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MATERIAL SAFETY DATA SHEET

**According to Regulation (EC) No 1272 of 2008 and
Regulation (EC) No 1907/2006 (REACH), as amended by Regulation (EU) 2020/878**

Organic Clove Oil

Version 02

Date of creation: 23.10.2019

Supersedes the version from: 23.10.2019

Date of new version: 19.12.2023

1. Identification of the substance/mixture and the company/undertaking

1.1. Product Identifiers

Product name	:	Organic Clove Oil
Substance name (INCI)	:	EUGENIA CARYOPHYLLUS BUD OIL
REACH Registration No	:	-
CAS No	:	84961-50-2
EO No	:	284-638-7
ISO	:	ISO 3142:1997
Biological origin	:	Organic essential Clove oil is obtained by steam or water distillation from dried clove buds, <i>Syzygium aromaticum</i> , syn. <i>Eugenia caryophyllus</i> , <i>Myrtaceae</i> . Contains eugenol (82-87%, including approx. 15% eugenyl acetate), caryophyllene.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of substance/mixture	:	Used in perfumery and cosmetics by itself or as a formulation constituent, a part of composition.
Recommended restrictions on use	:	Avoid contact with eyes!
Reason not to recommend use	:	Causes serious eye irritation.

1.3. Details of the supplier of the safety data sheet

Manufacturer	:	ALTEYA ORGANICS LLC
Mailing address/Postal code	:	6167, village of Yagoda, 1, Rozovarna St.

Country identifier/



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Postal code/city or town : Bulgaria
Telephone/Mobile/Fax : +359 700 15 502

E-mail of the competent person responsible for the Safety Data Sheet : salesbg@alteya.com
National contact person : Kaloyan Stoev

1.4. Emergency telephone number

Clinic of Toxicology at MPHATEM N.I. Pirogov
Emergency telephone number: 02 9154409; (regular working time, Saturdays and Sundays excluded) or 02 9154 346 (24h service, all week)
e-mail: poison_centre@mail.orbitel.bg
<http://www.pirogov.net>

2. Hazards Identification

2.1. Classification of the substance or mixture

2.1.1. Classification according to Regulation (EC) No 1272/2008 (CLP)

Classification according GHS				
Chapter	Subsection	Class of hazard	Class of hazard and category of hazard	Hazard statements
3.2	Skin	Skin irritation	Corrosion/irritation	H315
3.3	Eye	Eye irritation	(Corrosion) Damage/Irritation. 2A	H319
3.4	Sens.	Skin sensitization	(Skin sens 1)	H317
3.10	Inh.	Inhalation hazard	(Asp Tox 1)	H304

2.1.2. Additional information:

For full text of hazard statements and EC specific hazard statements: see SECTION 16.

2.2. Label Elements

Designation according Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms



GHS07 GHS05

Signal word : Hazardous
Hazard statements : H304 May be fatal if swallowed and enters respiratory tract.
H315 Causes skin irritation
H317 May cause allergic skin reaction
H319 Causes serious eye irritation
EUH208 Contains: Eugenol, Isoeugenol, Beta-Caryophyllene, Eugenyl Acetate. May cause allergic reaction.

Safety recommendations

Safety recommendations

- General

P102 Keep out of reach of children



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Safety recommendations

- Prevention

P264 Wash exposed skin thoroughly after use.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Use protective gloves/protective clothing/protective goggles.

Safety recommendations

- As a reaction

P305+ P351+ If in the eyes: Rinse carefully with water for several minutes. Remove contact lenses if there are such and if possible. Continue rinsing.

P338 In case skin irritation or rash occurs: Seek medical advice/help.

P337+P313 If eye irritation persists: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

P301+P310 IF SWALLOWED: immediately call TOXICOLOGY CENTRE or a physician.

P331 DO NOT induce vomiting.

P302+P352 IF CONTACT WITH SKIN: Wash with plenty of soap and water.

Safety recommendations

- At disposal:

P501

Dispose of contents/container in an approved place and in compliance with the local and national regulations.

2.3. Other hazards

Special hazard of slipping if product leaks/spills.

