# Product Specification

**Product Name:** TETRADECALACTONE DELTA NATURAL

**Vigon Code:** 508012

**CAS Number:** 2721-22-4

**FEMA Number:** 3590

| Characteristic: | Specification: | |
|---|---|---|
| Acid Value | 0.000 | 5.000 |
| Purity % | 98.00 | 100.00 |
| Gas Chromatograph | PASSES TEST | |
| Odor | FRUITY ODOR. | |
| Refractive Index (@20c) | 1.4590 | 1.4650 |
| Specific Gravity (@25c) | 0.9310 | 0.9370 |
| Color/appearance | COLORLESS TO 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 (46-90ºF) and dry location out of direct heat and light.

**Effective Date:** October 12, 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

# 508012 TETRADECALACTONE DELTA NATURAL



## 1. IDENTIFICATION

**Product Description:** **TETRADECALACTONE DELTA NATURAL**

**CAS #** 2721-22-4

**FEMA Number** 3590

**Other means of identification**

**Vigon Item #** 508012

**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, LLC
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, LLC | |
| **Address** | 127 Airport Road<br>E. Stroudsburg, PA 18301<br>United States | |
| **Telephone** | For information call: | 570-476-6300 |
| **Website** | www.vigon.com | |
| **E-mail** | regulatory@vigon.com | |
| **Emergency phone number** | INFOTRAC<br>1-800-535-5053<br>1-352-323-3500 | (ACCT# 78928);<br>WITHIN THE U.S.A.<br>OUTSIDE THE U.S.A. |

## 2. HAZARD(S) IDENTIFICATION

**Physical hazards** Not classified.

**Health hazards** Not classified.

**Environmental hazards** Not classified.

**Label elements**

**Hazard symbol** None.

**Signal word** None.

**Hazard statement** The substance does not meet the criteria for classification.

**Precautionary statement**

**Prevention** Observe good industrial hygiene practices.

**Response** Wash hands after handling.

**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** | 100% of the substance consists of component(s) of unknown acute oral toxicity. 100% of the substance consists of component(s) of unknown acute dermal toxicity. 100% of the substance consists of component(s) of unknown acute inhalation toxicity. 100% of the substance consists of component(s) of unknown long-term hazards to the aquatic environment. |

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substances**

| Chemical name | Common name and synonyms | CAS number | % |
|---|---|---|---|
| TETRADECALACTONE DELTA | 2H-Pyran-2-one, tetrahydro-6-nonyl-<br>Tetrahydro-6-nonyl-2H-pyran-2-one | 2721-22-4 | 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** | Direct contact with eyes may cause temporary irritation. |
| **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.<br><br>Large Spills: Dike the spilled material, where this is possible. Collect and dispose of spillage as indicated in section 13 of the SDS.<br><br>Absorb in vermiculite, dry sand or earth and place into containers. Prevent product from entering drains.<br><br>Small Spills: Clean surface thoroughly to remove residual contamination. Wipe up with absorbent material (e.g. cloth, fleece).<br><br>Never return spills in original containers for re-use. This material and its container must be disposed of as hazardous waste. Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. |
| **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. 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. |

**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** | 266 °F (130 °C) at 7 hPa |
| **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** | |
| **Explosive limit - lower (%)** | Not available. |
| **Explosive limit - upper (%)** | Not available. |
| **Vapor pressure** | 0.0003 mm Hg at 25 °C |
| **Vapor pressure temp.** | 77 °F (25 °C) |
| **Vapor density** | 7.8 |
| **Relative density** | Not available. |
| **Solubility(ies)** | |
| **Solubility (water)** | Insoluble |
| **Partition coefficient (n-octanol/water)** | Not available. |
| **Auto-ignition temperature** | Not available. |
| **Decomposition temperature** | Not available. |
| **Viscosity** | Not available. |
| **Other information** | |
| **Density** | 0.93 g/cm3 estimated at 25 °C |

| | |
|---|---|
| **Explosive properties** | Not explosive. |
| **Flammability class** | Combustible IIIA estimated |
| **Molecular weight** | 226.36 g/mol |
| **Oxidizing properties** | Not oxidizing. |
| **Specific gravity** | 0.93 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 mild skin irritation. |
| **Eye contact** | Causes mild eye irritation. |
| **Ingestion** | Expected to be a low ingestion hazard. |
| **Symptoms related to the physical, chemical and toxicological characteristics** | Direct contact with eyes may cause temporary irritation. |

**Information on toxicological effects**

| | |
|---|---|
| **Acute toxicity** | Not known. |
| **Skin corrosion/irritation** | Prolonged skin contact may cause temporary irritation. |
| **Serious eye damage/eye irritation** | Direct contact with eyes may cause temporary 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**

**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** | 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. |
| **Persistence and degradability** | No data is available on the degradability of this substance. |
| **Bioaccumulative potential** | No data available. |
| **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** | 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.

