

## G2 Natural MB

### **Technical & Regulatory Product Dossier**

Patent: U.S. Patent No. US 8993641 and US 10897899

Version 6.0: January 3, 2025

Dear Valued Customers,

Inolex, Inc. is committed to assisting customer qualification of our products to best meet our customers' needs. This typically translates into Inolex receiving a large quantity of unique questionnaires from our customers which often address the same technical, quality, and regulatory interests leading to a slow response time, inadequate response, and the potential loss of data integrity when changes happen.

In order to respond to your inquiries in a timely manner, we have established a standardized Product Dossier that directly captures and reports the information. (Additional documents such as Safety Data Sheets, Product Bulletins, and/or relevant certifications are also available upon request). The main goal of this information package is to ensure that consistent information is provided with a fast turnaround time.

We are convinced that this Product Dossier is an improvement to provide important technical, quality, and regulatory information to our customers.

Should you have further questions and/or feedback, please contact your Inolex Account Manager or Inolex distributor. Thank you for your continued interest in our products.

Sincerely,  
Inolex, Inc.

IMPORTANT NOTE: This technical product information and suggestions for use, while believed to be accurate and reliable, is given without any guarantee or warranty of any kind expressed or implied. Purchaser assumes all risk in acting on this information provided by Inolex Inc. and its representatives. Since product specifications may have individual requirements based on customer's specific needs, each purchaser is urged to perform their own tests, experiments, and investigations in the use of Inolex Inc. products and for purposes of determining compliance with applicable local laws and regulations. Inolex Inc. and its representatives assume no liability in connection with the use or utilization of the materials or the products described therein. Nothing stated herein is to be considered a recommendation or inducement of any use, manufacture, or sale that may infringe any patents or any other proprietary rights now or hereafter in existence. Moreover, no license is to be implied under any Inolex patents relating to the uses of the above.

## General Product Information

<b>INCI Name</b>	Caprylhydroxamic Acid (and) Glyceryl Caprylate (and) Glycerin
<b>CAS Number</b>	7377-03-9 (Caprylhydroxamic Acid) 11140-04-8; 26402-26-6 (Glyceryl Caprylate) 56-81-5 (Glycerin)
<b>Product Code</b>	69146

## Physiochemical Information

<b>Composition</b>	Caprylhydroxamic Acid – 10% Glyceryl Caprylate – 75% Glycerin – 15%
<b>Country of Origin</b>	United States, Korea
<b>Manufacturing Process</b>	Spectrastat™ G2 Natural MB is a blend of caprylhydroxamic acid, glyceryl caprylate, and glycerin. The product is then filtered and packaged.
<b>Statement of Origin</b>	<p>The components of Spectrastat™ G2 Natural MB are derived from plant-based or natural inorganic sources.</p> <ul style="list-style-type: none"><li>• Caprylhydroxamic Acid is synthesized by the transamidation of methyl caprylate (derived from coconut oil, sourced from Malaysia/Indonesia/Philippines) with hydroxylamine (synthesized from the O<sub>2</sub> oxidation of ammonia derived from atmospheric nitrogen and hydrogen (<math>N_2 + 3H_2 \rightarrow 2NH_3</math>)).</li><li>• Glyceryl Caprylate is derived from the esterification of caprylic acid with glycerin (both derived from either coconut oil or palm kernel oil sourced from Southeast Asia).<ul style="list-style-type: none"><li>○ Glycerin may also be derived from rapeseed oil/sunflower oil from the European Union.</li></ul></li></ul>

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## Regulatory & Compliance Information

<b>1223/2009 Compliance</b>	<ul style="list-style-type: none"><li>• The product complies with Annexes III, IV, V and VI, of the Cosmetic Regulation (EC) 1223/2009.</li><li>• The product does not contain any substance listed in Annex II of the Cosmetic Regulation 1223/2009, in the limit of Article 17.</li><li>• The product complies with Article 15 ("Substances classified as CMR substances") of the Cosmetic Regulation 1223/2009.</li></ul>
<b>Allergen Statement: EU Fragrance</b>	The product does not contain any of the allergens listed in Annex II or III of Commission Regulation (EC) No 1223/2009. The product does not contain any of the allergens listed in Annex II or III of Commission Regulation (EU) 2023/1545 of 26 July 2023 amending Regulation (EC) No 1223/2009.
<b>Allergen Statement: Food</b>	The product does not contain Crustacean Shellfish, Egg, Fish, Milk, Peanut, Soy, Tree Nuts, Sulfites, Buckwheat, Celery, Lupin, Molluscan Shellfish, Sesame, Bee Pollen, Beef, Chicken, Pork, Latex, Mango, Peach, Tomato, Royal Jelly.
<b>Animal Testing Statement</b>	Spectrastat™ G2 Natural MB has not been tested on animals since 1990. We are in compliance with Regulation (EC) No. 1223/2009, Chapter V; Article 18 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products.
<b>BSE/TSE Statement</b>	The product does not contain any animal derived ingredients, thus is Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) free with respect to source, manufacture, and treatment.
<b>California Proposition 65 Statement</b>	The product is not expected to contain any contaminants or by-products known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act.
<b>CITES Statement</b>	No components of the product are included on the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) list.
<b>CMR Statement</b>	The product is not expected to contain C (Carcinogen), M (Mutagen), or R (Toxic for Reproduction) Substances as indicated on REACH Annex VI or in Regulation

