

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	Standard personal protection equipment.
Environmental precautions	Not available
Methods for containment	Not available
Methods for cleaning up	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	No additional engineering controls needed for finished product
Personal protective equipment	See individual sections for specific requirements
General	Use personal protective equipment as required.
Eye / face protection	Not required for finished product
Skin protection	Wear appropriate clothing.
Respiratory protection	Not required for finished product
General hygiene Considerations	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	Orange
Physical state	Powder
Form	Solid
pH	Not available
Freezing point	Not available
Boiling point	Not available
Flash point	Does not flash
Evaporation rate	Not available
Flammability limits in air, upper, % by volume	NOT DETERMINED.
Flammability limits in air, lower, % by volume	NOT DETERMINED.
Vapor pressure	Not available or Unknown
Vapor density	Not available
Specific gravity	Not available
RVOC	Not available
Pour point	Not available
Viscosity	Not available
Percent volatile	Not available

10. Stability & Reactivity

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	No conditions known for finished product
Incompatible materials	Reacts with oxidizing agents and Strong acids.
Hazardous decomposition Products	None for strip in finished distributed
Possibility of hazardous Reactions	No dangerous reaction known under conditions of normal use. Follow product insert guidelines.

11. Toxicological Information

Toxicological data	Not Determined
Sensitization	Not classified.
Acute effects	Not Available
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Skin corrosion/irritation	Not available
Mutagenicity	No data available to indicate product or any components present are mutagenic or genotoxic.
Reproductive effects	Contains no ingredient listed as toxic to reproduction

12. Ecological Information

Ecotoxicological data	No data available
Persistence / degradability	Expected to be inherently biodegradable.
Bioaccumulation/Accumulation	No data available.
Mobility in environmental media	No data available for this product.

13. Disposal Considerations

Waste codes	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal instructions	Dispose in accordance with all applicable regulations for federal and state agencies.
Waste from residues / unused products	Dispose of in accordance with local regulations.
Contaminated packaging	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	FDA Regulated
Reportable Quantity	No Data Available
CERCLA (Superfund) reportable quantity	None
Superfund Amendments and Reauthorization Act of 1986 (SARA)	No
Section 302 extremely hazardous substance	No
Section 311 hazardous chemical	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)

COPY

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 •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.



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

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.



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

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.



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

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.
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.
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.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

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.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.



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

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

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.