Product Specification

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

CAS Number: MIXTURE

FEMA Number: N/A

Characteristic:	Specification:	
Purity %	0.50	1.10
Gas Chromatograph	PASSES TEST	
Odor	CHARACTERISTIC ODOR.	
Refractive Index (@20c)	1.4315	1.4355
Specific Gravity (@25c)	1.0350	1.0390
Color/appearance	COLORLESS TO PALE YELLOW LIQUID.	

Additional Product Information:

Flash Point: >200 °F

Shelf Life: 12 Months

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

Effective Date: August 21, 2017

Printed Date: February 29, 2024

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

504023 SOTOLONE NATURAL 1% IN PG

1. IDENTIFICATION

Product Description: **SOTOLONE NATURAL 1% IN PG**

CAS # MIXTURE

Other means of identification

Vigon Item # 504023

Recommended use Concentrated aromatic and flavor ingredient which may be used in flavor and fragrance compounds according to legal and IFRA or FEMA GRAS/FDA 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.

2. HAZARD(S) IDENTIFICATION

Physical hazards Not classified.

Health hazards Skin corrosion/irritation Category 2

Serious eye damage/eye irritation Category 2A

Environmental hazards Not classified.

Label elements

Signal word Warning

Hazard statement

H315 Causes skin irritation.
H315 + H320 Causes skin and eye irritation.
H319 Causes serious eye irritation.

Precautionary statement

Prevention

P264 Wash thoroughly after handling.
P280 Wear protective gloves.
P280 Wear eye/face protection.

Response

P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313 If skin irritation occurs: Get medical advice/attention.

P337 + P313	If eye irritation persists: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures

Chemical name	Common name and synonyms	CAS number	%
PROPYLENE GLYCOL	Propan-1,2-diol 1,2 dihydroxypropane trimethyl glycol methyl ethylene glycol	57-55-6	90 - 100
Other components below reportable levels			1 - < 3

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	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain.
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.

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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Eliminate all sources of ignition. Avoid contact with skin or inhalation of spillage, dust or vapor. 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	Eliminate all ignition sources (no smoking, flares, sparks or flames in immediate area). Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb with inert absorbent such as dry clay, sand or diatomaceous earth, commercial sorbents, or recover using pumps. This product is miscible in water. 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. Prevent product from entering drains. Do not allow material to contaminate ground water system. 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. Never return spills in original containers for re-use. This material and its container must be disposed of as hazardous waste. Collect and dispose of spillage as indicated in section 13 of the SDS.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid release to the environment. Retain and dispose of contaminated wash water. Contact local authorities in case of spillage to drain/aquatic environment.

7. HANDLING AND STORAGE

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

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
PROPYLENE GLYCOL (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

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.

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 Not available.

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 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.

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	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Molecular formula	Not applicable
Specific gravity	1.04 at 25 °C

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	Causes skin irritation.
Eye contact	Causes serious eye irritation.
Ingestion	Expected to be a low ingestion hazard.
Symptoms related to the physical, chemical and toxicological characteristics	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
PROPYLENE GLYCOL (CAS 57-55-6)		
Acute		
Dermal		
LD50	Rabbit	20800 mg/kg

Components	Species	Test Results
Oral		
LD50	Rat	30 g/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye irritation.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

12. ECOLOGICAL INFORMATION

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test Results
PROPYLENE GLYCOL (CAS 57-55-6)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	710 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

PROPYLENE GLYCOL -0.92

Mobility in soil No data available.

Other adverse effects 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

Disposal instructions	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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	Not established.
Waste from residues / unused products	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).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

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.

15. REGULATORY INFORMATION

US federal regulations

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

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

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.

US state regulations

US - Minnesota Haz Subs: Hazardous substance

PROPYLENE GLYCOL (CAS 57-55-6) Hazardous substance.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

PROPYLENE GLYCOL (CAS 57-55-6)

US. Pennsylvania Worker and Community Right-to-Know Law

PROPYLENE GLYCOL (CAS 57-55-6)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes

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

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

Issue date 01-21-2016

Revision date 01-21-2016

Version # 01

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

Disclaimer Vigon 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, 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.

בס"ד

KOF-K
Kosher Supervision

Kosher Certificate

Date: February 28, 2024
י״ט בְּאֲדָר א׳ תשפ״ד
Kof-K ID: K-0000507
Certificate ID: P205T-PYU7D
Product Count: 1

This certificate is valid through

12/31/2024

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#
504023	SOTOLONE NATURAL 1% IN PG	Parve	Kof-K symbol required	KF1RWGRK8WT

Rabbi Avram Ossey
Rabbinic Administrator

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

iKosher

Disclaimer: This certificate is the private property of KOF-K Kosher Supervision and cannot be reposted without the express permission of KOF-K Kosher Supervision.

المجلس الإسلامي الأمريكي للغذاء و التغذية

THE ISLAMIC FOOD AND NUTRITION COUNCIL OF AMERICA

IFANCA HALAL PRODUCT CERTIFICATE شهادة حلال

This is to certify that the following product(s) have been produced under the supervision of the Islamic Food and Nutrition Council of America(IFANCA). The production facility as well as component ingredients have been reviewed and approved. The product(s) are in compliance with the halal requirements under Islamic laws.

