

# Product Specification



**Product Name:** SAFRALEINE®

**Vigon Code:** 503031

**CAS Number:** 54440-17-4

**FEMA Number:** 4556

## Characteristic:

Purity %

Gas Chromatograph

Odor

Peroxide Value (mmol/l)

Refractive Index (@20c)

Specific Gravity (@25c)

Color/appearance

## Specification:

96.00            100.00

PASSES TEST

SPICY, LEATHERY, WOOD, FAINT ODOR.

0.00            20.00

1.5340           1.5400

1.0140           1.0240

PALE YELLOW LIQUID.

## Additional Product Information:

**Flash Point:** >200 °F

**Shelf Life:** 36 Months

**Storage Conditions:** Stable when stored in its original package, tightly sealed in a cool (46-90°F) and dry location out of direct heat and light.

**Effective Date:** May 12, 2022

Printed Date: August 31, 2023

**Vigon International, LLC.**

127 Airport Road East Stroudsburg, PA 18301-9629 USA | Tel: +1 570-476-6300 | Fax: +1 570-476-1110 | Email: regulatory@vigon.com | Web: vigon.com



## SAFETY DATA SHEET

### 503031 SAFRALEINE®

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Version # 02

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#### 1. IDENTIFICATION

**Product Description:** SAFRALEINE®  
**CAS #** 54440-17-4  
**FEMA Number** 4556  
**Other means of identification**  
**Vigon Item #** 503031  
**Recommended use** Concentrated aromatic ingredient which may be used fragrance compounds according to legal and IFRA guidelines.  
**Recommended restrictions** For Manufacturing Use Only

Company

Vigon International, Inc.  
127 Airport Road  
E. Stroudsburg, PA 18301  
For information call: 570-476-6300  
Web Site: www.vigon.com

24 Hour Emergency Response Information

INFOTRAC (ACCT# 78928);  
1-800-535-5053 WITHIN THE U.S.A.  
1-352-323-3500 OUTSIDE THE U.S.A.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

**Company name** Vigon International, Inc.  
**Address** 127 Airport Road  
E. Stroudsburg, PA 18301  
United States  
**Telephone** For information call: 570-476-6300  
**Website** www.vigon.com  
**E-mail** Not available.  
**Emergency phone number** INFOTRAC (ACCT# 78928);  
1-800-535-5053 WITHIN THE U.S.A.  
1-352-323-3500 OUTSIDE THE U.S.A.

#### 2. HAZARD(S) IDENTIFICATION

**Physical hazards** Not classified.  
**Health hazards** Acute toxicity, oral Category 5  
Acute toxicity, dermal Category 5  
Skin corrosion/irritation Category 2  
**Environmental hazards** Hazardous to the aquatic environment, acute hazard Category 3  
Hazardous to the aquatic environment, long-term hazard Category 3

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### Label elements



**Signal word**

Warning

**Hazard statement**

May be harmful if swallowed or in contact with skin. Causes skin irritation. Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

**Precautionary statement**

**Prevention**

Wash thoroughly after handling. Avoid release to the environment. Wear protective gloves.

**Response**

IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/doctor if you feel unwell. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

**Storage**

Store away from incompatible materials.

**Disposal**

Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)**

None known.

**Supplemental information**

100% of the substance consists of component(s) of unknown acute inhalation toxicity.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substances**

Chemical name	Common name and synonyms	CAS number	%
2,3,3-trimethyl-2H-inden-1-one	1H- inden-1-one, 2,3-dihydro-2,3,3-trimethyl 3,3,2- trimethyl-1-indanone 2,3- dihydro-2,3,3-trimethyl-1H-inden-1-one	54440-17-4	100

### 4. FIRST-AID MEASURES

**Inhalation**

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. For breathing difficulties, oxygen may be necessary. Call a physician if symptoms develop or persist.

**Skin contact**

Take off immediately all contaminated clothing. Get medical attention if irritation develops and persists. Wash skin thoroughly with soap and water for several minutes.