Results of PBT and vPvB assessment

According to the assessment results, the substance is not PBT or vPvB.

3. Composition/information on ingredients

3.1. Substances/ Mixture

INGRIDIENT	IDENTIFIERS	%	CLASSIFICATION
EUGENIA CARYOPHYLLUS BUD OIL	EINECS NO: 284-638-7 CAS NO: 84961-50-2	100,0	  <i>DANGER</i> Asp. Tox. 1 H304 Skin Irrit. 2 – H315 Skin Sens. 1B H317 Eye Irrit. 2A H319
EUGENOL	EINECS NO: 202-589-1 CAS NO: 97-53-0	72,0 – 88,0	Acute Tox. 4 / H302 Eye Irrit. 2 / H319 Skin Sens. 1 / H317



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<i>EUGENYL ACETATE</i>	<i>EINECS NO: 202-235-6 CAS NO: 93-28-7</i>	<i>5,0 – 15,0</i>	<i>Acute Tox. 4 / H302 Skin Irrit. 2 – H315 Skin Sens. 1 / H317</i>
<i>BETA-CARYOPHYLLENE</i>	<i>EINECS NO: 201-746-1 CAS NO: 87-44-5</i>	<i>3,0 – 8,0</i>	<i>Skin Sens. 1 / H317 Asp. Tox. 1 / H304</i>
<i>ISOEUGENOL</i>	<i>EINECS NO: 202-590-7 CAS NO: 97-54-1</i>	<i>0,05 – 0,2</i>	<i>Acute Tox. 4 / H302 Skin Sens. 1A / H317</i>
<i>α-Humulene</i>	<i>EINECS NO: 229-816-7 CAS NO: 6753-98-6</i>	<i>< 1,0</i>	<i>Skin Irrit. 2 / H315 Eye Irrit. 2 / H319 STOT SE 3 / H335</i>

4. First Aid Measures

4.1. Description of first aid measures



- General notes : In case of unwellness, in all seek medical attention (show label if possible). Remove contaminated clothing.
- Following inhalation : Provide fresh air. In all cases of or in the presence of symptoms, seek medical attention.
- Following skin contact : Remove contaminated clothing. Flush skin with water/take a shower. In case of skin contact wash thoroughly with water immediately. In case of skin reactions, seek medical attention. In case of skin irritation, call a doctor.
- Following eye contact : Flush with plenty of clean, fresh water for at least 10 minutes, keeping eyelids open. In case of eye irritation, consult an ophthalmologist.
- Following ingestion : Call a doctor immediately. In case of vomiting, be aware of the risk of inhalation.

4.2. Most important symptoms and effects, both acute and delayed

Note : Hazard by inhalation, Irritation, Allergic reactions

4.3. Indication of any immediate medical attention and special treatment needed

Treatment : There is no specific antidote.
Treat symptomatically.



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5. Fire-fighting Measures

5.1. Extinguishing media



Suitable extinguishing media	:	Coordinate fire-fighting measures with the surrounding area water sparge, dry extinguishing powder, BC-powder, carbon dioxide (CO ₂).
Unsuitable extinguishing media	:	Water jet

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products	:	Combustible.
Specific hazards during fire-fighting	:	Carbon monoxide (CO), carbon dioxide (CO ₂). Burning may release poisonous gases containing carbon monoxide.

5.3. Advice for firefighters:

Special protective equipment for firefighters	:	Do not inhale smoke in case of fire and/or explosion. Extinguish the fire with the usual precautions from a reasonable distance. Wear a self-contained breathing apparatus.
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6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures



6.1.1. For personnel not responsible for emergencies

Personal precautionary measures, protective equipment and emergency procedures	:	Avoid contact of the product with the skin, eyes and clothing. Do not breathe vapor/aerosol.
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6.1.2. For the persons responsible for emergencies

Wear personal protective equipment. Provide adequate ventilation. No unauthorized persons allowed. Avoid sources of ignition.

6.2. Environmental precautions

Environmental precautions : Protect against contamination of drains, surface and ground water.

6.3. Methods and materials for containment and cleaning up

6.3.1. For containment : Cover drains. Contain with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in waste disposal drums.

