

Product Specification



Product Name: AMBROX DL®

Vigon Code: 502738

CAS Number: 3738-00-9

FEMA Number: 3471

Characteristic:

Specification:

Acid Value	0.000	1.000
Assay (sum Of Isomers)%	85.00	100.00
Gas Chromatograph	PASSES TEST	
Odor	AMBER, WOODY ODOR.	
Color/appearance	COLORLESS TO PALE YELLOW SOLID OR LIQUID.	

Additional Product Information:

Flash Point: >200 °F

Shelf Life: 18 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.
If product is congealed, heat gently, melt completely, and mix before use.
Prolonged heat can impact product quality.

Effective Date: May 23, 2022

Printed Date: August 31, 2023

Vigon International, LLC.

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

SAFETY DATA SHEET

502738 AMBROX DL®

Revision Date: 03-22-2018
Version # 03

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Print Date: 03-22-2018

1. IDENTIFICATION

Product Description: AMBROX DL®
CAS # 3738-00-9
FEMA Number 3471
Other means of identification
Vigon Item # 502738
Recommended use Concentrated aromatic ingredient which may be used fragrance compounds according to legal and IFRA guidelines.
Recommended restrictions For Manufacturing Use Only

Company

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

24 Hour Emergency Response Information

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

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

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

2. HAZARD(S) IDENTIFICATION

Physical hazards Not classified.
Health hazards Acute toxicity, dermal Category 5
Environmental hazards Hazardous to the aquatic environment, Category 1
acute hazard
Hazardous to the aquatic environment, Category 1
long-term hazard

Label elements



Signal word

Warning



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Hazard statement	May be harmful in contact with skin. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
Precautionary statement	
Prevention	Avoid release to the environment.
Response	Call a POISON CENTER/doctor if you feel unwell. Collect spillage.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	100% of the mixture consists of component(s) of unknown acute oral toxicity. 100% of the mixture consists of component(s) of unknown acute inhalation toxicity.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substances

Chemical name	Common name and synonyms	CAS number	%
1,5,5,9-TETRAMETHYL-13-OXATRICYCLO(8.3.0.0(4,9))TRIDECAHENE	Naphtho 2,1-b furan, dodecahydro-3a,6,6,9a- tetramethyl-DODECAHYDRO- 3A,6,6,9A-TETRAMETHYL NAPHTHO[2,1-B] FURAN N 3a,6,6,9a- tetramethyl-2,4,5,5a,7,8,9,9b- octahydro-1H-benzo[e][1] benzofuran	3738-00-9	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.



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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.

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. 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	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.
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.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Use explosion-proof ventilation equipment to stay below exposure limits. Adequate ventilation should be provided so that exposure limits are not exceeded.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Chemical resistant gloves.
Other	Not available.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection not required.
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	167 - 185 °F (75 - 85 °C)
Initial boiling point and boiling range	Not available.
Flash point	> 200.0 °F (> 93.3 °C) Closed Cup
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.1 mm Hg at 20 °C
Vapor density	8.2

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Relative density	Not available.
Solubility(ies)	
Solubility (water)	Insoluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	215.6 - 222.8 °F (102 - 106 °C) at 25 mmHg
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Flammability class	Combustible IIIB estimated
Molecular formula	C16H28O
Molecular weight	236.4 g/mol
Oxidizing properties	Not oxidizing.

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	May be harmful in contact with skin. 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 May be harmful in contact with skin.

Product	Species	Test Results
1,5,5,9-TETRAMETHYL-13-OXATRICYCLO(8.3.0.0(4,9))TRIDECANE (CAS 3738-00-9)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg OECD 402:limit

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Product	Species	Test Results
<i>Oral</i> LD50	Rat	6.65 ml/kg OECD 401
Skin corrosion/irritation	Irritation (dermal)(FHSA): Non irritant @ 100% Irritation (dermal)(HRIPT): Non irritant @ 5%	
Serious eye damage/eye irritation	Irritation (ocular)(FHSA): Irritant @100% Irritation (ocular)(FHSA):Non Irritant @ 50%	
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	Sensitization (HRIPT): non sensitizing @ 2% Sensitization (HRIPT): non sensitizing @ 10% Sensitization (OECD 406: Buehler): non sensitizing @ 10% Photosensitization (HRIPT): No effects @ 5%	
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 1910.1001-1052)	Not regulated.	
US. National Toxicology Program (NTP) Report on Carcinogens	Not listed.	
US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not available.	
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	Very toxic to aquatic life with long lasting effects. Readily biodegradability(OECD 301B mod.) IC=22%, TOC= 64% Long-term toxicity testing on Daphnia: study scientifically unjustified (Waiver) Long-term toxicity testing on fish: study scientifically unjustified (Waiver) Biotic degradation (ready test), OECD 301F: Readily biodegradable Adsorption/desorption screening study, OECD 121: log Koc = 3.72 Bioaccumulation in (one) aquatic species, preferably fish, OECD 305: BCF = 560
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Product	Species		Test Results
1,5,5,9-TETRAMETHYL-13-OXATRICYCLO(8.3.0.0(4,9))TRIDECANE (CAS 3738-00-9)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Algae	> 1.4 mg/l, 72 hours
	NOEC	Algae	> 1.4 mg/l
Crustacea	EC50	Daphnia	> 1.8 mg/l, 48 hours
Fish	LC50	Fish	> 0.51 mg/l, 96 hours
Other	EC50	Activated Sludge	> 100 mg/l, 3 hours
	NOEC	Activated Sludge	> 100 mg/l

