



Product Specification

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

CAS Number: 8008-57-9

FEMA Number: 2825

Characteristic:

Odor

Refractive Index (@20c)

Specific Gravity (@25c)

Color/appearance

Specification:

CHARACTERISTIC ODOR.

1.4623 1.4723

0.8759 0.8870

PALE YELLOW TO YELLOW ORANGE LIQUID.

Additional Product Information:

Flash Point: 151 °F

Shelf Life: 24 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: July 16, 2024

Printed Date: July 18, 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

508712 ORANGE JUICE CARBONYLS

Revision Date: 05-01-2020

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Version # 02

Print Date: 05-01-2020

1. IDENTIFICATION

Product Description: ORANGE JUICE CARBONYLS
CAS # 8008-57-9
FEMA Number 2825
Other means of identification
Vigon Item # 508712
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.

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	regulatory@vigon.com	
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	Flammable liquids	Category 3
Health hazards	Skin corrosion/irritation	Category 2
	Sensitization, skin	Category 1
	Aspiration hazard	Category 1
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 2
	Hazardous to the aquatic environment, long-term hazard	Category 2

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Label elements



Signal word

Danger

Hazard statement

Combustible liquid. May be fatal if swallowed and enters airways. May cause an allergic skin reaction. Toxic to aquatic life. Toxic to aquatic life with long lasting effects.

Precautionary statement

Prevention

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.

Response

IF SWALLOWED: Immediately call a POISON CENTER/doctor. Do NOT induce vomiting. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. In case of fire: Use appropriate media to extinguish. Collect spillage.

Storage

Store in a well-ventilated place. Keep cool. Store locked up.

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 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substances

Chemical name	Common name and synonyms	CAS number	%
ORANGE JUICE CARBONYLS		8008-57-9	100
Composition comments	Other related CAS # 8028-48-6		

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

Aspiration may cause pulmonary edema and pneumonitis. Direct contact with eyes may cause temporary irritation. May cause an allergic skin reaction. Dermatitis. Rash.



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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.

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

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.
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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.
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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.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational exposure limits	This substance has no PEL, TLV, or other recommended exposure limit.
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Biological limit values	No biological exposure limits noted for the ingredient(s).
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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.
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Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles). Face shield is recommended.
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Skin protection

Hand protection	Chemical resistant gloves.
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Other	Use of an impervious apron is recommended.
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Respiratory protection	Respiratory protection not required. If ventilation is insufficient, suitable respiratory protection must be provided.
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Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
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General hygiene considerations	When using do not smoke. 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. Contaminated work clothing should not be allowed out of the workplace.
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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Refer to Spec Sheet
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Physical state	Liquid.
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Form	Liquid.
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Color	Refer to Spec Sheet
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Odor	Characteristic.
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Odor threshold	Not available.
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pH	Not available.
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Melting point/freezing point	Not available.
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Initial boiling point and boiling range	349 °F (176.11 °C)
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Flash point	151.0 °F (66.1 °C) Closed Cup
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Evaporation rate	Not available.
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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) Insoluble

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

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Density 0.84 g/cm³ estimated at 25 °C

Explosive properties Not explosive.

Flammability class Combustible II estimated

Molecular formula Not applicable

Oxidizing properties Not oxidizing.

Specific gravity 0.85 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 heat, sparks, open flames and other ignition sources. 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 Knowledge about health hazard is incomplete.

Skin contact Causes mild skin irritation. May cause an allergic skin reaction.

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Eye contact	Knowledge about health hazard is incomplete. Causes mild eye irritation.
Ingestion	Knowledge about health hazard is incomplete. Droplets of the product aspirated into the lungs through ingestion or vomiting may cause a serious chemical pneumonia.
Symptoms related to the physical, chemical and toxicological characteristics	Aspiration may cause pulmonary edema and pneumonitis. May cause an allergic skin reaction. Dermatitis. Rash.
Information on toxicological effects	
Acute toxicity	May be fatal if swallowed and enters airways.
Skin corrosion/irritation	Due to partial or complete lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to partial or complete lack of data the classification is not possible.
Respiratory or skin sensitization	
Respiratory sensitization	Due to partial or complete lack of data the classification is not possible.
Skin sensitization	May cause an allergic skin reaction.
Germ cell mutagenicity	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	Knowledge about health hazard is incomplete.
Specific target organ toxicity - repeated exposure	Due to partial or complete lack of data the classification is not possible.
Aspiration hazard	May be fatal if swallowed and enters airways.