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(EC) No. 1272/2008 (categories 1A, 1B, or 2).

## **Conflict Minerals Statement**

Based on currently available information, Inolex does not source raw materials from Democratic Republic of the Congo and its adjoining countries. A “Conflict Mineral” is considered to be any of the following minerals or their derivatives originating in the Democratic Republic of the Congo (the “DRC”) or any of the adjoining countries with which the DRC shares a recognized international border:

- Tin (cassiterite)
- Tantalum (columbite-tantalite)
- Tungsten (Wolframite)
- Gold

## **EUDR Statement**

Spectrastat™ G2 Natural MB is in compliance with the European Union Regulation on Deforestation-Free Products (EU 2023/111) as its products do not involve the use of commodities specified in the regulation (palm, soya, rubber, wood, cocoa, coffee, cattle) or fall under the listed HS codes in Annex 1.

## **Endocrine Disruptors Statement**

Spectrastat™ G2 Natural MB does not include any substances found on the Endocrine Disruptor Assessment List I and II, nor does it contain any substances found on List II that are currently being evaluated as potential endocrine disruptors.

## **Genetic Modification Statement**

The product is not expected to contain genetically modified material. The starting raw materials do not intentionally include genetically modified organisms (GMOs) and no GMO materials are introduced during the manufacturing process.

## **Gluten-Free Statement**

The product is not expected to contain gluten. The starting raw materials do not contain gluten and no gluten is introduced during the manufacturing process.

## **Halal Statement**

Spectrastat™ G2 Natural MB is a Halal certified product. Certificate available upon request.

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## Heavy Metals Statement

<b>Ag</b>	<b>As</b>	<b>Ba</b>	<b>Cd</b>	<b>Cr</b>
<1 ppm	<1 ppm	<1 ppm	<1 ppm	<1 ppm
<b>Hg</b>	<b>Ni</b>	<b>Pb</b>	<b>Sb</b>	<b>Sn</b>
<1 ppm	<1 ppm	<1 ppm	<1 ppm	<1 ppm

## Impurities Statement

The following list of chemicals are not expected to be present in the Inolex family of products based on our knowledge of the starting raw materials used and the current manufacturing processes – This includes strict controls of raw materials, optimized synthesis processes for the production of new chemical entities, and the use of analytical testing to ensure the quality of the finished chemicals (though not all of the below chemicals are routinely analyzed).

- Oxides (butylene oxide, ethylene oxide, propylene oxide, etc.)
- Amines (melamine, nitrosamines, etc.)
- Glycol ethers
- Silicone
- Dioxane
- Polyaromatic Hydrocarbons
- Halogenated compounds
- Phthalates
- Parabens
- Sulfates

Please note that the above list of chemicals is not an exhaustive list.

## Irradiation Statement

The product has not been subject to irradiation of any kind during or after manufacturing, and no known irradiated ingredients are present.

## ISO 16128 Standard

These indexes have been calculated according to the ISO 16128 standard. The calculation is based on the carbon atom number of the ingredient.

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Natural Index	Natural Origin Index	Organic Index	Organic Origin Index
0	1	0	0

## **Kosher Statement**

Based on the review of the raw materials and the manufacturing process, the product meets the following Kosher requirements:

- The product does not contain any ingredient of animal origin.
- The equipment used for manufacturing the product is not used for the manufacturing of products containing ingredients of animal origin.
- The product does not come in contact with any products of animal origin or products containing such ingredients.
- The product does not contain the following: tree nuts, peanuts, soybeans, wheat, eggs, milk, fish, and crustacean shellfish.