**Eye contact**

Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists. Promptly wash eyes with plenty of water while lifting the eye lids.

**Ingestion**

Call a physician or poison control center immediately. If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting. If vomiting occurs, the head should be kept low so that stomach vomit doesn't enter the lungs.

**Most important symptoms/effects, acute and delayed**

Skin irritation. May cause redness and pain.

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**Indication of immediate medical attention and special treatment needed**

Not available.

**General information**

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

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### 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media**

Water spray, fog, CO2, dry chemical, or alcohol resistant foam.

**Unsuitable extinguishing media**

Do not use a solid water stream as it may scatter and spread fire.

**Specific hazards arising from the chemical**

Fire may produce irritating, corrosive and/or toxic gases.

**Special protective equipment and precautions for firefighters**

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA. Structural firefighters protective clothing will only provide limited protection. Wear self-contained breathing apparatus with a full facepiece operated in the positive pressure demand mode when fighting fires.

**Fire fighting equipment/instructions**

In case of fire and/or explosion do not breathe fumes. Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk. Water runoff can cause environmental damage. Ventilate closed spaces before entering them. Keep run-off water out of sewers and water sources. Dike for water control.

**Specific methods**

Use water spray to cool unopened containers.

**General fire hazards**

Static charges generated by emptying package in or near flammable vapor may cause flash fire.

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### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**

Eliminate all sources of ignition. Avoid contact with skin or inhalation of spillage, dust or vapor. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them.

**Methods and materials for containment and cleaning up**

Collect and dispose of spillage as indicated in section 13 of the SDS.

Absorb with inert absorbent such as dry clay, sand or diatomaceous earth, commercial sorbents, or recover using pumps.

The product is immiscible with water and will spread on the water surface.

Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible.

Never return spills in original containers for re-use. This material and its container must be disposed of as hazardous waste. Eliminate all ignition sources (no smoking, flares, sparks or flames in immediate area). Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.



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**Environmental precautions** Retain and dispose of contaminated wash water. Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water.

### 7. HANDLING AND STORAGE

**Precautions for safe handling** Do not handle or store near an open flame, heat or other sources of ignition. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Avoid breathing vapor. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Wash thoroughly after handling.

**Conditions for safe storage, including any incompatibilities** Keep container closed. Handle containers with care. Open slowly in order to control possible pressure release. Store in a cool, well-ventilated area.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Occupational exposure limits** This substance has no PEL, TLV, or other recommended exposure limit.

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls** Use explosion-proof ventilation equipment to stay below exposure limits. Adequate ventilation should be provided so that exposure limits are not exceeded.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Skin protection**

**Hand protection** Chemical resistant gloves.

**Other** Wear suitable protective clothing.

**Respiratory protection** Respiratory protection not required. If ventilation is insufficient, suitable respiratory protection must be provided.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations** Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** Refer to Spec Sheet

**Physical state** Liquid.

**Form** Liquid.

**Color** Refer to Spec Sheet

**Odor** Characteristic.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

**Flash point** > 200.0 °F (> 93.3 °C) Closed Cup

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not applicable.

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### Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure 0.01 mm Hg at 25 °C

Vapor density 6

Relative density Not available.

### Solubility(ies)

Solubility (water) Insoluble

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature 483.8 °F (251 °C)

Decomposition temperature Not available.

Viscosity Not available.

### Other information

Explosive properties Not explosive.

Molecular formula C<sub>12</sub>H<sub>14</sub>O

Molecular weight 174.24 g/mol

174.24 g/mol

Oxidizing properties Not oxidizing.

Specific gravity 1.02 at 25 °C

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## 10. STABILITY AND REACTIVITY

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Avoid temperatures exceeding the flash point. Contact with incompatible materials.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** No hazardous decomposition products if stored and handled as indicated.

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## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Inhalation** Knowledge about health hazard is incomplete.

