprofen	CAS:5104-49-4 EINECS:225-827-6	0.03%	UN GHS: NDA
Polyvinyl alcohol	CAS:9002-89-5	1.4%	UN GHS: NDA
Potassium chloride	CAS:7447-40-7 EINECS:231-211-8	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; STOT RE 1
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Sodium Citrate Dihydrate	CAS:68-04-2 EINECS:200-675-3	1% TO 5%	UN GHS: Eye Irrit. 2A
Thimerosal	CAS:54-64-8 EINECS:200-210-4	0.005%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Classification criteria not met

Hydrochloric Acid (CAS:7647-01-0, EINECS:231-595-7) and/or Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

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.

Skin

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

Eye

- For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention if eye irritation persists.

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.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Notes to Physician

- With some nonsteroidal anti-inflammatory drugs, there exists the potential for increased bleeding due to interference with thrombocyte aggregation.

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media - Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media - No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards - None known - product is not flammable or combustible.

Hazardous Combustion Products - No data available

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions - No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8.

Emergency Procedures - No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available

Methods and material for containment and cleaning up

Containment/Clean-up Measures - Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Section 7 - Handling and Storage

Precautions for safe handling

Handling - No special handling is required. Refer to Section 8. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

Storage - Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product

integrity. Use before date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines - Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering Measures/Controls - 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 to an acceptable level.

Personal Protective Equipment

Respiratory - No respiratory protection required during normal handling.

Eye/Face - Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands - Gloves are not required under normal handling conditions.

Skin/Body - No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Environmental Exposure Controls - No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Clear Colorless to slightly yellow.
Odor	No odor.	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	6 to 7
Specific Gravity/Relative Density	= 1.016	Water Solubility	Miscible
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Burning Rate Test	Not relevant
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reactions known.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

Other Material Information - Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
Flurbiprofen (0.03%)	5104-49-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • 117 mg/kg; <i>Behavioral:Ataxia; Gastrointestinal:Hypermotility, diarrhea; Blood:Normocytic anemia</i>
Polyvinyl alcohol (1.4%)	9002-89-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 23854 mg/kg; <i>Behavioral:Muscle weakness; Gastrointestinal:Hypermotility, diarrhea; Liver:Other changes</i>
Thimerosal (0.005%)	54-64-8	Acute Toxicity: Ingestion/Oral-Rat LD50 • 75 mg/kg
Edetate Disodium Dihydrate (< 1%)	139-33-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2 g/kg
Potassium chloride (< 1%)	7447-40-7	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2600 mg/kg
Citric acid (< 0.1%)	77-92-9	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3 g/kg
Sodium Citrate Dihydrate (1% TO 5%)	68-04-2	Acute Toxicity: Intravenous-Mouse LD50 • 170 mg/kg; <i>Behavioral:Convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration:Cyanosis; Gastrointestinal:Changes in structure or function of salivary glands</i>
Sodium chloride (0.1%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met

Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Mild Irritation 2B

Potential Health Effects Inhalation

Acute (Immediate) - Under normal conditions of use, no health effects are expected.

Chronic (Delayed) - Under normal conditions of use, no health effects are expected.

Skin

Acute (Immediate) - Under normal conditions of use, no health effects are expected.

Chronic (Delayed) - Under normal conditions of use, no health effects are expected.

Eye

Acute (Immediate) - May cause mild irritation. Transient ocular burning and stinging. With some nonsteroidal anti-inflammatory drugs, there exists the potential for increased bleeding due to interference with thrombocyte aggregation.

Chronic (Delayed) - Under normal conditions of use, no health effects are expected.

Ingestion

Acute (Immediate) - Under normal conditions of use, no health effects are expected.

Chronic (Delayed) - Under normal conditions of use, no health effects are expected.

Other

Acute (Immediate) - Under normal conditions of use, no health effects are expected.

Chronic (Delayed) - Under normal conditions of use, no health effects are expected.

Carcinogenic Effects			
	CAS	IARC	NTP
Polyvinyl alcohol	9002-89-5	Group 3-Not Classifiable	Evidence of Carcinogenicity

Reproductive Effects - While the finished product is believed to be safe, some ingredients are suspected of causing cancer. The safety of this product in pregnant women has not been established. Flurbiprofen has been shown to be embryocidal, delay parturition, prolong gestation, reduce weight, and/or slightly retard growth of fetuses when given to rats in daily oral doses of 0.4 mg/kg (approximately 300 times the human daily topical dose) and above.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods**Product waste**

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user - No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code - No data available

Section 15 - Regulatory Information**Safety, health and environmental regulations/legislation specific for the substance or mixture**

SARA Hazard Classifications - Nodataavailable

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Flurbiprofen	5104-49-4	Yes	Yes	No
Edetate Disodium Dihydrate	139-33-3	Yes	Yes	Yes
Citric acid	77-92-9	Yes	Yes	Yes
Thimerosal	54-64-8	Yes	Yes	Yes
Polyvinyl alcohol	9002-89-5	Yes	No	Yes
Potassium chloride	7447-40-7	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Sodium Citrate Dihydrate	68-04-2	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada**Labor****Canada - WHMIS - Classifications of Substances**

• Sodium Citrate Dihydrate	68-04-2	Uncontrolled product according to WHMIS classification criteria
• Edetate Disodium Dihydrate	139-33-3	Uncontrolled product according to WHMIS classification criteria (including 3.5%)

• Thimerosal	54-64-8	Not Listed
• Potassium chloride	7447-40-7	Uncontrolled product according to WHMIS classification criteria (including 23.8%)
• Citric acid	77-92-9	E (including 40%)
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Flurbiprofen	5104-49-4	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Polyvinyl alcohol	9002-89-5	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Thimerosal	54-64-8	0.1 %
• Potassium chloride	7447-40-7	Not Listed
• Citric acid	77-92-9	1 %
• Sodium chloride	7647-14-5	Not Listed
• Flurbiprofen	5104-49-4	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Thimerosal	54-64-8	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Citric acid	77-92-9	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Flurbiprofen	5104-49-4	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Thimerosal	54-64-8	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Citric acid	77-92-9	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Flurbiprofen	5104-49-4	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Sodium Citrate Dihydrate	68-04-2	Not Listed
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• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Thimerosal	54-64-8	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Citric acid	77-92-9	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Flurbiprofen	5104-49-4	developmental toxicity, initial date 8/20/99
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Thimerosal	54-64-8	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Citric acid	77-92-9	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Flurbiprofen	5104-49-4	female reproductive toxicity, initial date 8/20/99
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Thimerosal	54-64-8	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Citric acid	77-92-9	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Flurbiprofen	5104-49-4	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed

Section 16 - Other Information

Last Revision Date _ 20/February/2018

Preparation Date _ 20/February/2018

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