## 15. REGULATORY INFORMATION

**US federal regulations**

**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<br>Serious eye damage or eye 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. |

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

| | |
|---|---|
| **Issue date** | 08-31-2017 |
| **Revision date** | 04-03-2023 |
| **Version #** | 03 |

**HMIS® ratings**

Health: 1
Flammability: 1
Physical hazard: 0

**List of abbreviations**

ACGIH: American Conference of Governmental Industrial Hygienists.
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS: Chemical Abstract Service.
IARC: International Agency for Research on Cancer.
IATA: International Air Transport Association.
IBC Code: International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk.
IMDG: International Maritime Dangerous Goods.
MARPOL: International Convention for the Prevention of Pollution from Ships.
RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.
STEL: Short term exposure limit.
TWA: Time Weighted Average.

**Disclaimer**

Vigon International, LLC 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.

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: U6IO8-3KQ94
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# |
|---|---|---|---|---|
| 508012 | Tetradecalacotone Delta Natural | Parve | Only Lot #62501A is certified by this certificate | KF4OH72G4XQ |

**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.II233954**

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. | Tetradecalactone Delta Natural | 508012 | C35116 | HC-23VIHW52 |

Muhammad Munir Chaudry, Ph.D.
President

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

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: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

**FEMA #: 3590**

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: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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

# Organic Statement

**Product Name: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

Vigon International, LLC. declares that the product listed above meets the requirements for nonagricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" [7 CFR 205.605(a)(9)].

All of the flavor constituents in the natural flavor product named above meet the FDA definition of a natural flavor.

No synthetic solvents were used.

This natural flavor product, including any solvents, carriers, preservatives or other processing aids used or contained therein, was produced and handled **without** the use of excluded (GMO) methods.

Ionizing radiation as described in 21 CFR 179.26 was **not** used in the processing of this natural flavor product.

This natural flavor product was **not** derived from products using sewage sludge in their agricultural production.

Sincerely,

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

# GMO Status Statement

**Product Name: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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

# Ingredient Statement

**Product Name: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

**CAS #: 2721-22-4** **100%**

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

# Nutritional Statement

**Product Name: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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:** **TETRADECALACTONE DELTA NATURAL**

**Vigon Code:** **508012**

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: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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

| | |
|---|---|
| **Vegans**<br>Do not eat meat, poultry, fish/seafood,eggs,dairy products, honey | ✔ |
| **Lacto-Vegetarians**<br>Do not eat meat, poultry, fish/seafood, eggs, but do eat dairy products | ✔ |
| **Ovo-Vegetarians**<br>Do not eat meat, poultry, fish/seafood, dairy products, but do eat eggs | ✔ |
| **Vegetarians**<br>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: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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

# Proposition 65 Statement

**Product Name: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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: February 29, 2024

# EU Declaration

**Vigon Code:** 508012
**Product Name:** TETRADECALACTONE DELTA NATURAL

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

Printed: **02/29/24**

## NATURAL FLAVOR PRODUCT QUESTIONNAIRE - NATIONAL ORGANIC PROGRAM USE

The **USDA National Organic Program (NOP)** allows the use of certain natural (non-synthetic) substances, including flavors, in products labeled as "Organic" or "Made with Organic…(specified ingredients or food groups)" providing they comply with provisions established in the USDA NOP (*7 CFR Part 205*).

The NOP defines **Non-synthetic** (natural) in 7 CFR 205.2: a substance that is derived from mineral, plant or animal matter and does not undergo a synthetic process as defined in section 6502 (21) of the Act (*7 U.S.C. 6502(21)*). Under the terms of the Act, **"synthetic"** means a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

**Non-synthetic Flavors authorized under the NOP, Section 205.605 (a)(9)** must be from non-synthetic sources only and must not be produced using synthetic solvents, carrier systems or any artificial preservative.
In addition, **Sections 205.105 (e)(f)** respectively prohibit so-called "excluded" methods (GMOs) and ionizing radiation from being used to produce or during the handling of any ingredients or products under the NOP.