**Skin contact** May be harmful in contact with skin. Causes skin irritation.

**Eye contact** Direct contact with eyes may cause temporary irritation. Causes mild eye irritation.

**Ingestion** May be harmful if swallowed.

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**Symptoms related to the physical, chemical and toxicological characteristics**      Skin irritation. May cause redness and pain.

**Information on toxicological effects**

**Acute toxicity**      May be harmful in contact with skin. May be harmful if swallowed.

Product	Species	Test Results
2,3,3-trimethyl-2H-inden-1-one (CAS 54440-17-4)		
<i>Acute</i>		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg OECD Test Guideline 402
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg OECD Test Guideline 423

**Skin corrosion/irritation**      Causes skin irritation.  
Species: rabbit  
Skin irritation  
Method: OECD Test Guideline 404

**Serious eye damage/eye irritation**      Direct contact with eyes may cause temporary irritation.  
Species: rabbit  
No eye irritation  
Method: OECD Test Guideline 405

**Respiratory or skin sensitization**

**Respiratory sensitization**      Due to partial or complete lack of data the classification is not possible.

**Skin sensitization**      Due to partial or complete lack of data the classification is not possible.  
HRIPT Human  
Result: Not sensitizing  
at 10% in Diethyl phthalate/ Ethanol  
LLNA mouse  
Result: Not sensitizing  
Method: OECD Test Guideline 429

Phototoxicity  
UV-VIS absorption spectra  
Results: negative

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### Germ cell mutagenicity

Genotoxicity in vitro:

Ames test

negative

Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)

Chromosome aberration test in vitro

positive

Method: Mutagenicity (in vitro mammalian cytogenetic test)

Genotoxicity in vivo

Micronucleus test Species:mouse

Method: Mutagenicity (micronucleus test) Due to partial or complete lack of data the classification is not possible.

### Carcinogenicity

Due to partial or complete lack of data the classification is not possible.

#### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

#### US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

### Reproductive toxicity

Due to partial or complete lack of data the classification is not possible.

### Specific target organ toxicity - single exposure

Due to partial or complete lack of data the classification is not possible.

### Specific target organ toxicity - repeated exposure

Due to partial or complete lack of data the classification is not possible.

Target Organ Systemic Toxicant - Repeated exposure

Species: rat, male and female

NOAEL: 450 mg/kg

Method: OECD Test Guideline 407

Repeated dose (28 days) toxicity (oral)

### Aspiration hazard

Due to partial or complete lack of data the classification is not possible.

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

Harmful to aquatic life with long lasting effects.

#### Product

#### Species

#### Test Results

2,3,3-trimethyl-2H-inden-1-one (CAS 54440-17-4)

#### Aquatic

#### Acute

Crustacea

EC50

Daphnia magna

27 mg/l, 48 hours OECD Test Guideline 202





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<b>Persistence and degradability</b>	Biodegradability Result: Not readily biodegradable 0% Method: OECD Test Guideline 301F Result: Not inherently biodegradable 0% Method: OECD Test Guideline 302C
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

### 13. DISPOSAL CONSIDERATIONS

<b>Disposal instructions</b>	Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	Not established.
<b>Waste from residues / unused products</b>	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

### 14. TRANSPORT INFORMATION

#### ADN

Not regulated as dangerous goods.

#### ADR

Not regulated as dangerous goods.

#### RID

Not regulated as dangerous goods.

#### DOT

#### BULK

Not regulated as dangerous goods.

#### DOT

#### NON-BULK

Not regulated as dangerous goods.

#### IATA

Not regulated as dangerous goods.

#### IMDG

Not regulated as dangerous goods.