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

UN number	3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,5,5,9-TETRAMETHYL-13-OXATRICYCLO(8.3.0.0(4,9))TRIDECANE)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packing group	III
Environmental hazards	Yes
Labels required	9

ADR

UN number	3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,5,5,9-TETRAMETHYL-13-OXATRICYCLO(8.3.0.0(4,9))TRIDECANE)

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Transport hazard class(es)	9
Subsidiary class(es)	-
Packing group	III
Environmental hazards	Yes
Labels required	9

RID

UN number	3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,5,5,9-TETRAMETHYL-13-OXATRICYCLO(8.3.0.0(4,9))TRIDECANE)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packing Group	III
Environmental Hazards	Yes
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. (1,5,5,9-TETRAMETHYL-13-OXATRICYCLO(8.3.0.0(4,9))TRIDECANE)
Hazard class	9
Packing group	III
Environmental hazards	
Marine pollutant	Yes
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. (1,5,5,9-TETRAMETHYL-13-OXATRICYCLO(8.3.0.0(4,9))TRIDECANE)
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.

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502738 AMBROX DL®

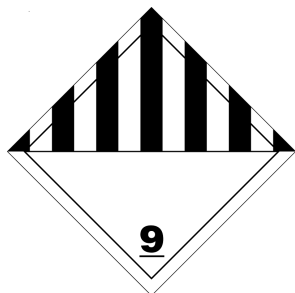
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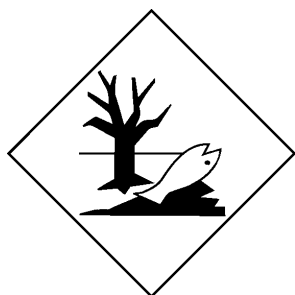
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ADN; ADR; DOT BULK; IMDG; RID



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.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

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

Not available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

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

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Acute toxicity (any route of exposure)

SARA 313 (TRI reporting)

Not regulated.



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Other federal regulations

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

Not regulated.

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

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

California Proposition 65

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

Not listed.

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

Issue date	12-30-2016
Revision date	03-22-2018
Version #	03
HMIS® ratings	Health: 1 Flammability: 1 Physical hazard: 0

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.

Food Grade Certification



Product Name: AMBROX DL®

Vigon Code: 502738

FEMA #: 3471

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

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

Sincerely,

Vigon Regulatory Department
regulatory@vigon.com

Date of Issue: August 31, 2023



Allergen/Sensitive Agents Identification Sheet

Product Name: AMBROX DL®

Vigon Code: 502738

* 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: August 31, 2023



GMO Status Statement

Product Name: AMBROX DL®

Vigon Code: 502738

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

Sincerely,

Vigon Regulatory Department
regulatory@vigon.com

Date of Issue: August 31, 2023



Ingredient Statement

Product Name: AMBROX DL®

Vigon Code: 502738

CAS #: 3738-00-9 3a,6,6,9a- tetramethyl-2,4,5,5a,7,8,9,9b-hydro-1H-benzo[e][1]benzofuran 100%

Sincerely,

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

Nutritional Statement



Product Name: AMBROX DL®

Vigon Code: 502738

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

Sincerely,

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



Irradiation and Sewage Sludge Statement

Product Name: AMBROX DL®

Vigon Code: 502738

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

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

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

Sincerely,

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



Heavy Metals and Pesticide Statement

Product Name: AMBROX DL®

Vigon Code: 502738

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

Sincerely,

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

Stabilizer Statement



Product Name: AMBROX DL®

Vigon Code: 502738

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

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

Sincerely,

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



Continuing Product Guarantee

Product Name: AMBROX DL®

Vigon Code: 502738

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

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

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

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

Sincerely,

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



Dietary Preferences & Restrictions

Product Name: AMBROX DL®

Vigon Code: 502738

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: August 31, 2023



Animal Testing Statement

Product Name: AMBROX DL®

Vigon Code: 502738

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

Sincerely,

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



Proposition 65 Statement

Product Name: AMBROX DL®

Vigon Code: 502738

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

Sincerely,

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

Nanomaterials



Product Name: AMBROX DL®

Vigon Code: 502738

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

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

Sincerely,

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

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



Product Name: AMBROX DL®

Vigon Code: 502738

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

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

We further declare that our products are Dioxin Free.