12. ECOLOGICAL INFORMATION

Ecotoxicity	Toxic to aquatic life with long lasting effects.
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.
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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

UN number	3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ORANGE OIL CONCENTRATED)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packing group	III
Environmental hazards	No
Labels required	9

ADR

UN number	3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ORANGE OIL CONCENTRATED)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packing group	III
Environmental hazards	No
Labels required	9

RID

UN number	3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ORANGE OIL CONCENTRATED)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packing Group	III
Environmental Hazards	No
Labels required	9
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

DOT

BULK

UN number	3082
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ORANGE OIL CONCENTRATED)
Hazard class	9
Packing group	III
Environmental hazards	
Marine pollutant	Yes

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Packaging exceptions	155
Packaging bulk	241
Labels required	9

DOT

NON-BULK

Not regulated as dangerous goods.

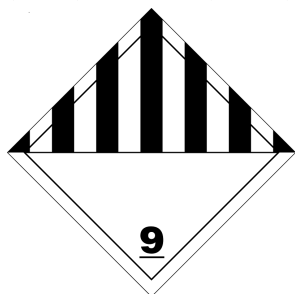
IATA

Not regulated as dangerous goods.

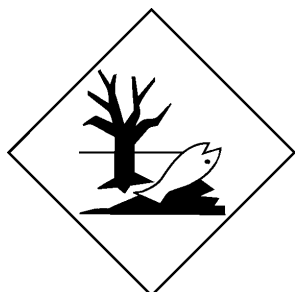
IMDG

UN number	3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ORANGE OIL CONCENTRATED)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
Labels required	9
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

ADN; ADR; DOT BULK; IMDG; RID



Marine pollutant



15. REGULATORY INFORMATION

US federal regulations

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



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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 Flammable (gases, aerosols, liquids, or solids)
Respiratory or skin sensitization
Aspiration hazard

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 10-05-2018
Revision date 05-01-2020
Version # 02
HMIS® ratings Health: 2*
Flammability: 2
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.



Date: May 1, 2024 | כ"ג בנִסָן תשפ"ד
Kof-K ID: K-0000507 | Certificate ID: YLMNC-K4LWC
Product Count: 1

Kosher Certificate

Vigon International, LLC

127 AIRPORT RD., EAST STROUDSBURG, PA 18301 UNITED STATES

This certificate is
valid through

12/31/2024

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

Code	Name	Status	Restriction	UKD#
508712	ORANGE JUICE CARBONYLS	Parve	Kof-K symbol required 	KF4MGVF15SI



Rabbi Avram Ossey

Rabbinic Administrator

To verify or for the most up to date certificate please visit www.koshercertificate.com

201 The Plaza, Teaneck, NJ 07666 | Phone 201.837.0500

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.



Food Grade Certification

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

FEMA #: 2825

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: July 18, 2024



US - Natural Status Certificate

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024



Allergen/Sensitive Agents Identification Sheet

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

* 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, basil 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: July 18, 2024



Organic Statement

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024



GMO Status Statement

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024

Ingredient Statement



Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

CAS #: 8008-57-9

100%

Sincerely,

Vigon Regulatory Department
regulatory@vigon.com
Date of Issue: July 18, 2024



Irradiation and Sewage Sludge Statement

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024



Heavy Metals and Pesticide Statement

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024



Stabilizer Statement

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024



Continuing Product Guarantee

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024



Dietary Preferences & Restrictions

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024



Animal Testing Statement

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024

EU Declaration



Vigon Code: 508712

Product Name: ORANGE JUICE CARBONYLS

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: July 18, 2024



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): ORANGE JUICE CARBONYLS/508712

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

- 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**
- 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**



> 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:** 07/18/24

Nanomaterials



Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024

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



Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024

International Inventories

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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 China (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: July 18, 2024

Residual Solvents



Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024



Melamine Statement

Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024

Phthalate Statement



Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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: July 18, 2024

ISO 9235 Statement



Product Name: ORANGE JUICE CARBONYLS

Vigon Code: 508712

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

Cold-pressed Essential Oil

Sincerely,

Vigon Regulatory Department

regulatory@vigon.com

Date of Issue: July 18, 2024