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## 15. REGULATORY INFORMATION

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**Toxic Substances Control Act (TSCA)**

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories** Skin corrosion or irritation

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations**

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

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## 16. OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Issue date** 11-23-2015

**Revision date** 10-23-2019

**Version #** 02

**HMIS® ratings** Health: 2  
Flammability: 1  
Physical hazard: 0



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### Disclaimer

Vigon International, Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available. The above information relates only to this product and not to its use in combination with any other material or any particular process and is designed only as guidance for the safe handling, use, processing, storage, transportation, and disposal and should not be considered as a guarantee or quality specification. This product has not been evaluated for safe use in e-cigarettes or any vaping application where the product(s) is/are intentionally vaporized and inhaled. Vigon International, Inc. has performed no testing on these products in e-cig/vaping applications. It is the sole responsibility of the individual(s) purchasing this product to assess its' safety in the final application. The above information relates only to this product and not to its use in combination with any other material or any particular process and is designed only as guidance for the safe handling, use, processing, storage, transportation, disposal, and should not be considered as a guarantee or quality specification. The above information is based on data provided by and collected from recognized sources such as distributors, manufacturers, and technical groups and is considered to be accurate to the best of Vigon's knowledge as of the date of this document. It is the responsibility of the user to review all safety information about this product and determine its safety and suitability in their own processes and operations. Appropriate warnings and safe handling procedures should be provided to all handlers and users, taking into account the intended use and the specific conditions and factors relating to such use in accordance with all applicable laws and regulations.

### Revision information

This document has undergone significant changes and should be reviewed in its entirety.



# Kosher Certificate

T"03



Date: August 30, 2023  
ג.ג באלול תשפ"ג  
Kof-K ID: K-0000507  
Certificate ID: ZNA15-BSMTZ  
Product Count: 1



This certificate is valid through  
**12/31/2023**

**Vigon International, LLC**  
127 AIRPORT RD.  
EAST STROUDSBURG, PA 18301 UNITED STATES

The following product(s) Manufactured By Vigon International, LLC are certified kosher with the listed restrictions.

Product Code	Product Name	Status	Restriction	UKD#
503031	SAFRALEINE	Parve	Kof-K symbol required	KF7KN2F31Y7

To verify or for the most up to date certificate please go to [www.koshercertificate.com](http://www.koshercertificate.com)  
201 The Plaza, Teaneck, NJ 07666 | Phone 201.837.0500 | fax 201.837.0126



**Rabbi Avram Ossey**  
**Rabbinic Administrator**

# Food Grade Certification

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

**FEMA #: 4556**

Vigon International, LLC. certifies that the above ingredient is **not** food grade.

Vigon International, LCC. may terminate this certification at any time upon written notice in which this certification shall be null and void as to any material supplied after termination of the certification.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023



# Allergen/Sensitive Agents Identification Sheet

Product Name: SAFRALEINE®

Vigon Code: 503031

\* A check mark (✓) indicates the Allergen/Sensitive Agent is present. If blank it means that there is no Allergen/Sensitive present.

<b>ALLERGEN/SENSITIVE AGENTS</b>	*
<b>CORN &amp; CORN PRODUCTS</b> Includes modified starch, hydrolyzed protein, sweeteners, sugars, spice carriers	
<b>EGG &amp; EGG PRODUCTS</b> liquid and powders	
<b>FISH</b> Includes any and all species of fresh and salt water fish	
<b>GARLIC</b> Dehydrated, powdered, granules, and flakes	
<b>GLUTEN</b> Wheat, rye, barley, oats, flour, etc.	
<b>MILK &amp; DAIRY PRODUCTS</b> Includes whey, lactose, cheese, casein, spice carriers, milk, cream, etc.	
<b>MONOSODIUM GLUTAMATE</b>	
<b>PEANUTS, PEANUT OIL &amp; PEANUT DERIVED ITEMS</b> Peanut meal, flour & ground nuts, szechwan sauce, mandelona nuts, etc.	
<b>SESAME SEEDS &amp; SESAME OIL</b>	
<b>CRUSTACEANS</b> Shrimp, lobster, rock lobster, crab, crayfish, and products made from them	
<b>MOLLUSKS</b> Clams, mussels, oysters, scallops, and products made from them	
<b>SOY</b> Includes soya powder, protein, oil, lecithin, tofu	
<b>SULFITES</b> Includes sulfur dioxide, sodium dithionite, chemicals that lists sulfite, etc.	
<b>TREE NUTS</b> Includes almonds, beechnuts, basil nuts, nutmeg, cashews, chestnuts, etc.	
<b>WHEAT</b> Includes hydrolyzed wheat protein, flour, gluten flour, starches	
<b>MUSTARD &amp; MUSTARD OIL</b>	
<b>LUPIN</b>	
<b>CELERY</b>	