6.3.2. For cleanup : Should be mechanically absorbed with a binding material (sand, diatomaceous earth, acid binder or universal) Collect in appropriate containers.

6.3.3. Other information : Wear protective clothing as described in Section 8 of this Material Safety Data Sheet. Place in appropriate containers for disposal. Ventilate the affected area.

6.4. Reference to other sections

Hazardous combustion products: see Section 5. Personal protective equipment: see Section 8. Incompatible materials: see Section 10. Waste disposal: see Section 13.

7. Handling and Storage

7.1. Precautions for safe handling

Precautions : Handle according to the regulations concerning good hygiene and safety.

Fire-fighting measures : Keep away from ignition sources. Do not smoke while using the product.

Measures to avoid transformation into aerosols and powder : Provide adequate ventilation of the operation area.

Environmental precautions : Avoid release in sewer systems and water sources. In case of release in water sources or sewer systems inform competent authorities.



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Advice on general occupational hygiene :

Wash your hands before breaks and at the end of the working day. Avoid eye and skin contact. Contaminated clothing and boots should be cleaned before reuse. Keep away from drinks and food for humans and animals.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions :

Store the container tightly closed.

Store the product in original container, tightly closed in a dry, well ventilated place, away from possible ignition sources and protected against light. Observe the guidelines for combined storage.

Packing materials :

Use packing materials preserving the integrity of the product.

Requirements to storage areas or containers :

Store in cold premises and in full containers.

Storage class :

No information

Recommendations for protection from fire and explosions :

Not known

Recommendations for primary storage :

Store in galvanized and steel containers under ordinary conditions, phenols react and sludge is formed, and the color becomes dark brown-purple.

General rules are recommended as per

БДС ISO 210:2023

7.3. Specific end use(s)

Recommendations :

No data available.

Solutions specific to the industry sector :

No data available.

Specific use(s) :

Used in perfumery and cosmetics by itself or as a formulation constituent, a part of composition.



Additional information:

Follow the regulation relative to the application:

- The cosmetics product regulations if advertised as cosmetics (for instance perfume, highly diluted essential oils for use on the body as massage oils or bath supplements).

8. Exposure controls/Personal protection equipment

8.1. Control parameters

Occupational exposure limits are determined on the basis of data base of international limit values GESTIS

Components	CAS-No.	Value type (Form of exposure)	Control parameters / permissible concentrations	Base
Isoeugenol	97-54-1	TWA	250 µg/m ³ (OEB 2)	Internal
	Additional information: DSEN			
		Wipe limit	100 µg/100 cm ²	Internal

Other occupational exposure limits

Information on monitoring procedures

Relevant DNEL - mixture components

*Eugenol 97-53-0 DNEL 21,2 mg/m³ human, inhalation industrial worker chronic - systemic effects
Eugenol 97-53-0 DNEL 6 mg/kg bw/day human, dermal industrial worker chronic - systemic effects*

Relevant PNEC- mixture components

Eugenol 97-53-0 PNEC 1,13 µg/l aquatic organisms freshwater short-term (instant)

Eugenol 97-53-0 PNEC 0,113 µg/l aquatic organisms marine short-term (instant)

Eugenol 97-53-0 PNEC 0,081 mg/kg aquatic organisms sediments freshwater short-term (instant)

Eugenol 97-53-0 PNEC 0,008 mg/kg aquatic organisms marine sediments short-term (instant)

Eugenol 97-53-0 PNEC 0,015 mg/kg terrestrial organisms soil short-term (instant)

8.2. Exposition controls

Engineering measures

Measures related to the substance/
mixture to prevent exposure during
identified uses

The description of the appropriate exposition control
measures refer to the specified in subsection 1.2 identified
uses of the substance or the mixture.

This information is sufficient to make it possible for the
employer, when appropriate, to assess the risk caused by the
presence of the substance or the mixture for the health and



safety of employees according articles 4—6 of Directive 98/24/EC and articles 3—5 of Directive 2004/37/EC.

This information supplements the information presented in Section 7. Provide adequate ventilation. The good practices of personal hygiene are always recommended especially when handling chemicals/oils.



