

GMS

Technical & Regulatory Product Dossier

Version 5.0: April 3, 2024

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

INCI Name Glyceryl Stearate

CAS Number 85251-77-0

Product Code 63108

Physiochemical Information

Composition Glyceryl Stearate – 100%

Country of Origin United States

Manufacturing Process Glyceryl Stearate is manufactured via the esterification of glycerin with stearic acid. The product is then purified, filtered, pastillated and packaged.

Statement of Origin SustOleo™ GMS is derived from vegetable sources.

- Stearic acid is derived from olive oil sourced from Italy, Spain and Greece.
- Glycerin is derived from the hydrolysis of coconut oil sourced from Southeast Asia (Indonesia/Malaysia/Philippines) or rapeseed oil/sunflower oil from the European Union.

Regulatory & Compliance Information

- 1223/2009 Compliance**
- The product complies with Annexes III, IV, V and VI, of the Cosmetic Regulation (EC) 1223/2009.
 - The product does not contain any substance listed in Annex II of the Cosmetic Regulation 1223/2009, in the limit of Article 17.
 - The product complies with Article 15 ("Substances classified as CMR substances") of the Cosmetic Regulation 1223/2009.

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Allergen Statement: EU Fragrance	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.
Allergen Statement: Food	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.
Animal Testing Statement	Inolex has never conducted nor commissioned animal testing on SustOleo™ GMS. 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.
BSE/TSE Statement	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.
California Proposition 65 Statement	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.
CITES Statement	No components of the product are included on the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) list.
CMR Statement	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 (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: <ul style="list-style-type: none">• Tin (cassiterite)• Tantalum (columbite-tantalite)

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- Tungsten (Wolframite)
- Gold

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

SustOleo™ GMS is a Halal certified product. Certificate available upon request.

Heavy Metals Statement

Ag	As	Bi	Cd	Cr	Cu
<1 ppm	<1 ppm	<1 ppm	<1 ppm	<1 ppm	<1 ppm
Fe	Hg	Mo	Pb	Sb	Sn
<1 ppm	<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

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- 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.

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.

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Microplastic Statement	SustOleo™ GMS 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	<p>SustOleo™ GMS does not contain palm, palm derivatives, palm oil or palm oil derivatives.</p> <p>Inolex is a member of the Roundtable on Sustainable Palm Oil (RSPO) and has achieved RSPO Supply Chain Certification.</p>
Pesticide Statement	The product is not expected to contain residual pesticides.
Preservatives Statement	No preservatives are present in the product.
Residual Monomer Statement	Not applicable.
Residual Solvent Statement	SustOleo™ GMS conforms with both the USP <467> and ICH Q3C residual solvent guidelines. Inolex assures that there are no USP or ICH regulated solvents used or generated in the manufacture of SustOleo™ GMS. Inolex also assures that, based raw on the raw material composition, the manufacturing, handling, and storage procedures utilized at our plant sites, there is no potential for residual solvents of class 1, 2, or 3 as mentioned in the guidelines for residual solvents (CPMP/ICH/283/95) of the European Pharmacopoeia, to be present in SustOleo™ GMS.
SVHC Statement	The product does not contain any Substances of Very High Concern (SVHC) under REACH.

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- Vegan Statement** The product is suitable for vegans. It is derived from vegetable and petrochemical sources only and does not contain any animal derived ingredients.
- VOC Statement** The product does not meet the definition as a Volatile Organic Compound (VOC) under any of the following regulations:
- 40 CFR Part 51 Section 51.100
 - California Air Resources Board's definition of reactive organic gas (ROG) or total organic gases (TOG)
 - DIRECTIVE 2010/75/EU
 - The Swiss Federal Council (based on 35a and 35c of the Environmental Protection Act)

Toxicity Review

Skin Sensitization (CIR Safety Assessment of Monoglyceryl Monoesters) Glyceryl stearate is safe in the present practices of use and concentration described in the safety assessment.

Acute Oral Toxicity (Public Domain – REACH Registration Dossier, OECD 401) **Glyceryl Stearate (CAS #: 85251-77-0)**
LD50 > 2000 mg/kg bw

Acute Dermal Toxicity (Public Domain – REACH Registration Dossier) **Glyceryl Stearate (CAS #: 85251-77-0)**
LD50 > 2000 mg/kg bw

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Acute Inhalation Toxicity (Public Domain – REACH Registration Dossier, OECD 403)

Glyceryl Stearate (CAS #: 85251-77-0)
LC50 > 1.86 mg/L air (nominal)

Skin Sensitization (Public Domain – REACH Registration Dossier)

Glyceryl Stearate (CAS #: 85251-77-0)
All skin examination were negative, both at 24 and 48 hours after challenge exposure. None of the animals showed abnormalities in clinical observations and body weight gain. **Glyceride, C16-18 and C18 Mono- and Dihydroxy was classified as non-sensitizing.**

Eye Irritation (Public Domain – REACH Registration Dossier, OECD 405)

Glyceryl Stearate (CAS #: 85251-77-0)
0.1 mL of the test substance was instilled into the eyes of six New Zealand White rabbits and observed for 72 hours. The substance is classified as non-irritating.

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

Glyceryl Stearate (CAS #: 85251-77-0)
No indication of irritation.

Genotoxicity (Public Domain – REACH Registration)

Glyceryl Stearate (CAS #: 85251-77-0)
Glyceride, C14-18 and C16-22 unsaturated, mono- and di- was not mutagenic in 5 different Salmonella typhimurium strains

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**Dossier, OECD
471)**

**Biodegradation
(Public Domain –
REACH
Registration
Dossier, OECD
301B and 301F)**

Glyceryl Stearate (CAS #: 85251-77-0)
Fatty Acid Glycerides are readily biodegradable.

**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.

	SustOleo™ GMS
	Glyceryl Stearate (CAS #: 85251-77-0)
EU	Compliant
Canada	Listed on DSL
Canada NHPID	Not listed
Australia	Listed on AIIC
Australia TGA	Listed
Japan	ENCS No. 2-669X (2-669)
Korea	ECL Serial NO. KE-17918
China	Listed on IECSC and IECIC
Philippines	Listed on PICCS
Taiwan	Listed on TSCI
United States	Listed on TSCA
New Zealand	Listed on NZIoC
ASEAN Cosmetic Directive	Compliant

Certifications

EcoCert, COSMOS, NSF/ANSI 305 certified, NATRUE, USDA BioPreferred® (100%)
Certificates available upon request.

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Storage

Storage Conditions

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

Recommended Re-Evaluation Date

The recommended re-evaluation date is 36 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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