Vigon International, LLC. follows Good Manufacturing Practices and has implemented HACCP systems. Our personnel are trained on the proper handling of allergenic materials.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023



# GMO Status Statement

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

Vigon International, LLC. declares that the product listed above is not derived from or produced using genetically modified organisms or their derivatives.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com

Date of Issue: August 31, 2023



# Ingredient Statement

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

**CAS #: 54440-17-4      2,3,3-trimethyl-2H-inden-1-one      100%**

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023



# Nutritional Statement

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

Vigon International, LLC. certifies that, to the best of our knowledge, the product listed above does not contribute to the nutritional value of flavors due to their extremely low usage levels and therefore falls under the nutritional labeling exemption defined in Section 101.9(a) and (j) of Title 21 of the Code of Federal Regulations.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023



# Irradiation and Sewage Sludge Statement

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

Vigon International, LLC. declares that the product listed above has **not** been:

- a) Exposed to Ionizing Radiation
- b) Derived from Sewage Sludge
- c) Treated with Ethyl Oxide

Vigon International, LLC. may terminate this statement at any time upon written notice in which this statement shall be null and void as to any material supplied after termination of the statement.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023



# Heavy Metals and Pesticide Statement

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

Vigon International, LLC. declares that, to the best of our knowledge and belief, all ingredients in the product listed above are listed as being generally recognized as safe (GRAS) by the Food and Drug administration (FDA) when used in accordance with the FDA's good manufacturing practices (GMP) and contain no residues of heavy metals and pesticides in excess of tolerances set by the FDA and the Environmental Protection Agency (EPA).

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com

Date of Issue: August 31, 2023

# Stabilizer Statement

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

Vigon International, LLC. declares that, to the best of our knowledge that the product listed above has not been treated with BHT, BHA, Tocopherols or any other stabilizer.

Vigon International, LLC. may terminate this statement at any time upon written notice in which this statement shall be null and void as to any material supplied after termination of the statement.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023



# Continuing Product Guarantee

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, Vigon International, LLC. hereby provides continuing guarantee for the item listed above.

The article(s) comprising each shipment or other delivery hereafter made by Vigon International, LLC. is hereby guaranteed, as of the date of shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

The guarantee herein given shall be a continuing guarantee and shall remain in full force and effect until revoked in writing by the undersigned. This guarantee shall not limit or preclude the operation and effect of any and all provisions of any agreement(s) under which the articles covered by this guarantee are sold, and the provisions of such agreement(s) shall govern in the event of any conflict or inconsistency herewith. Supplier's liability for breach of this guarantee shall in no event exceed the value of such of the articles of the supplier shipped to or on the order of Purchaser hereunder as may fail to comply with this guarantee.

This guarantee shall be void and of no effect in any instance where the particular use by Purchaser of any article to which this guarantee would otherwise apply is a use which is not in accordance with the requirements of the Federal Food, Drug and Cosmetic Act. Any and all prior guarantees and/or indemnity agreements heretofore given by supplier, are hereby revoked.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023

# Dietary Preferences & Restrictions



**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

Vigon International, LLC. certifies that the product listed above is suitable for consumption by:

<b>Vegans</b> Do not eat meat, poultry, fish/seafood, eggs, dairy products, honey	
<b>Lacto-Vegetarians</b> Do not eat meat, poultry, fish/seafood, eggs, but do eat dairy products	
<b>Ovo-Vegetarians</b> Do not eat meat, poultry, fish/seafood, dairy products, but do eat eggs	
<b>Vegetarians</b> Do not eat meat, poultry, fish/seafood, but do eat dairy products and eggs	

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com

Date of Issue: August 31, 2023



# Animal Testing Statement

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

Vigon International, LLC. is not in the practice of performing or commissioning animal testing on its finished products and actively evaluates the ingredients of its products through non-animal testing methods and through computational (predictive) toxicology programs.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023



## Proposition 65 Statement

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

Vigon International, LLC. certifies that the product above is **not listed** on the California's Safe Drinking Water and Toxic Enforcement Act of 1986, also known as Proposition 65.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023



# Nanomaterials

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

We hereby confirm, to the best of our knowledge, that the above referenced product has not been formulated with engineered nanomaterials.

