

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078495024

N/A


# SAFETY DATA SHEET

## AK-FLUOR® (fluorescein injection, USP) 10% and 25%

### 1. IDENTIFICATION

<b>Product Identifier:</b>	AK-FLUOR® (fluorescein injection, USP) 10% and 25%
<b>Synonyms:</b>	spiro[isobenzofuran-1 (3 <i>H</i> ),9'-[9 <i>H</i> ]xanthene]-3-one,3'6'-dihydroxy, disodium salt
<b>National Drug Code (NDC):</b>	17478-253-10 17478-250-20
<b>Recommended Use:</b>	AK-FLUOR® is indicated in diagnostic fluorescein angiography or angiography of the retina and iris vasculature.
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
<b>Contact Telephone:</b>	1-800-932-5676
<b>E mail:</b>	customer.service@akorn.com
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards:</b>	Not classifiable.
<b>Health Hazards:</b>	Serious Eye Damage/Eye Irritation      Category 2A
<b>Symbol(s):</b>	
<b>Signal Word:</b>	Warning.
<b>Hazard Statement(s):</b>	H319 Causes serious eye irritation.
<b>Precautionary Statement(s):</b>	<p>P264 Wash hands and other exposed areas thoroughly after handling.</p> <p>P280 Wear protective gloves/protective clothing/eye protection/face protection.</p> <p>P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>+ P351 + P338</p> <p>P337 IF eye irritation persists: Get medical advice/attention.</p> <p>+ P313</p>

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Hazards Not Otherwise Classified:	P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
Supplementary Information:	None.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Chemical Name	CAS Number	Chemical Formula	Molecular Weight	Percentage
Fluorescein	spiro[isobenzofuran-1(3 <i>H</i> ),9'-[9 <i>H</i> ]xanthene]-3-one,3'6'-dihydroxy, disodium salt	2321-07-5	C <sub>20</sub> H <sub>12</sub> O <sub>5</sub>	376.27	10% and 25%

The formula also contains Water for Injection. Sodium Hydroxide and/or Hydrochloric Acid may be used to adjust pH (8.3 to 9.8).

### 4. FIRST AID MEASURES

<b>Ingestion:</b>	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
<b>Eye Contact:</b>	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Skin Contact:</b>	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).

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<b>Signs and Symptoms:</b>	Fluorescein may cause yellow discoloration of skin or eyes. Nausea, vomiting, headache, dizziness, fainting, low blood pressure.
<b>Medical Conditions Aggravated by Exposure:</b>	May aggravate allergies and bronchial asthma.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

#### 5. FIREFIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Use water, carbon dioxide, dry chemical or water spray.
<b>Unsuitable Extinguishing Media:</b>	Not determined.

#### Specific Hazards Arising from the Chemical

<b>Hazardous Combustion Products:</b>	Carbon oxides and sodium oxides.
<b>Other Specific Hazards:</b>	Closed containers may explode from the heat of fire.
<b>Special Protective Equipment and Precautions for Firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.

#### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
<b>Personal Protective Equipment:</b>	For personal protection see section 8.
<b>Methods for Cleaning Up:</b>	Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations. Wipe working area surfaces to dryness, and then wash with soap and water.
<b>Environmental Precautions:</b>	Avoid release to the environment. Contain material and prevent release to basements, confined spaces, waterways or soil.
<b>Reference to Other Sections:</b>	Refer to Sections 8, 12 and 13 for further information.

#### 7. HANDLING AND STORAGE

<b>Precautions for Safe Handling:</b>	Handle in accordance with product label and/or product insert information and in accordance with good industrial hygiene and safety practices.
<b>Conditions for Safe Storage, Including Any Incompatibilities:</b>	Store at 20° to 25°C (68° to 77°F). Do not freeze.
<b>Specific End Use:</b>	Pharmaceutical drug product.



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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Occupational Exposure Guidelines:

Ingredient	Type	Value
Fluorescein	No data available	No data available

#### Engineering Controls:

Engineering controls should be used as the primary means to control exposures.

#### Respiratory Protection:

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

#### Eyes Protection:

Avoid contact with eyes. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

#### Hand Protection:

Wear chemically compatible gloves for handling solutions and ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

#### Skin Protection:

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

#### General Hygiene Considerations:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	Dark reddish orange solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	8.3 to 9.8.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.



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Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Miscible in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

#### 10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Strong oxidizing agents.
Hazardous Decomposition Products:	No data available.

#### 11. TOXICOLOGICAL INFORMATION

##### Information on the Likely Routes of Exposure

Inhalation:	May cause irritation to the respiratory system.
Ingestion:	May be harmful if swallowed.
Skin Contact:	May cause skin irritation. May cause yellowish discoloration.
Eye Contact:	Causes eye irritation.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure:	Hives, itching, bronchospasm, and anaphylaxis have been reported. Syncope and hypotension may occur. Cardiac arrest, basilar artery ischemia, severe shock and death may occur rarely.

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### Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Fluorescein	Rabbit	Oral	LD <sub>50</sub>	2,500 mg/kg

### Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

### Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

### Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

### Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

#### Aspiration Hazard:

No data available.

#### Toxicokinetics/Metabolism:

No data available.

#### Target Organ Effects:

Based on clinical use, possible target organs include the central and peripheral nervous system and the cardiovascular system.

#### Systemic Effects:

No data available.

#### Reproductive Effects:

Pregnancy Category C. Adequate animal reproduction studies have not been conducted with fluorescein sodium.

#### Carcinogenicity:

There have been no long-term studies done using fluorescein in animals to evaluate carcinogenic potential.

#### National Toxicology Program (NTP):

Not considered to be a carcinogen.

#### International Agency for Research on Cancer (IARC):

Not considered to be a carcinogen.

#### Occupational Safety and Health Administration (OSHA):

Not considered to be a carcinogen.



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### 12. ECOLOGICAL INFORMATION

#### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

Terrestrial Toxicity: No data available.  
Persistence and Degradability: No data available.  
Bioaccumulative Potential: No data available.  
Mobility in Soil: No data available.  
Mobility in Environment: No data available.  
Other Adverse Effects: No data available.

### 13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

### 15. REGULATORY INFORMATION

#### US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Fluorescein	Yes

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable





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#### EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

#### U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Fluorescein	Listed	Listed	Not Listed

#### California Proposition 65:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

#### 16. OTHER INFORMATION

The vial stopper is not made with natural rubber latex.

See footer of this document for Revision Date and Revision Number.

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