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

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

Sincerely,

Vigon Regulatory Department
regulatory@vigon.com

Date of Issue: August 31, 2023

IFRA

Product Name: AMBROX DL®

Vigon Code: 502738

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

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

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

Sincerely,

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

International Inventories



Product Name: AMBROX DL®

Vigon Code: 502738

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: August 31, 2023

Residual Solvents



Product Name: AMBROX DL®

Vigon Code: 502738

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

Sincerely,

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



EU Fragrance Allergen Statement

Product Name: AMBROX DL®

Vigon Code: 502738

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: August 31, 2023

Melamine Statement

Product Name: AMBROX DL®

Vigon Code: 502738

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

Sincerely,

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

Phthalate Statement



Product Name: AMBROX DL®

Vigon Code: 502738




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

Sincerely,

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

AMBROX DL®

Code: 502738 ID #: EXAMPLE

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

Country of Origin: SWITZERLAND
 Chemical Name: 1,5,5,9-TETRAMETHYL-13-OXATRICYCLO(8.3.0.0(4,9))TRIDECANE
 CAS#: 3738-00-9
 Flash Point: > 200°F (93°C)
 Allergens: NONE
 Liters: 0.000

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

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

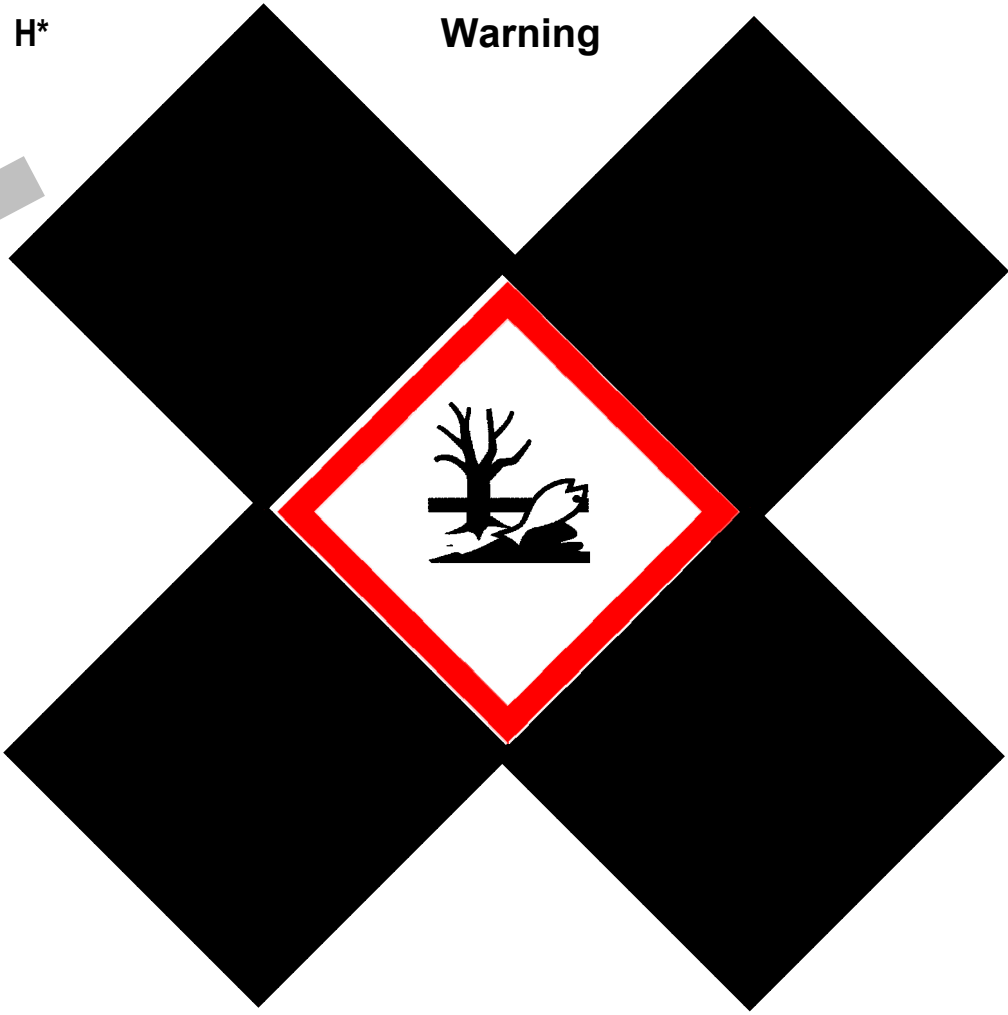
INSTRUCTIONS FOR USE: Ask your employer for guidance regarding the safe use and handling of this product in your specific workplace environment based on the information provided in Vigon's Safety Data Sheet (SDS).

HAZARD STATEMENT: May be harmful in contact with skin. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
PRECAUTIONARY STATEMENT:
 -PREVENTION- Avoid release to the environment.-RESPONSE- Call a POISON CENTER/doctor if you feel unwell. Collect spillage.-STORAGE- Store away from incompatible materials.-DISPOSAL- Dispose of contents/container in accordance with local/regional/national/international regulations.



H*

Warning



PPE: B