# **Product Specification**



Product Name: MACROLIDE® SUPRA

Vigon Code: 502516

CAS Number: 106-02-5

FEMA Number: 2840

### Characteristic:

Acid Value Purity % Gas Chromatograph Odor Color/appearance Specification:0.0001.00098.50100.00PASSES TESTCHARACTERISTIC ODOR.WHITISH TO WHITE CRYSTALS OR COLORLESS SOLID.

### Additional Product Information:

Flash Point: >200 °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: March 30, 2005

Printed Date: May 17, 2017



# 502516 MACROLIDE® SUPRA

Revision Date: 03-31-2015 Version # 02 Page 1 of 11 Print Date: 11-29-2015

### 1. IDENTIFICATION

Product Description:	MACROLIDE® SUPRA	
CAS #	106-02-5	
FEMA Number	2840	
Other means of identification Vigon Item #	502516	
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	
<u>Company</u>	24 Hour Emergency Response Information	
Vigon International, Inc.	INFOTRAC (ACCT# 78928);	
127 Airport Road	1-800-535-5053 WITHIN THE U.S.A.	
E. Stroudsburg, PA 18301	1-352-323-3500 OUTSIDE THE U.S.A.	
For information call: 570-476-6300		
Web Site: www.vigon.com		

### 2. HAZARD(S) IDENTIFICATION

Physical hazards	Not classified.	
Health hazards	Skin corrosion/irritation	Category 3
	Sensitization, skin	Category 1
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 1
	Hazardous to the aquatic environment, long-term hazard	Category 1

Label elements



Warning

#### Hazard statement

Signal word

riazaru statement	
H316	Causes mild skin irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statement	
Prevention	
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves.



# 502516 MACROLIDE® SUPRA

Revision Date: 03-31-2015	Page 2 of 11
Version # 02	Print Date: 11-29-2015

Response	
P302 + P352	IF ON SKIN: Wash with plenty of water.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.
Storage	Store away from incompatible materials.
Disposal	
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

#### Substances

Chemical name	Common name and synonyms	CAS number	%
16- oxacyclohexadecan-1-one	PENTADECALACTONE	106-02-5	100
	Oxacyclohexadecan-2-one		
	Pentadecan-15-olide		
	OMEGA-PENTADECALACTONE		

#### **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	Mild skin irritation. May cause an allergic skin reaction. Dermatitis. Rash.
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.



## 502516 MACROLIDE® SUPRA

Revision Date: 03-31-2015	Page 3 of 11
Version # 02	Print Date: 11-29-2015
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	EMEASURES
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.
	The product is immiscible with water and will spread on the water surface.
	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. 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.



## 502516 MACROLIDE® SUPRA

Revision Date: 03-31-2015 Version # 02 Page 4 of 11 Print Date: 11-29-2015

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational exposure limits	No exposure limits noted for ingredient(s).	
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, su Eye/face protection	<b>ch as personal protective equipment</b> Wear safety glasses with side shields (or goggles). Face shield is recommended.	
Skin protection Hand protection	Chemical resistant gloves.	
Other	Use of an impervious apron is recommended.	
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. Contaminated work clothing should not be allowed out of the workplace.	

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Refer to Spec Sheet
Physical state	Solid.
Form	Solid.
Color	Refer to Spec Sheet
Odor	Characteristic.
Odor threshold	Not available.
рН	Not available.
Melting point/freezing point	93.2 - 100.4 °F (34 - 38 °C)
Initial boiling point and boiling range	278.6 °F (137 °C) at 2 mmHg
Flash point	> 200.0 °F (> 93.3 °C) Closed Cup
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
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	1 mm Hg at 20 °C
Vapor density	8.3



# 502516 MACROLIDE® SUPRA

Revision Date: 03-31-2015 Version # 02 Page 5 of 11 Print Date: 11-29-2015

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	
Flammability class	Combustible IIIB estimated
Molecular formula	C15H28O2
Molecular weight	240.39 g/mol

