AK-Fluor® Fluorescein injection, USP

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Issue date: 03/18/2024 Version: 1.0

SECTION 1: Identification

1.1. Identification

Product form : Mixture

Product name : AK-Fluor® Fluorescein injection, USP

1.2. Recommended use and restrictions on use

Use of the substance/mixture : Pharmaceuticals

1.3. Supplier

Long Grove Pharmaceuticals, LLC.
9450 W. Bryn Mar Ave., Suite 200
Rosemont, IL 60018 - USA
T 847-999-0600

1.4. Emergency telephone number

Emergency number : CHEMTREC +1 (800) 424-9300 (Toll Free) +1 (703) 527-3887 (Local) 24/7

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

This product is not classifiable as a hazardous mixture under the OSHA Hazard Communication Standard (29 CFR 1910.1200). Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

2.2. GHS Label elements, including precautionary statements

GHS US labelling

No labelling applicable

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%
Contains no hazardous ingredients at levels requiring disclosure by the OSHA Hazard Communication Standard (29 CFR 1910.1200)		

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.

First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a comfortable position for breathing.

First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes.

First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. Continue rinsing.

First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center or medical professional. Get medical attention immediately.

4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : May cause skin irritation. May cause yellowish discoloration

Symptoms/effects after eye contact	:	Direct contact with eyes is likely to be irritating.
Symptoms/effects after ingestion	:	May cause gastrointestinal irritation.
Other information	:	No additional information available.

4.3. Immediate medical attention and special treatment, if necessary

No additional information available

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media	:	Use extingushing media appropriate for surrounding fire (e.g, carbon dioxide (CO2), dry powder, foam, water spray).

5.2. Specific hazards arising from the chemical

Fire hazard	:	The product is not flammable.
Explosion hazard	:	Product is not explosive. Closed containers exposed to heat may explode.
Reactivity	:	No data available.

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions	:	Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not dispose of fire-fighting water in the environment.
Protection during firefighting	:	Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	:	Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.1.1. For non-emergency personnel

Protective equipment	:	Wear Protective equipment as described in Section 8.
Emergency procedures	:	Evacuate unnecessary personnel. Keep upwind.

6.1.2. For emergency responders

Protective equipment	:	For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment	:	Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Prevent entry to sewers and public waters.
Methods for cleaning up	:	Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Clean surface thoroughly to remove residual contamination. Keep in properly labeled containers. This material and its container must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	:	Do not handle until all safety precautions have been read and understood. Handle in accordance with good industrial hygiene and safety procedures. Wear recommended personal protective equipment. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not breathe mist, vapors. Avoid accidental injection.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	:	Keep container tightly closed. Store in a dry, cool and well-ventilated place. Protect from light.
Incompatible materials	:	Oxidizers. Acids. Bases.
Storage temperature	:	Store at 20° to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Not applicable

8.2. Appropriate engineering controls

Appropriate engineering controls : Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment symbol(s):



Personal protective equipment:

Safety glasses. Gloves.

Hand protection:

For bulk processing operations and if skin contact with the product is possible, wear impermeable protective gloves. Gloves should be classified under Standard EN 374 or ASTM F1296. Suitable gloves for this specific application can be recommended by the glove supplier.

Eye protection:

Use eye protection suitable to the environment. Avoid direct contact with eyes.

Skin and body protection:

Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure.

Respiratory protection:

Use NIOSH (or other equivalent national standard) -approved dust/particulate respirator. Where vapor, mist, or dust exceed PELs or other applicable OELs, use NIOSH-approved respiratory protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Appearance	:	Solution.
Color	:	Reddish-orange
Odor	:	No data available
Odor threshold	:	No data available
pH	:	8.3 – 9.8
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Relative evaporation rate (butylacetate=1)	:	No data available
Flammability (solid, gas)	:	No data available
Vapor pressure	:	No data available
Relative vapor density at 20°C	:	No data available
Relative density	:	No data available
Solubility	:	Miscible in water.
Partition coefficient n-octanol/water (Log Pow)	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive limits	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

Oxidizers. Acids. Bases.

10.6. Hazardous decomposition products

None under normal use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified

Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

AK-Fluor® Fluorescein injection, USP	
LD50 oral rat	6721 mg/kg

Skin corrosion/irritation : Not classified
pH: 8.3 – 9.8

Serious eye damage/irritation : Not classified
pH: 8.3 – 9.8

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

Viscosity, kinematic : No data available

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : May cause skin irritation. May cause yellowish discoloration.

Symptoms/effects after eye contact : Direct contact with eyes is likely to be irritating.

Symptoms/effects after ingestion : May cause gastrointestinal irritation.

Other information : No additional information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available.

12.2. Persistence and degradability

AK-Fluor® Fluorescein injection, USP	
Persistence and degradability	No data available.

12.3. Bioaccumulative potential

AK-Fluor® Fluorescein injection, USP	
Bioaccumulative potential	No data available.

12.4. Mobility in soil

AK-Fluor® Fluorescein injection, USP	
Ecology - soil	No data available.

12.5. Other adverse effects

Other information : No data available.

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Do not discharge to public wastewater systems without permit of pollution control authorities. No discharge to surface waters is allowed without an NPDES permit. Incinerator may be used.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not regulated for transport

Transport by sea (IMDG)

Not regulated for transport

Air transport (IATA)

Not regulated for transport

SECTION 15: Regulatory information

15.1. US Federal regulations

AK-Fluor® Fluorescein injection, USP
This product is regulated under the United States Federal Food, Drug, and Cosmetic Act (FFDCA) and is exempt from listing on TSCA

15.2. International regulations

No additional information available

15.3. US State regulations

This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm

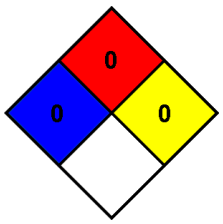
SECTION 16: Other information

Other information : Author: SS.

NFPA health hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA fire hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS Hazard Rating	
Health	: 0
Flammability	: 0
Physical	: 0

Indication of changes:
Revision 1.0: New SDS Created.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.