

SAFETY DATA SHEETS

This SDS packet was issued with item:

078011373

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078930692

1. Product and Company Identification

Material name Ful-Glo Fluorescein Sodium Ophthalmic Strips, 0.6mg and 1.0mg
Version # 1
Revision date 05-14-2015
Product code A02-01, A03-02
Chemical class FDA Regulated Product
Manufacturer Nomax, Inc.
9735 Green Park Industrial Drive
Saint Louis, MO 63123
Medical (314) 815-5200

Emergency

General information General (314) 815-5200

2. Hazards Identification

Emergency overview Material Not Considered Hazardous
Potential health effects None Determined for Material
Eyes No Hazard Determined
Skin No Hazard Determined
Inhalation No Hazard Determined
Ingestion No Hazard Determined

3. Composition / Information on Ingredients

Components	CAS #	Percent
Fluorescein Sodium	518-47-8	Proprietary

4. First Aid Measures

First aid procedures No special precautions needed if directions on product container are followed.

Eye contact Not Applicable

Skin contact Wash with water.

Inhalation Not available.

Ingestion Not available

Notes to physician Refer to product container for additional information

General advice Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties Not flammable by OSHA criteria. Not combustible by OSHA criteria.

Suitable extinguishing media Water spray. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing Media Not available

Protection of firefighters No additional precautions needed

Specific hazards arising from the chemical Emits toxic fumes under fire conditions.

Protective equipment and precautions Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental Release Measures

Personal precautions
Environmental precautions
Methods for containment
Methods for cleaning up

Standard personal protection equipment.
Not available
Not available
For waste disposal, see section 13 of the SDS.

7. Handling and Storage

Handling

Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling.

Storage

Keep away from heat, sparks and open flame. Store in original closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure Controls / Personal Protection

Engineering controls
Personal protective equipment
General
Eye / face protection
Skin protection
Respiratory protection
General hygiene Considerations

No additional engineering controls needed for finished product
See individual sections for specific requirements
Use personal protective equipment as required.
Not required for finished product
Wear appropriate clothing.
Not required for finished product
When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking.

9. Physical & Chemical Properties

Color
Physical state
Form
pH
Freezing point
Boiling point
Flash point
Evaporation rate
Flammability limits in air, upper, % by volume
Flammability limits in air, lower, % by volume
Vapor pressure
Vapor density
Specific gravity
RVOC
Pour point
Viscosity
Percent volatile

Orange
Powder
Solid
Not available
Not available
Not available
Does not flash
Not available
NOT DETERMINED.
NOT DETERMINED.
Not available or Unknown
Not available
Not available
Not available
Not available
Not available
Not available

10. Stability & Reactivity

Chemical stability
Conditions to avoid
Incompatible materials
Hazardous decomposition Products
Possibility of hazardous Reactions

Material is stable under normal conditions.
No conditions known for finished product
Reacts with oxidizing agents and Strong acids.
None for strip in finished distributed
No dangerous reaction known under conditions of normal use.
Follow product insert guidelines.

11. Toxicological Information

Toxicological data
Sensitization
Acute effects
Carcinogenicity

Not Determined
Not classified.
Not Available
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Not available
No data available to indicate product or any components present are mutagenic or genotoxic.
Contains no ingredient listed as toxic to reproduction

Skin corrosion/irritation
Mutagenicity**Reproductive effects****12. Ecological Information****Ecotoxicological data**
Persistence / degradability
Bioaccumulation/Accumulation
Mobility in environmental media

No data available
Expected to be inherently biodegradable.
No data available.
No data available for this product.

13. Disposal Considerations**Waste codes****Disposal instructions****Waste from residues / unused products**
Contaminated packaging

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Dispose in accordance with all applicable regulations for federal and state agencies.
Dispose of in accordance with local regulations.
Not available

14. Transport Information**Notes**

Refer to bill of lading or container label for DOT or other transportation hazard classification, if any.

15. Regulatory Information**US federal regulations**
Reportable Quantity
CERCLA (Superfund) reportable quantity
Superfund Amendments and Reauthorization Act of 1986 (SARA)
Section 302 extremely hazardous substance
Section 311 hazardous chemical

FDA Regulated
No Data Available
None
No
No
No

16. Other Information**Disclaimer**

Terms and Conditions. This SDS is designed only as guidance for the products to which it applies. To the greatest extent permitted by applicable law, nothing contained herein creates any legal obligation including contractual obligations, expressed or implied warranties, including any warranties of merchantability or fitness for particular purpose; or confers any intellectual property rights, including rights to use trademarks or a license to use patents, issued or pending. The information contained herein is based on the manufacturer's own study and the work of others, and is subject to change at any time without further notice. There is no warranty, expressed or implied, as to the accuracy, completeness or adequacy of the information contained herein, and neither the provider nor the manufacturer (nor the agents, directors, officers, contractors or employees of either) are liable to any party for any damages of any nature, including direct, special or consequential damages arising out of

NOMAX INC.