### **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 ex	(posure		
Inhalation	No adverse effects due to inhalation are expected.		
Skin contact	Causes mild skin irritation. May cause an allergic skin reaction.		
Eye contact	Direct contact with eyes may cause temporary irritation. Causes mild eye irritation.		
Ingestion	Expected to be a low ingestion hazard.		
Symptoms related to the physical, chemical and toxicological characteristics	Mild skin irritation. Not available. May cause an allergic skin reaction. Dermatitis. Rash.		
Information on toxicological effe	cts		
Acute toxicity	May cause an allergic skin reacti	on.	
Product	Species	Test Results	
16- oxacyclohexadecan-1-one (	CAS 106-02-5)		
Acute			
Dermal			

LD50



# 502516 MACROLIDE® SUPRA

Revision Date: 03-31-2015 Version # 02 Page 6 of 11 Print Date: 11-29-2015

Product	Species	Test Results
Oral		
LD50	Rat	> 5000 mg/kg
* Estimates for product may	be based on additional component	data not shown.
Skin corrosion/irritation	Causes mild skin irritation. Irritation (dermal, rabbit)(LD50 study): slight irritant @ 100% Irritation (dermal, mouse)(photoxicity study): Non irritant @ 100% Irritation (dermal, pig)(phototoxicity study): Non irritant @ 100% Irritation (dermal)(Human max.): Non irritant @ 4% Irritation (dermal, human)(single patch): Non irritant @ 10%	
Serious eye damage/eye irritation	Direct contact with eyes may can Irritation (ocular, rabbit) (OECD 4	
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	May cause an allergic skin react Sensitization (HRIPT): Non sens Sensitization (Human max.): Not	itizing @ 2%
	Photo-toxicity (rabbit): Effects@ Photo-toxicity (guinea pig): Effect Photo-toxicity (guinea pig): No e Photo-toxicity (mouse): No effect Photo-toxicity (pig): No effects @	ts @ 50%, no effects @ 10% ffects @ 20% ts @ 100%
Germ cell mutagenicity	Mutagenicity (OECD 471): Non r Genotoxicity (micronucleus test)	
Carcinogenicity		
OSHA Specifically Regulate Not listed.	d Substances (29 CFR 1910.1001-1	050)
Reproductive toxicity	This product is not expected to c	ause 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 INFORI	MATION	
Ecotoxicity	Very toxic to aquatic life with lon	g lasting effects.
Product	Species	Test Results

#### Aquatic

Crustacea

EC50



# 502516 MACROLIDE® SUPRA

 Revision Date: 03-31-2015
 Page 7 of 11

 Version # 02
 Print Date: 11-29-2015

Product	Species	Test Results		
Fish	LC50 Fish	> 0.11 mg/l, 96 hours		
* Estimates for product may	be based on additional component data r	ot shown.		
Persistence and degradability	Readily biodegradability (OECD 301 F): readily biodegradable Readily biodegradability (OECD 301 D): readily biodegradable Readily biodegradability (OECD 301 B): readily biodegradable			
Bioaccumulative potential	No data available.	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 CONSIDE	RATIONS			
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 applica	ble 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		an approved waste handling site for recycling or disposal. product residue, follow label warnings even after container is		

ADN	
UN number	3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (16- oxacyclohexadecan-1-one)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packing group	III
Environmental hazards	Yes
Labels required	9
<b>D</b> R	
UN number	3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (16- oxacyclohexadecan-1-one)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packing group	III
Environmental hazards	Yes
Labels required	9



# 502516 MACROLIDE® SUPRA

Revision Date: 03-31-2015 Version # 02 Page 8 of 11 Print Date: 11-29-2015

### RID

UN number UN proper shipping name	3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (16- oxacyclohexadecan-1-one)
Transport hazard class(es) Subsidiary class(es)	9 -
Packing group	
Environmental hazards	Yes
Labels required	9
DOT	
BULK	
UN number	3077
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (16- oxacyclohexadecan-1-one)
Hazard class	9
Packing group	III
Environmental hazards	
Marine pollutant	Yes
Packaging exceptions	155
Packaging bulk	240
Labels required	9
DOT	
NON-BULK	
Not regulated as dangerous g	oods.
IATA	
Not regulated as dangerous g	oods.
IMDG	
UN number	3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (16- oxacyclohexadecan-1-one)
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.