**FDA Definition of Natural Flavors** *FDA 21 CFR Part 101.22(a)(3)* : "...**natural flavor** or **natural flavoring** means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include [*but not exclusively* ] the natural essences or extractives obtained from plants listed in §§182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in §172.510 of this chapter."

In order to approve the use of a natural flavor used in an "organic" or "made with" product, QAI requests the information below in order to determine compliance under the terms of the NOP. QAI may request additional information as needed.

**Identification of Natural Flavor Product (Name/code):** TETRADECALACTONE DELTA NATURAL/508012

**Supplier Name and Address:** Vigon International, LLC. 127 Airport Road East Stroudsburg, PA 18301 USA

**Type of flavor (select one or more as necessary):**

| | | | | | |
|---|---|---|---|---|---|
| ☐ | **Protein Hydrolysate** | ☐ | **Extracts** | ☐ | **Essential oil** |
| ☐ | **Compounded flavor** | ☐ | **Oleoresin** | ☐ | **Isolate** |
| ☐ | **Distillate** | ☐ | **Compounded WONF** | ☒ | **Other** |

**Natural Flavor Product**

**A. Flavor constituents**

1. Do all of the flavor constituents in the natural flavor product named above meet the FDA definition of a natural flavor (see above)?
   ☒ **Yes** ☐ **No**

2. **Natural flavors** authorized for use in NOP "organic" or "made with organic" products, in addition, must not be produced using **synthetic extraction solvents.** Extraction may only use natural, non-petroleum based solvents. Is/are the natural flavor constituent(s) made using NOP-suitable extraction solvents?*
   ☐ **Yes** ☐ **No** ☒ **N/A, no extraction solvents used**



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> Please list any solvent(s) used in the production of this Natural Flavor Product:
NONE

*Allowed natural extraction solvents include water, natural ethanol, super-critical carbon dioxide, authentic essential oil, and natural vegetable oils. No hydrocarbon solvents, or chlorinated, or halogenated solvents may be used. Propane, hexane, and freon are examples of solvents that are prohibited.

**B. Non-flavor constituents and other ingredients**

**Natural flavors** authorized for use in NOP "organic" or "made with organic" products must not contain any **synthetic carrier systems** or any **artificial preservatives,** including but not limited to, propylene glycol, polyglycerol esters of fatty acids, mono- and di-glycerides, benzoic acid, polysorbate 80.

> Please list any carrier system(s) used in this Natural Flavor Product or attach an Ingredient Statement:
_____ ☒ **N/A, no carrier system(s) used**

> Please list any preservative(s) used in this Natural Flavor Product or attach an Ingredient Statement:
_____ ☒ **N/A, no preservative(s) used**

**C. Genetically Modified Organism (GMO)** products may not be used at any stage in the process of making natural flavor products for NOP goods. **Excluded methods** (= GMO use) include a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include, but are not limited to, recombinant DNA technology (including gene deletion, gene doubling, introduction of a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology); therefore, GMO-plant extracts may not be used nor may natural flavors be the product of GMO-yeast fermentation.

> *This natural flavor product, including any solvents, carriers, preservatives or other processing aids used or contained therein, was produced and handled* ***without the use of*** *excluded (GMO) methods?*

☒ **Yes** ☐ **No**

**D. Ionizing Radiation** is prohibited for all uses involving food preservation, pest control and pathogen control in NOP products. Other radiation uses, including food inspection, are permitted providing such use meets applicable FDA regulations, which establish limitations applicable to all (organic and non-organic) food products.

> *Ionizing radiation as described in 21 CFR 179.26 was* ***not*** *used in the processing of this natural flavor product?*

☒ **Yes** ☐ **No**

***Please sign this questionnaire below***

Pursuant to 7CFR §205.605(a)(9) and §205.105(e)(f), I, on behalf of the supplier, hereby attest that the information provided in this form is accurate and truthful to the best of my knowledge.

**Company Name:** Vigon International LLC.

**Printed Name:** Amanda Moyer **Title:** Manager of Regulatory

**Signature:** Amanda Moyer **Date:** 02/29/24



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# Nanomaterials

**Product Name: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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:** **TETRADECALACTONE DELTA NATURAL**

**Vigon Code:** **508012**

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

# IFRA

**Product Name: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

- 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: February 29, 2024

# Botanical Species

**Product Name:** **TETRADECALACTONE DELTA NATURAL**

**Vigon Code:** **508012**

**Botanical Species:** **coconut**

**Part of plant used:** **Not specified**

**Country of origin for the plant:** **Not specified**

Sincerely,

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

# International Inventories

**Product Name: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|---|---|---|
| Australia | Australian Inventory of Chemical Substances (AICS) | Yes |
| Canada | Domestic Substances List (DSL) | Yes |
| 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) | Yes |
| 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: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