## **Microbiological Testing Statement**

Inolex ingredients are from five classes of chemistries: liquid esters, liquid polyesters, solid esters, solid amidoamines and related blends, and liquid glycols and glycol blends. These classes are anhydrous and/or hydrophobic and/or water activity reducing, and as a result, microbial growth is not supported. Inolex has been producing these materials for many years, and our experience, and that of our customers, is that these materials have proven to be uncontaminated during storage and use in standard cosmetic manufacturing environments. Neither preservation nor irradiation is needed to assure their safety.

## **Microplastic Statement**

Spectrastat™ G2 Natural MB does not contain polymers. It is excluded from microplastic regulation as defined by Commission Regulation (EU) 2023/2055.

## **Nanomaterial Statement**

Nanomaterials, in accordance with Article 16 of Cosmetic Regulation (EC) 1223/2009, are not used in the manufacturing or processing of the product and are not expected to be present.

## **Palm Status**

Spectrastat™ G2 Natural MB contains RSPO Mass Balanced certified palm derivatives.

- Palm Kernel Oil: 75.8%
- Palm Oil: 15.2%

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Inolex is a member of the Roundtable on Sustainable Palm Oil (RSPO) and has achieved RSPO Supply Chain Certification.

<b>Pesticide Statement</b>	The product is not expected to contain residual pesticides.
<b>Preservatives Statement</b>	No preservatives are present in the product.
<b>Residual Monomer Statement</b>	Not applicable.
<b>Residual Solvent Statement</b>	Spectrastat™ G2 Natural MB conforms with both the USP <467> and ICH Q3C residual solvent guidelines. Class 1 solvents are not added or generated in the manufacturing process of Spectrastat™ G2 Natural MB. Class 2 solvents (methanol, ethyl acetate) and class 3 solvents (acetic acid) are present, however, Inolex assures that the total quantity of class 2 and class 3 solvents in Spectrastat™ G2 Natural MB is well below the compendial permissible limits of 3000ppm and 5000ppm, respectively.
<b>SVHC Statement</b>	The product does not contain any Substances of Very High Concern (SVHC) under REACH.
<b>Vegan Statement</b>	The product is suitable for vegans. It is derived from vegetable and petrochemical sources only and does not contain any animal derived ingredients.
<b>VOC Statement</b>	<p>The product does not meet the definition as a Volatile Organic Compound (VOC) under any of the following regulations:</p> <ul style="list-style-type: none"><li>• 40 CFR Part 51 Section 51.100</li><li>• California Air Resources Board's definition of reactive organic gas (ROG) or total organic gases (TOG)</li><li>• DIRECTIVE 2010/75/EU</li><li>• The Swiss Federal Council (based on 35a and 35c of the Environmental Protection Act)</li></ul>

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## Toxicity Review

### Acute Oral Toxicity (Public Domain – REACH Registration Dossier)

#### **Glyceryl Caprylate (CAS #: 11140-04-8)**

LD50 was found to be greater than 2000 mg/kg bodyweight.

### Skin Sensitization (INOLEX Study – HRIPT)

#### **Spectrastat™ G2 Natural MB (INCI: Caprylhydroxamic Acid (and) Glyceryl Caprylate (and) Glycerin)**

The upper back between the scapulae and the waist served as the treatment area on 104 subjects. Approximately 0.2 ml of Spectrastat™ G2 Natural MB was applied to the 3/4" x 3/4" absorbent pad portion of an adhesive dressing. This was then applied to the appropriate treatment site to form an occlusive patch. The induction patches were applied three times per week, for a total of nine applications. Two weeks after the final induction patch application, a challenge patch was applied to a virgin site and scored 24 and 64 hours, post-application. Under the conditions of this study, Spectrastat™ G2 Natural MB did not indicate a potential for dermal irritations and/or sensitization.

#### **Caprylhydroxamic Acid (CAS #: 7377-03-9)**

The upper back between the scapulae and the waist served as the treatment area on 52 human subjects. Approximately 0.2 ml of Caprylhydroxamic acid was applied to the 3/4" x 3/4" gauze portion of a clear adhesive dressing that was dampened with water. It was then applied to the treatment site to form a semi-occluded patch. This procedure was followed three times a week for a total of nine applications. Two weeks following the ninth application, a challenge patch was applied to the original site and to a virgin site. Each site was evaluated at 24 and 48 hours after application. Observations on all subjects remained negative throughout the test interval. Under the conditions of this study, Caprylhydroxamic acid did not indicate a potential for dermal irritation and/or sensitization.