# 502516 MACROLIDE® SUPRA

Revision Date: 03-31-2015 Version # 02 Page 9 of 11 Print Date: 11-29-2015

#### ADN; ADR; DOT BULK; IMDG; RID





#### **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

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 No chemical



## 502516 MACROLIDE® SUPRA

Revision Date: 03-31-2015 Version # 02 Page 10 of 11 Print Date: 11-29-2015

Yes

SARA 313 (TRI reporting Not regulated.	g)	
Other federal regulations		
Clean Air Act (CAA) Sect	ion 112 Hazardous Air Pollutants (HAPs) List	
Not regulated.		
Clean Air Act (CAA) Sect	ion 112(r) Accidental Release Prevention (40 CFR 68.130)	
Not regulated.		
Safe Drinking Water Act (SDWA)	Not regulated.	
US state regulations		
US. Massachusetts RTK	- Substance List	
Not regulated.		
US. New Jersey Worker	and Community Right-to-Know Act	
Not listed.		
•	r and Community Right-to-Know Law	
Not listed. US. Rhode Island RTK		
Not regulated.		
US. California Propositio	- 65	
•	osition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance	
Not listed.		
International Inventories		
Country(s) or region Australia	Inventory name Australian Inventory of Chemical Substances (AICS)	On inventory (yes/no)* Yes
Canada	-	Yes
	Domestic Substances List (DSL)	
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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)	Yes
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

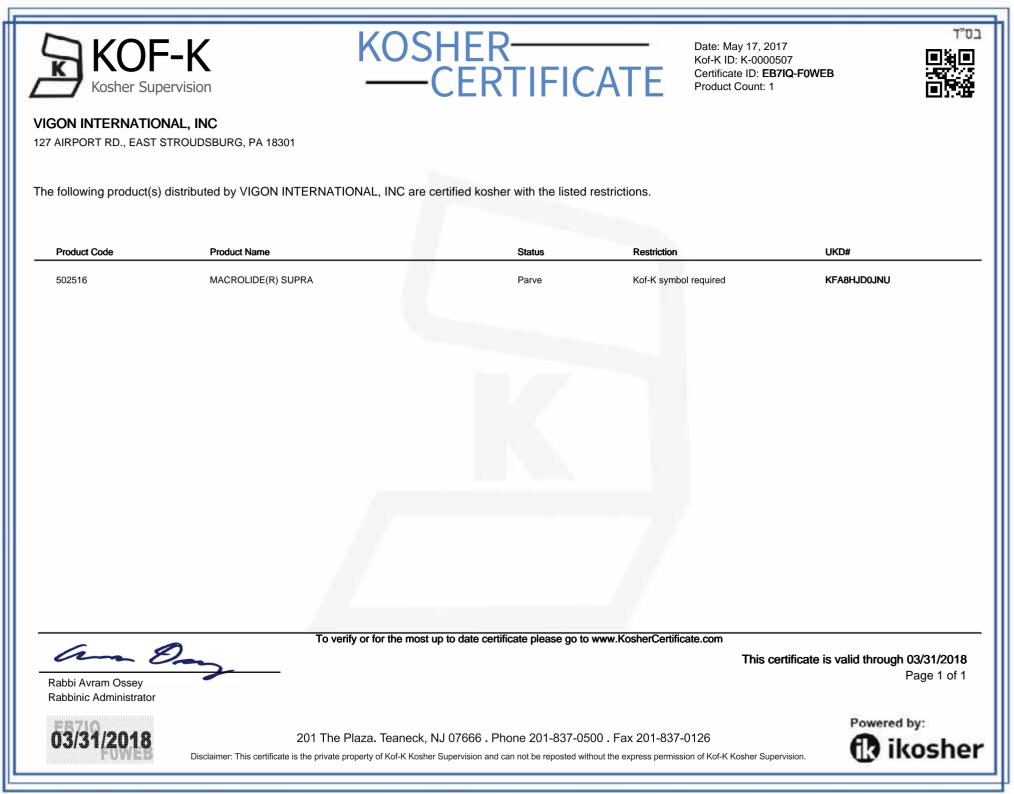
\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).