8.2.1. Appropriate engineering control

8.2.1.1. Eyes and face protection:

Use safety masks with side protection.

Use safety goggles designed to protect against liquid splashes. Before work, wear safety goggles with a protective side in accordance with the EN166 standard. In case of great danger, protect the face with a face shield. Contact lens wearers should wear safety goggles during work when may be exposed to irritating vapours. Provide eyewash rooms in facilities where the product is continuously handled.



8.2.1.2. Skin protection

Hand protection

:

Wear suitable gloves. Chemical protection gloves that have been tested in accordance with EN 374 are suitable.

For special purposes, it is recommended to check the chemical resistance of the protective gloves, mentioned above, together with the supplier of these gloves. Times are approximate values from measurements at 22°C and constant contact. Elevated temperatures due to heated substances, body heat, etc. and reducing the effective layer thickness by stretching can result in the corresponding breakthrough time being doubled / halved. The data refer to the pure substance only. When transferred to mixtures of substances, they can only be considered as a guide.

- *type of material NBR (Nitrile rubber)*
- *material thickness 0.7 mm*
- *glove material wear > 480 minutes (penetration: level 6)*
- *Splash protection - Safety gloves*
- *type of material: NBR (Nitrile rubber)*



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- *material thickness: > 0.11 mm*
- *glove material wear: > 10 minutes (penetration: level 1)*

Other skin protection : Allow recovery periods for skin regeneration. Prophylactic skin protection (protective creams/ointments) is recommended.



8.2.1.3. Respiratory tract protection : Respiratory protection is required in case of: Formation of aerosol mist. Type: A (against organic gases and vapours with boiling point > 65°C, color code: Brown). Type: ABEK (combined gas and vapour filters, colour code: Brown/Grey/Yellow/Green).

8.2.1.4. Thermal hazards : Unknown

8.2.3. Environmental exposure controls : Protect against contamination of drains, surface water and ground water.

Measures related to substance/mixture required to avoid exposition : No data available.

Training measures related to the avoiding of exposition : Staff training as per internal schedule.

Organization measures to avoid exposition : Staff training

Technical measures to avoid exposition : Staff training

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance : Transparent, mobile liquid - sometimes slightly viscous

Color : Yellow to light brown colour



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Odor	:	spicy, characteristic of eugenol smell
Taste	:	spicy-peppery
Odor threshold	:	No current information
Phenols content in %	:	minimum 72.0
pH value	:	Not defined
Melting point/freezing point	:	-9°C
Boiling point or initial boiling point and boiling range	:	248°C
Flammability	:	This material is combustible but will not ignite easily
Upper flammability/ explosion limit	:	No data available
Lower flammability/ explosion limit	:	No data available
Flash point	:	117°C
Autoignition temperature	:	380°C
Decomposition temperature	:	No data available
Evaporation rate	:	No data available
Flammability (solid substance, gas):		Not applicable
Vapor pressure at 20°C	:	No data available
Solubility (s)	:	Soluble in all respects in benzyl benzoate, diethyl phthalate, propylene glycol, vegetable oils (with opalescence); Ethanol - P70 up to 1:2
Insoluble in	:	water, glycerin, mineral oils
Partition coefficient n-octanol/water, log Pow	:	No data available
Explosivity	:	No data available
Oxidizing properties	:	No data available



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Other information

Refractive index : 1.5280 – 1.5380 (20°C)

Relative density at d²⁰ : 1.042 – 1.063 g/cm³ at 20°C

Optical rotation at 20°C : -15° to 0°

No other information available.

10. Stability and Reactivity

10.1 Reactivity

Note : This material is not reactive under normal environmental conditions.

When heated : Vapour can form explosive mixtures with air.

10.2. Chemical stability

Note : The material is resistant to temperature and pressure or in the usual environment and under the foreseeable conditions of storage and use. It is non-resistant to alkalis, and quite resistant to organic acids.

10.3. Possible hazardous reactions

Hazardous reactions : Reacts violently with: strong oxidizer.

10.4. Conditions to avoid

Conditions to avoid : Avoid heat, flames and other sources of ignition.

Thermal decomposition : No data available.