Safety Data Sheet

Ful-Glo 0.6mg and 1.0mg
(#A02-01, #A03-02)

or in connection with the accuracy, completeness, adequacy or
furnishing of any information in this SDS, or in any other way
related (directly or indirectly) to this SDS. The receipt and use of
this information constitutes consent to these terms and
conditions.
05-14-2015

Issue date



SDS: Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP

SAFETY DATA SHEET

1. Identification

Product Identifier: Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP 0.6 mg
Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP 1.0 mg

Synonyms: Ful-Glo®, Fluorescein sodium; Acid Yellow 73; Uranine; FD&C yellow 8; CI acid yellow 73; Spiro[isobenzofuran-1(3H), 9'-[9H]xanthen]-3-one, 3',6'-dihydroxy-, disodium salt; C.I. 45350

National Drug Code (NDC): 17478-403-03
17478-404-01

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product. Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention.



SDS: Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Spiro[isobenzofuran-1(3H), 9'-[9H]xanthen]-3-one, 3',6'-dihydroxy-, disodium salt	518-47-8	Fluorescein Sodium; Acid Yellow 73; Uranine; FD&C Yellow 8; CI Acid Yellow 73; C.I. 45350	$C_{20}H_{10}O_5 \cdot Na_2$	376.27	100%*

* *Each sterile strip is impregnated with Fluorescein Sodium:

NDC 17478-403-03: Fluorescein Sodium, 0.6 mg;

NDC 17478-404-01: Fluorescein Sodium, 1.0 mg.

4. First Aid Measures

Ingestion:

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.

Eye Contact:

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.

Skin Contact:

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.

Inhalation:

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.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

Signs and Symptoms:

No data available.



SDS: Ful-Glo® Fluorescein Sodium Sterile Ophthalmic Strips, USP

Medical Conditions Aggravated by Exposure:

May aggravate allergies and bronchial asthma.

Notes to Physician:

Treat supportively and symptomatically.

5. **Firefighting Measures**

Suitable Extinguishing Media:

Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media:

Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:

These products include carbon oxides and sodium oxides.

Other Specific Hazards:

Closed containers may explode from the heat of fire.

Special Protective Equipment/Precautions for Firefighters:

Wear self-contained breathing apparatus and full and protective gear.

6. **Accidental Release Measures**

Personal Precautions:

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment:

For personal protection see section 8.

Methods for Cleaning Up:

Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions:

Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections:

Refer to Sections 8, 12 and 13 for further information.

7. **Handling and Storage**

Precautions for Safe Handling:

Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities:

Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.

Specific End Use:

Pharmaceuticals.



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8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Fluorescein sodium	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:

Safety glasses with side shields are recommended. 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:

Chemically compatible gloves. For handling solutions, 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:

Protective laboratory coat, apron, or disposable garment.

9. Physical and Chemical Properties

Physical State/Color:

Solid strips/Red-orange tip.

Odor:

No data available.

Odor Threshold:

No data available.

pH:

No data available.

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.

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.



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Decomposition Temperature: No data available.
Viscosity: No data available.

10. Stability and Reactivity

Reactivity: No data available.

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: Oxidizers, acids, and bases.

Hazardous Decomposition Products: No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion: May be harmful if swallowed.

Skin Contact: May be harmful if absorbed through the skin. May cause yellowish discoloration. May cause irritation.

Eye Contact: May cause 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.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Fluorescein Sodium	Rat	Oral	LD ₅₀	6,721 mg/kg

Acute Toxicity – Dermal: No data available.

Acute Toxicity – Inhalation: No data available.

Corrosivity: No data available.

Dermal Irritation: No data available.

Eye Irritation: No data available.

Sensitization: No data available.

Toxicokinetics/Metabolism: No data available.



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Target Organ Effects:	No data available.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.

National Toxicology Program (NTP):	Not considered to be a carcinogen.
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International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
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Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
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Mutagenicity:	No data available.
Aspiration Hazard:	No data available.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	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

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.

Department of Transportation:	Not regulated as a hazardous material.
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International Air Transport Association (IATA):	Not regulated as a dangerous good.
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International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.
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15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
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CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
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SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

Massachusetts: Not listed.
New Jersey: Not listed.
Pennsylvania: Not listed.
California Proposition 65: Not listed.

16. Other Information

NFPA Rating:	HMIS Classification:
Health: 0	Health: 0
Flammability: 0	Flammability: 0
Reactivity: 0	Physical Hazard: 0

Revision Date: 06/29/2015

Revision Number: 2

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