"Engineered nanomaterial" means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100nm but retain properties that are characteristic of the nanoscale.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023

# Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE) Statement



**Product Name:** SAFRALEINE®

**Vigon Code:** 503031

Vigon International, LLC. products are manufactured wholly from synthetic, natural or manufactured materials and do not contain any raw materials produced from or substances derived of animal origin. Moreover, these products do not contain, and are not derived from, specified risk material as defined in Commission Decision 97/534/EC or mechanically recovered meat obtained from the vertebral column of bovine, ovine or caprine animals.

The manufacturing process does not use any ingredient of animal origin nor do our products come in contact with animal products during storage and transportation.

We further declare that our products are Dioxin Free.

Therefore, to the best of our knowledge the product listed above are free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE).

Vigon International, LLC. may terminate this statement at any time upon written notice, in which this statement shall be null and void as to any material supplied after termination of the statement.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com

Date of Issue: August 31, 2023

## IFRA

**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

- Is not restricted as such according to the Standards of the International Fragrance Association (IFRA) (up to and including the 51th amendment)
- Bears no IFRA specifications

The IFRA Standards regarding use restriction are based on safety assessments by the Panel of Experts of the Research Institute for Fragrance Materials (RIFM) and are enforced by the IFRA Scientific Committee.

It is the ultimate responsibility of our customer to ensure the safety of the final product by further testing if need be.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023

# International Inventories



**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances and Control Act (TSCA) Inventory	Yes

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023

# Residual Solvents

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

Based on our knowledge of our production process, raw materials and equipments used we do not expect residual solvents to be present.

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023

# EU Fragrance Allergen Statement

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

The product listed above contains the following substances listed in European Directive 76/768/EEC established by the SCCNFP declared allergens.

**Benzyl alcohol (CAS 100-51-6) 0.007%**

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023

# Melamine Statement

**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

**Based on our knowledge of our production process, raw materials and equipment used we do not expect melamine to be present.**

Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023

# Phthalate Statement

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**Product Name: SAFRALEINE®**

**Vigon Code: 503031**

**We've performed a risk assessment on our product contact plastics which include tubes, joints, caps, pumps, as well as packaging (e.g. plastic wraps and bags) and can confirm that our plastic products do not contain certain phthalate esters (most notably bis-2-Ethylhexyl phthalate[DEHP] and dibutyl phthalate [DBP]).**




Sincerely,

Vigon Regulatory Department  
regulatory@vigon.com  
Date of Issue: August 31, 2023



# SAFRALEINE®

**Code: 503031 ID #: EXAMPLE**

	KG	LB
Approx. Gross: 	0.000	0.000
Approx. Tare: 	0.000	0.000
<b>Net:</b> 	<b>0.000</b>	<b>0.000</b>

Country of Origin: CHINA  
 Chemical Name: 2,3,3-trimethyl-2H-inden-1-one  
 CAS#: 54440-17-4  
 Flash Point: > 200°F (93°C)  
 Allergens: NONE  
 Liters: 0.000

Produced on: N/A  
 Best used before: N/A  
 Lot #: **EXAMPLE**

**STORAGE CONDITIONS:** Stable when stored in its original package, tightly sealed in a cool (46-90°F) and dry location out of direct heat and light.

**INSTRUCTIONS FOR USE:** Ask your employer for guidance regarding the safe use and handling of this product in your specific workplace environment based on the information provided in Vigon's Safety Data Sheet (SDS).