10.5. Incompatible materials

Materials to avoid : Alkalies

10.6. Hazardous decomposition products

Hazardous decomposition products : Hazardous decomposition products may be generated in case of fire, see p.5.



11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Note : Not to be classified as acutely toxic.

Acute toxicity of mixture components

Eugenol 97-53-0 oral LD50 1.930 mg/kg rat

Beta-Caryophyllene
oral LD50 >5.000 mg/kg mouse ECHA

ISOEUGENOL

LD50 Oral - rat - 1.560 mg/kg

Notes: Liver: impairment in liver function tests.

Nutritional and gross metabolism. Changes in: Reduction of body temperature (RTECS)

Assessment of acute toxicity Skin - 1.100, 1 mg/kg (Expert decision)

Acute inhalation toxicity : Acute toxicity estimate: 3 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: Calculation method

Eugenyl Acetate

LD50 Oral - Rat – male and female - 1.670 mg/kg

Notes: (ECHA)

Inhalation: No data available

LD50 Skin - Rabbit - > 5.000 mg/kg

(OECD Test Guideline 402)

Corrosion/Skin irritation

ISOEUGENOL

Skin – Rabbit

Result: Skin irritation

Notes: (RTECS)

Notes : Causes skin irritation.

Serious damage/eye irritation

Eugenyl Acetate

May cause slight irritation.

Result : Causes serious eye irritation



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Respiratory or skin sensitization

Beta-Caryophyllene

Local lymph node assay (LLNA) - Guinea pig Result: positive (OECD Test Guideline 429)
May cause allergic skin reaction.

Eugenyl Acetate

Local lymph node assay (LLNA) – Mouse (OECD Test Guideline 429)

ISOEUGENOL

Maximization test - Guinea pig

Result: positive

(OECD Test Guideline 406)

Notes: Classified according to Regulation (EU) 1272/2008, Annex VI (Table 3.1/3.2)

Note : May cause allergic skin reaction.

Ingestion

Note : Harmful if ingested.

Mutagenicity of germ cells

Rat (eugenol)

Liver

DNA damage

Mouse (eugenol), lymphocytes

Mutation in mammalian somatic cells.

Hamster (eugenol) embryo. Not scheduled.

DNA synthesis

Hamster (eugenol) embryo

Morphological transformations.

Hamster (eugenol) embryo

Carcinogenicity

IARC: 3-Group 3: Cannot be classified as to its carcinogenicity to humans.



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Summary of the assessment of CMR properties

Note : No data available

STOT (specific target organ toxicity) — single exposure

Note : Do not classify as specific target organ toxicity (single exposure).

STOT (specific target organ toxicity) — repeated exposure

Note : Do not classify as specific target organ toxicity (repeated exposure).

Aspiration hazard

Beta-Caryophyllene

It can be fatal if swallowed and enters the respiratory tract.

Note : It can be lethal if swallowed and enters the respiratory tract.

Phototoxicity

Note : No data available

Information on possible routes of exposure

Note : No data available

Symptoms related to physical, chemical and toxicological characteristics

- If swallowed - vomiting, fainting, Cramps, hazard on inhalation
- Eye contact - Causes serious eye irritation
- If inhaled - Coughing, difficulty breathing
- Skin contact - Causes skin irritation, May cause allergic reactions, itching, local redness

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Note : Toxicological characteristics are not comprehensively studied



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Interactions

Note : Toxicological characteristics are not comprehensively studied

Lack of specific data

Note : Toxicological characteristics are not comprehensively studied

Mixtures

Note : Toxicological characteristics are not comprehensively studied

Medical consideration

Note : The persons having rash are directed to dermal specialist to be examined for allergic eczema.