# 502516 MACROLIDE® SUPRA

Revision Date: 03-31-2015 Version # 02 Page 11 of 11 Print Date: 11-29-2015

16. OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION		
Issue date	11-29-2015	
Revision date	03-31-2015	
Version #	02	
HMIS® ratings	Health: 2 Flammability: 1 Physical hazard: 1	
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.	
Revision Information	This document has undergone significant changes and should be reviewed in its entirety.	





## شهادة حلال FANCA HALAL PRODUCT CERTIFICATE

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<sup>®</sup>). 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: December 09, 2016 Document #: 6718.12506.II165337





Vigon Code: 502516

FEMA #: 2840

Vigon International, Inc. certifies that the above flavor or ingredient is FDA/FEMA GRAS. We would like to assure you that we use only flavor ingredients that are listed as being generally recognized as safe (GRAS) on a reliable published industry association (FEMA) list and/or are approved for use in a regulation of the U.S. Food and Drug Administration. We hereby certify that this flavor or ingredient is safe for its intended use in food.

Vigon International, Inc. 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,

Amancia Moyer

Amanda Moyer Product Documentation Coordinator Date of Issue: May 17, 2017

#### Vigon International, Inc.



#### Vigon Code: 502516

\* 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.	
TREENUTS	
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, Inc. follows Good Manufacturing Practices and has implemented HACCP systems. Our personnel are trained on the proper handling of allergenic materials. Sincerely,

Amancia Moyer

Amanda Moyer Product Documentation Coordinator Date of Issue: May 17, 2017

#### Vigon International, Inc.

## **GMO Status Statement**



Product Name: MACROLIDE® SUPRA

Vigon Code: 502516

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

Sincerely,

Amancia Moyer

Amanda Moyer Product Documentation Coordinator Date of Issue: May 17, 2017



Product Name: MACROLIDE® SUPRA

Vigon Code: 502516

Vigon International, Inc. declares that the product listed above has <u>not</u> been:

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

Vigon International, Inc. 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,

Amancia Moyer

Amanda Moyer Product Documentation Coordinator Date of Issue: May 17, 2017



Vigon Code: 502516

Vigon International, Inc. 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,

Amancia Moyer

Amanda Moyer Product Documentation Coordinator Date of Issue: May 17, 2017



### Vigon Code: 502516

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

The article(s) comprising each shipment or other delivery hereafter made by Vigon International, Inc. 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,

Amancia Moyer

Amanda Moyer Product Documentation Coordinator Date of Issue: May 17, 2017



#### Vigon Code: 502516

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

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

Sincerely,

Amancia Moyer

Amanda Moyer Product Documentation Coordinator Date of Issue: May 17, 2017

#### Vigon International, Inc.

# **Animal Testing Statement**



Product Name: MACROLIDE<sup>®</sup> SUPRA

Vigon Code: 502516

Vigon International, Inc. 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. However, some ingredients used in our products have been subjected to animal testing by the academic community, government agencies, or within the chemical industry.

Sincerely,

Amancia Moyer

Amanda Moyer Product Documentation Coordinator Date of Issue: May 17, 2017



Product Name: MACROLIDE® SUPRA

Vigon Code: 502516

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

Sincerely,

Amancia Moyer

Amanda Moyer Product Documentation Coordinator Date of Issue: May 17, 2017