### Eye Irritation

#### **Caprylhydroxamic Acid (CAS #: 7377-03-9)**

Ocular toxicity or irritation potential of the test substance is determined by the ET50 for MTT viability of EpiOcular samples. EpiOcular tissue samples were treated with

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**(INOLEX Study –  
EpiOcular OECD  
492)**

test substance followed by viability testing of the tissues using MTT uptake and conversion. Resulting absorbance of each sample was measured at 540 nm and the viability was then expressed as a percentage versus the control values. The calculated ET50 represents the time at which the EpiOcular tissue viability was reduced by 50% compared to the control tissues. Caprylhydroxamic Acid is classified as Non-Irritating / Minimal.

**Skin Irritation  
(INOLEX Study –  
EpiDerm OECD  
439)**

**Caprylhydroxamic Acid (CAS #: 7377-03-9)**

Dermal toxicity or irritation potential of the test substance is determined by the ET50 for MTT viability of EpiDerm samples. EpiDerm was used to evaluate skin irritation potential of the test article. Tissue viability following topical application of the test article was evaluated via MTT assay. Caprylhydroxamic Acid is classified as Non-Irritating.

**Skin Irritation  
(Public Domain –  
REACH  
Registration  
Dossier, OECD  
404)**

**Glyceryl Caprylate (CAS #: 11140-04-8)**

The test substance at 20% w/w was tested on shaved rabbits in a semi-occlusive test at 24, 48, and 72 hours. The test material was found to be a mild irritant to rabbit skin. No corrosive effects were noted.

**Genotoxicity  
(INOLEX Study –  
Ames OECD 471)**

**Caprylhydroxamic Acid (CAS #: 7377-03-9)**

The test sample did not produce a two-fold increase in the number of revertants or a clear dose related response in any of the tester strains. Caprylhydroxamic Acid did not meet the criteria for a potential mutagen, therefore it is not mutagenic.

**Biodegradation  
(INOLEX Study –  
OECD 301A)**

**Caprylhydroxamic Acid (CAS #: 7377-03-9)**

The biodegradation test of Caprylhydroxamic Acid was conducted in activated sludge in an aerobic aqueous medium and the accumulated percentage biodegradation was observed. Caprylhydroxamic Acid was concluded to be readily biodegradable (98.2% biodegradation after 28 days).

**Biodegradation  
(Public Domain –  
REACH)**

**Glyceryl Caprylate (CAS #: 11140-04-8)**

Fatty Acid Glycerides are readily biodegradable.

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## Registration Dossier)

## International Regulatory Status

Please note that the table below is not a confirmation of your compliance. It is aimed to inform you about the regulatory status of Inolex raw materials. Compliance is the responsibility of each importer/manufacturer.

	Spectrastat™ G2 Natural MB		
	Glyceryl Caprylate (CAS#: 26402-26-6)	Caprylhydroxamic Acid	Glycerin
EU	Compliant	Compliant	Compliant
Australia	Listed on AIIC	Listed on AIIC	Listed on AIIC
Australia TGA	Listed with approved concentration up to 1.3%		
Canada	Listed on NDSL	Listed on NDSL	Listed on DSL
Canada NHPID	NMI listed	NMI listed	NMI listed
China	Listed on IECSC	Not listed on IECSC	Listed on IECSC
	Listed on IECIC	Listed on IECIC	Listed on IECIC
Japan	ENCS No. 2-666x; 2-669x	ENCS No. 2-2502	ENCS No. 2-242
Korea	Listed: KE-26647	Not listed; Compliant for personal care applications	Listed: KE-29297
New Zealand	Listed on NZIoC	Not listed; Compliant for personal care applications	Listed on NZIoC
Philippines	Listed on PICCS	Not listed; Compliant for personal care applications	Listed on PICCS
Taiwan	Listed on TCSI	Listed on TCSI	Listed on TCSI
United States	Listed on TSCA	Listed on TSCA	Listed on TSCA
ASEAN Cosmetic Directive	Compliant	Compliant	Compliant

## Certifications

NSF/ANSI, USDA BioPreferred® (100%), NATRUE Certificates available upon request.

## Storage

### Storage Conditions

It is recommended that Inolex Inc. products be stored in unopened, original containers and be kept indoors.

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**Recommended  
Re-Evaluation  
Date**

The recommended re-evaluation date is 24 months from the date of the previous analysis. The recommended re-evaluation date is the time-period in which the product is expected to maintain its initial physical and chemical characteristics from the Date of Manufacture as indicated on the Certificate of Analysis. The recommended re-evaluation date period will be affected by storage conditions such as temperature, humidity, and the environment of the storage area.

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