Other information

Note : Toxicological characteristics are not comprehensively studied

11.2. Properties disturbing the functions of the endocrine system

Note : Not listed

11.3. Information on other hazards

Note : No additional data available

12. Ecological information

Note : No additional data available

12.1. Toxicity

Product: Not to be classified as hazardous to the aquatic environment

Acute (short-term) toxicity of mixture components:

Fish

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EC50 (*Oncorhynchus mykiss* (rainbow trout)): 5.1 mg/l

Exposure time: 96 h



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Toxic for Daphnia and other aquatic invertebrates

Eugenol 97-53-0 EC50 1.05 mg/l giant water flea 48 h

Beta-Caryophyllene

static test EC50 - Daphnia magna Straus (Water flea) - > 0.17 mg/l - 48 h (OECD Test Guideline 202)

ISOEUGENOL

EC50 - Daphnia (Water flea) - 7.5 mg/l - 48 h

EC50 - Daphnia (Water flea) - 4.8 mg/l - 48 h Notes: (calculated)

Algae/aquatic plants

Eugenol 97-53-0 ErC50 24 mg/l algae 72 h

Beta-Caryophyllene

ErC50 >0.033 mg/l algae ECHA 72 h

ISOEUGENOL

ErC50 (Skeletonema costatum (marine diatom)): 3.76 mg/l

Exposure time: 72 h

NOEC (Skeletonema costatum (marine diatom)): 1.7 mg/l

Exposure time: 72 h

Bacteria

Note : No data available

Chronic (long-term) toxicity:

Note : No data available

Fish

Note : No data available

Shellfish

Note : No data available



Algae/water plants

ISOEUGENOL

NOEC: 0.4 mg/l

Exposure time: 21 d

Species: Daphnia magna (Water flea), Method: OECD Test Guideline 211

Other organisms

Note : No data available

12.2. Persistence and degradability

Product:

Abiotic degradation

Degradation of mixture components

Eugenol 97-53-0 biotic/abiotic 82 % 28 d

Eugenol 97-53-0 oxygen depletion 50 % 7 d ECHA

β-caryophyllene 87-44-5 oxygen depletion 10 % 28 d ECHA

α-Humulene

Theoretical Oxygen Demand: 3.288 mg/mg

Theoretical Carbon Dioxide: 3.23 mg/mg

ISOEUGENOL

Biodegradation: 79 %

Exposure time: 28 d

Method: OECD Test Guideline 301F

Eugenyl Acetate aerobic - Exposure time 28 d

Result: 81 % - Easily biodegradable.

(OECD Test Guideline 301F)

Physical and photo-chemical elimination

Note : No data available

Biochemical degradation

Note : Biodegradation expected

12.3. Bioaccumulation

Product: No data available



Bioaccumulation potential of mixture components:

Eugenol 97-53-0 1.83 (pH value: 5,5, 30 °C)

Beta-Caryophyllene log KOW 6.23 (pH value: 7,25 °C) (ECHA)

Isoeugenol 97-54-1 2.1

ISOEUGENOL log Pow: 3.04

Bioconcentration factor (BCF)

Notes : Does not accumulate in biological environment

12.4. Mobility in soil

Product: No data available

Known or predicted distribution in environmental components

Note : No data available

Surface tension

Note : No data available

Adsorption/desorption

Note : No data available

12.5. Results of PBT and vPvB assessment

Notes : No data available

12.6. Endocrine-disrupting properties

Results from PBT and vPvB assessment

Notes : No data available

12.7. Other adverse effects

Notes : No data available

13. Disposal Considerations

13.1. Waste treatment methods





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Product : Treat this material and its packaging as hazardous waste.
Dispose of contents/container in accordance with the local/regional/national/international regulation.

Information on discharge in sewer systems

Do not discharge into drains.

13.2. Relevant provisions relating to waste

Placing codes/names on the waste should be carried out in accordance with the Regulation on the catalog of waste, according to the specifics of the given production or process.

Properties of waste that make it hazardous

HP 4 irritant - skin irritation and eye damage
HP 13 sensitizing

European Catalogue : * 16 03 05
waste number organic waste containing hazardous substances

Notes

Waste must be separated into categories that can be treated separately by local or national waste management authorities. Note any national or regional regulations that are relevant.

14. Transport Information

14.1. UN number

Not subject to transport regulations

14.2. UN proper shipping name

Not specified

14.3. Transport hazard class(es)

There is no

14.4. Packing group

Not specified



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14.5. Environmental hazards

No environmental hazard acc. Dangerous goods Regulations

14.6. Special precautions for user

No additional information

14.7. Sea transport of cargo in bulk according to instruments of the International Maritime Organization

The cargo is not intended for transport in bulk.