Date: **November 21, 2023**

Document #: **6718.12506.II233606**

Company Name & Address: **Vigon International, LLC** 127 Airport Road East Stroudsburg, Pennsylvania 18301 USA

Plant Name & Address: **Vigon International, LLC** 127 Airport Road East Stroudsburg, Pennsylvania 18301 USA

	ProductName	Product Code	Halal-ID	Product Certificate #
1.	SOTOLONE NATURAL 1% IN PG	504023	A77850	HC-23VI6U01

Muhammad Munir Chaudry, Ph.D.
President

THE ISLAMIC FOOD AND NUTRITION COUNCIL OF AMERICA INCORPORATED ILLINOIS 1982

This Certificate is valid until **January 31, 2025** and subject to renewal at that time.

WORLD HALAL FOOD COUNCIL WHFC MEMBER

WWW.IFANCA.ORG • IFANCA Head Office • 2004 Miner Street • Des Plaines, Illinois 60016 USA • Tel: (847) 993-0034 • Fax: (847) 993-0038

Food Grade Certification

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

FEMA #: N/A

Vigon International, LLC. certifies that the above flavor or ingredient is Food Grade in accordance with at least one of the following recognized organizations:

FDA/FEMA GRAS	(Flavor and Extract Manufacturers Assoc. Generally Recognized as Safe)
JECFA	(Joint FAO/WHO Expert Committee on Food Additives)
CoE	(Council of Europe)
FLAVIS	(Assigned by EFSA – European Food Safety Authority)

As a US based company, we have included the FEMA Number on this certificate however, the remaining numbers can be provided upon request. We hereby certify that this flavor or ingredient is safe for its intended use in food.

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

Sincerely,

Vigon Regulatory Department
regulatory@vigon.com
Date of Issue: February 29, 2024

US - Natural Status Certificate

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

Vigon International, LLC. certifies that the product listed above is declared ***natural*** and ***meets*** the criteria of Naturalness as defined in Section 101.22 (a) (3) of Title 21 of the United States Code of Federal Regulations.

Vigon International, LLC. certifies that the product meets the following criteria:

- Does not contain any artificial flavors
- Is not adulterated or misbranded according to Food and Drug laws

Vigon International, LLC. 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: February 29, 2024

Allergen/Sensitive Agents Identification Sheet

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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

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

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: February 29, 2024

GMO Status Statement

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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: February 29, 2024

Nutritional Statement

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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: February 29, 2024

Irradiation and Sewage Sludge Statement

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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: February 29, 2024

Heavy Metals and Pesticide Statement

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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: February 29, 2024

Stabilizer Statement

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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: February 29, 2024

Continuing Product Guarantee

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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: February 29, 2024

Dietary Preferences & Restrictions

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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

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

Sincerely,

Vigon Regulatory Department
regulatory@vigon.com
Date of Issue: February 29, 2024

Animal Testing Statement

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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: February 29, 2024

EU Declaration

Vigon Code: 504023
Product Name: SOTOLONE NATURAL 1% IN PG

The product listed above is acceptable and/or approved for use in the European Union.
Below is the flavoring status based on European Regulation 2008/1334/EC.

	Flavouring Preparation
	Natural Flavouring Substance
	Flavouring Substance
	Thermal Process Flavouring
	Smoke Flavouring
	Flavour Precursor
✔	Other Flavouring
	Not Applicable: Contains no ingredients whose use is intended primarily for flavour.
	Not Permitted: Contains ingredient(s) which are not permitted in flavours in the EU.

Sincerely,

Vigon Regulatory Department
regulatory@vigon.com
Date of Issue: February 29, 2024

Nanomaterials

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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 producted 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: February 29, 2024

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

Product Name: **SOTOLONE NATURAL 1% IN PG**

Vigon Code: **504023**

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: February 29, 2024

International Inventories

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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 Chine (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
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: February 29, 2024

Residual Solvents

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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: February 29, 2024

EU Fragrance Allergen Statement

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

The product listed above is in compliance with the European Directive 76/768/EEC established by the SCCNFP declared allergens. This product is free of these fragrance allergens.

Sincerely,

Vigon Regulatory Department
regulatory@vigon.com
Date of Issue: February 29, 2024

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

Melamine Statement

Product Name: SOTOLONE NATURAL 1% IN PG

Vigon Code: 504023

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: February 29, 2024

Phthalate Statement

Product Name: **SOTOLONE NATURAL 1% IN PG**

Vigon Code: **504023**

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: February 29, 2024

VIGON
PASSION FOR SIMPLICITY
Vigon International, LLC.
127 Airport Road
East Stroudsburg, PA 18301-9629 USA
+1.570.476.6300 | sales@vigon.com

SOTOLONE NATURAL 1% IN PG

Code: 504023 **ID #: EXAMPLE**

	KG	LB
Approx. Gross:	0.000	0.000
Approx. Tare:	0.000	0.000
Net:	**0.000**	**0.000**

Country of Origin:	USA
Chemical Name:	
CAS#:	MIXTURE
Flash Point:	> 200ºF (93ºC)
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 (46-90ºF) 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: Causes skin irritation. Causes skin and eye irritation. Causes serious eye irritation.PRECAUTIONARY STATEMENT: -PREVENTION- Wash thoroughly after handling. Wear protective gloves. Wear eye/face protection.-RESPONSE- IF ON SKIN: Wash with plenty of water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If skin irritation occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.-STORAGE- Store away from incompatible materials.-DISPOSAL- Dispose of waste and residues in accordance with local authority requirements.

EXAMPLE