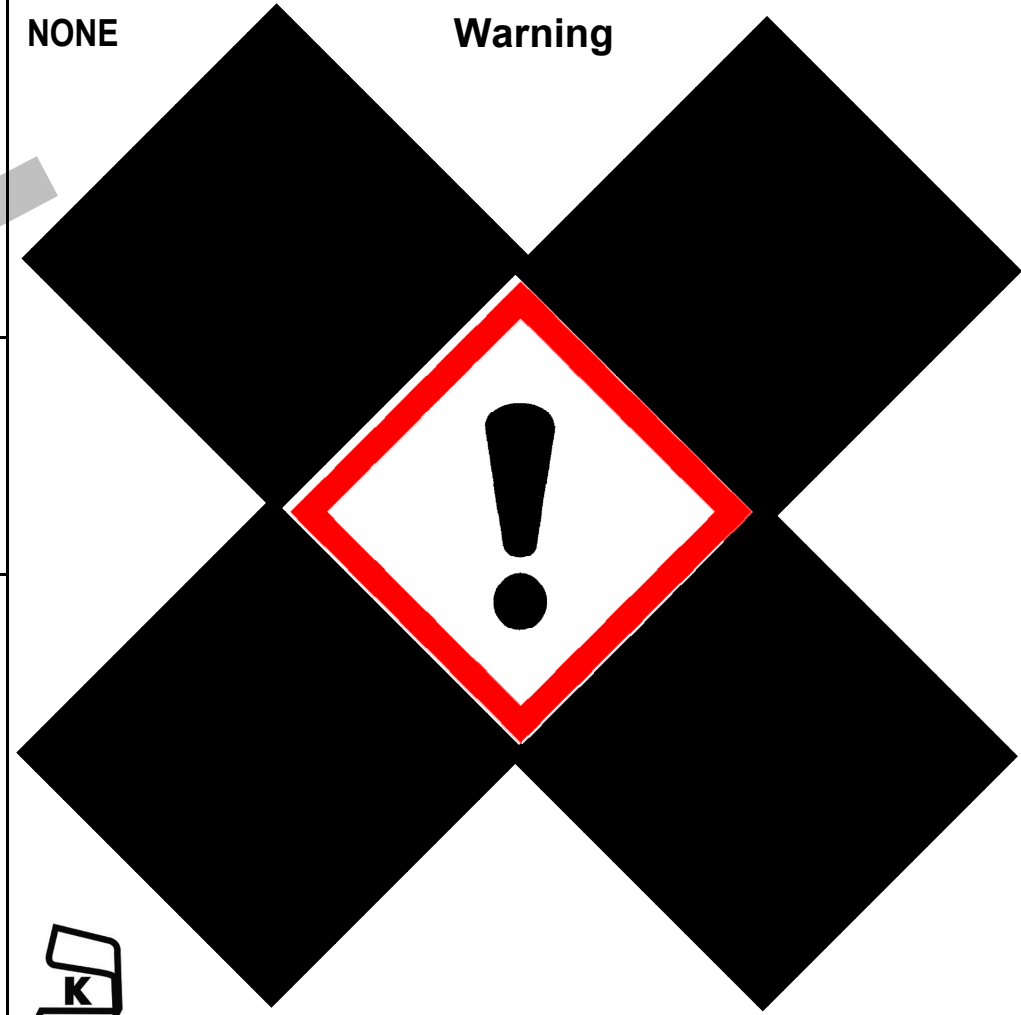
**HAZARD STATEMENT:** May be harmful if swallowed or in contact with skin. Causes skin irritation. Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

**PRECAUTIONARY STATEMENT:** -PREVENTION- Wash thoroughly after handling. Avoid release to the environment. Wear protective gloves. -RESPONSE- IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/doctor if you feel unwell. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. -STORAGE- Store away from incompatible materials. -DISPOSAL- Dispose of contents/container in accordance with local/regional/national/international regulations.



NONE

Warning



PPE: B