14.8. Information on all UN Model rules

Road, rail and inland water transport of dangerous goods (ADR/RID/ADN) - Additional information

Not subject to ADR, RID and ADN.

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG

International Civil Aviation Organization (ICAO-IATA/DGR) -Additional information

Not subject to ICAO-IATA/DGR

15. Regulatory information

15.1. Legislation specific for the substance or mixture/safety, health and environmental regulations

The relevant European Union (EU) regulations

Restrictions according to REACH Annex XVII

Substance name	Name in accordance with the inventory	CAS No.	Restriction	No.
Oil of clove	This product meets the criteria for classification according to Regulation No. 1272/2008/EC		R3	3
Oil of clove	substances in tattoo inks and permanent makeup		R75	75
β-caryophyllene	substances in tattoo inks and permanent makeup		R75	75

Legend

R3 1. Shall not be used in:

- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays;

- tricks and jokes;

- games for one or more participants, or any article intended to be used as such, even with ornamental aspects.

2. Articles not complying with paragraph 1 shall not be placed on the market.



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3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:

- can be used as fuel in decorative oil lamps for supply to the general public, and,
- present an aspiration hazard and are labelled with risk phrase H304.

4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).

5. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of dangerous substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:

- a) lamp oils, labelled with risk phrase H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil — or even sucking the wick of lamps — may lead to life-threatening lung damage";
- b) grill lighter fluids, labelled with risk phrase H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: "Just a sip of grill lighter may lead to life threatening lung damage";
- c) lamp oils and grill lighters, labelled with risk phrase H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010;

R75 1. Shall not be placed on the market in mixtures intended for tattooing, and mixtures, containing any of these substances, shall not be used for tattooing purposes after 4 January 2022, if the substance or substances in question are present in the following circumstances:

- a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogenic, category 1A, 1B or 2, or mutagenic to germ cells, category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0.00005 weight percent;
- b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as toxic for reproduction, category 1A, 1B or 2, the substance is present in the mixture at a concentration equal to or greater than 0.001 weight percent;
- c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as a skin sensitiser, category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0.001 weight percent;
- d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as causing skin corrosion, category 1, 1A, 1B or 1C, or skin irritation, category 2, the substance is present in the mixture in a concentration equal to or greater than:
 - i) 0.1 weight percent if the substance is used solely as a pH regulator;
 - ii) 0.01 weight percent in all other cases;
- e) in the case of a substance classified in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present in the mixture in a concentration equal to or greater than 0.00005 weight percent;
- f) in the case of a substance for which a condition is indicated for one or more of the following types in column g (Type of product, body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0.00005 weight percent:
 - i) „Rinse-off products“
 - ii) „Not to be used in products for application on mucous membranes“;
 - iii) „Not to be used in eye products“;
- g) in the case of a substance for which a condition is specified in column h (Maximum concentration in the ready-to-use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration or otherwise not meeting the condition specified in this column;
- h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry the use of a mixture "for tattooing" means the injection or introduction of the mixture into the skin, mucous membrane or eyeball of a person by a process or procedure (including procedures commonly referred to as "permanent makeup", "cosmetic tattooing", "microblading" and "micropigmentation") aimed at achieving a mark or drawing on his body.

3. If a substance not listed in Appendix 13 falls within the scope of more than one of points a) to g) of paragraph 1, the most stringent concentration limit established in those points shall apply to that substance. If a substance listed in



Appendix 13 also falls within the scope of one or more of points a) to g) of paragraph 1, the concentration limit set out in point h) of paragraph 1 applies to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:

- a) Pigment Blue 15:3 (CI 74160, EO number 205-685-1, CAS number 147-14-8);
- b) Pigment Green 7 (CI 74260, EO number 215-524-7, CAS number 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or reclassify a substance so that it falls under points a), b), c) or (d) of paragraph 1 of this entry or falls under a different point from that in which it previously fell, and the date of application of that new or revised classification is after the date specified in paragraph 1 or, as the case may be, in paragraph 4 of this entry, then, for the purposes of applying this entry to the specified substance, that amendment shall be treated as coming into force on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to add a substance to the list or to change its entry so that it falls under points e), f) or g) of paragraph 1 of this entry, or fall in a different point from that in which it previously fell, and the amendment takes effect after the date specified in paragraph 1 or, as the case may be, paragraph 4 of this entry, then for the purposes of the application of this entry in relation to the specified substance, this amendment shall be treated as coming into force 18 months after the entry into force of the act which the said amendment is made by.