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: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

**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:** **TETRADECALACTONE DELTA NATURAL**

**Vigon Code:** **508012**

**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

# ISO 9235 Statement

**Product Name: TETRADECALACTONE DELTA NATURAL**

**Vigon Code: 508012**

**The product listed above is natural according to ISO 9235 definition below:**

Natural Raw Material

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

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

# TETRADECALACTONE DELTA NATURAL

**Code: 508012** **ID #: EXAMPLE**

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

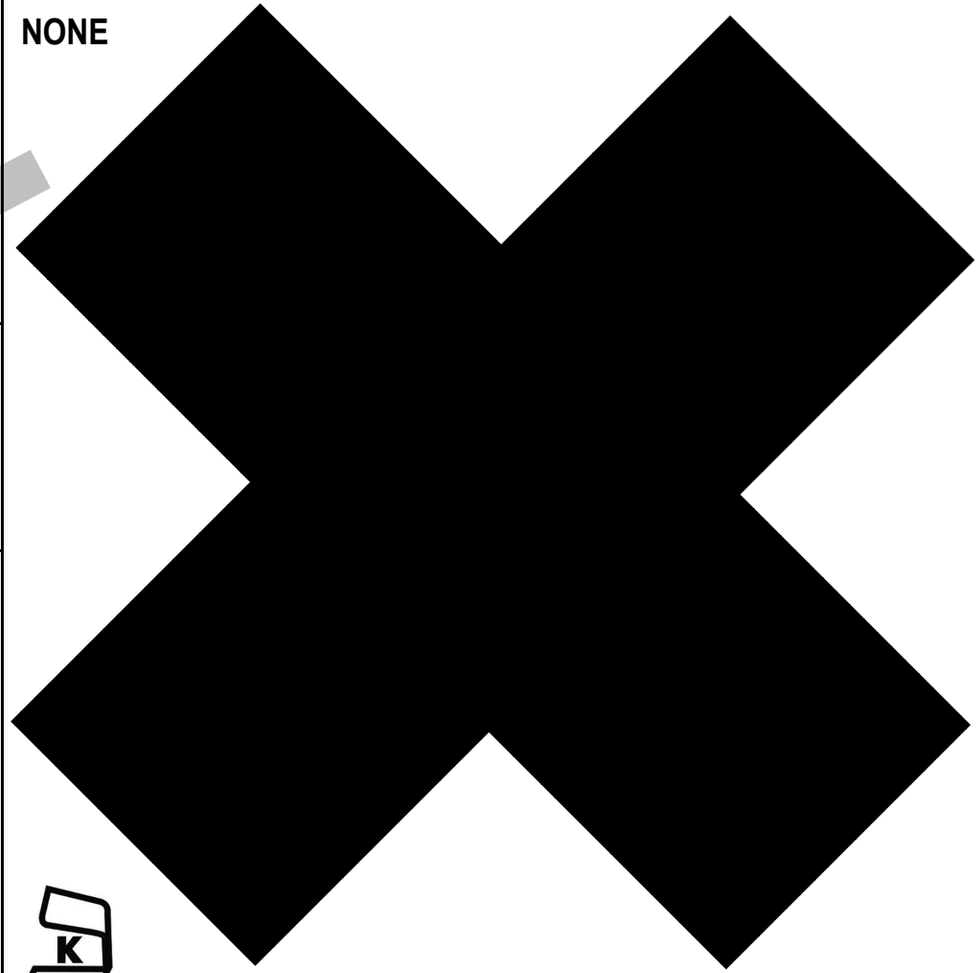
| | |
|---|---|
| Country of Origin: | CHINA |
| Chemical Name: | TETRADECALACTONE DELTA |
| CAS#: | 2721-22-4 |
| Flash Point: | > 200ºF (93ºC) |
| Allergens: | NONE |
| Liters: | 0.000 |
| Produced on: | N/A |
| Best used before: | N/A |
| **Lot #:** | **EXAMPLE** |

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: The substance does not meet the criteria for classification.PRE CAUTIONARY STATEMENT: -PREVENTION- Observe good industrial hygiene practices.-RESPONSE- Wash hands after handling.-STORAGE- Store away from incompatible materials.-DISPOSAL- Dispose of waste and residues in accordance with local authority requirements.

**NONE**



K
PARVE

**PPE: B**

EXAMPLE