7. Suppliers that place on the market a mixture intended for tattooing shall ensure that, after 4 January 2022, the following information is indicated on the label of the mixture:

- a) the text "Mixture intended for tattoos or permanent make-up";
- b) a unique lot identification reference number;
- c) the list of ingredients in accordance with the nomenclature established with the Glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common name of an ingredient, the IUPAC name. In the absence of a name or IUPAC name, the CAS number and the EC number. Ingredients are listed in descending order by weight or volume of ingredients at the time of formulation.

"Ingredient" means any substance added during the formulation process and present in the mixture intended for tattooing. Impurities are not considered ingredients. If there is already a requirement for the name of a substance used as an ingredient within the meaning of this entry to be indicated on the label in accordance with Regulation (EC) No 1272/2008, this ingredient is not necessary to be indicated in accordance with this regulation;

- d) the additional text "pH regulator" for substances covered by paragraph 1, letter d), subsection i);
- e) the text "Contains nickel. May cause allergic reactions.", if the mixture contains nickel below the limit concentration, specified in Appendix 13;

f) the text "Contains chromium (VI). May cause allergic reactions.", if the mixture contains chromium (VI) below the concentration limit, specified in Appendix 13;

g) instructions for safe use to the extent that until now, according to Regulation (EC) No 1272/2008, they were not required to be indicated on the label. The information is clearly visible, easy to read and marked to be indelible. The information shall be written in the official language(s) of the Member State(s) in which the mixture is placed on the market, unless otherwise provided in the Member State(s) concerned. Where this is required due to the size of the package, the information referred to in the first paragraph, with the exception of letter a), shall instead be included in the instructions for use. Before using a mixture for the purpose of tattooing, the person using the mixture shall provide the person undergoing the procedure with the information marked on the packaging or included in the instructions for use under this paragraph.

8. Mixtures which labels do not contain the text "Mixture intended for tattooing or permanent make-up" are not used for the purpose of tattooing.

9. This entry does not apply to substances which are gases at a temperature of 20 °C and a pressure of 101,3 kPa or generate a vapor pressure of more than 300 kPa at a temperature of 50 °C, with the exception of formaldehyde (CAS number 50-00-0, EC number 200-001-8).

10. This entry does not apply to the placing on the market of a mixture intended for tattooing or to the use of a mixture for the purposes of tattooing when it is placed on the market exclusively as a medical device or an accessory to a medical device within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or accessory to a medical device in the same sense. When the placing on the market or use may not be exclusively as a medical device or accessory to a medical device, the requirements under Regulation (EU) 2017/745 and under this Regulation shall apply cumulatively.



List of substances subject to authorization (REACH, Annex XIV)/SVHC - list of candidate substances

Not listed

Seveso Directive

2012/18/EC (Seveso III)			
No.	Hazardous substance/hazard categories	Threshold quantity (in tonnes) for the application of the requirements at low and high risk potential	Notes
	not specified		

Deco-Paint Directive

VOC content 100 %
1,060 g/l

Directive on industrial emissions

VOC content	100 %
VOC content	1,060 g/l

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Not listed

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

Not listed

Regulation on the marketing and use of explosives precursors

Not listed

Regulation on drug precursors

Not listed

Regulation on substances that deplete the ozone layer (ODS)

Not listed

Regulation concerning the export and import of hazardous chemicals (PIC)

Not listed



Persistent Organic Pollutants (POP) Regulation

Not listed

Other information

Directive 94/33/EC on the protection of young people at work. The restrictions on the employment of pregnant and breast-feeding women according to the Law on the Protection of Women at Work (92/85/EEC) should be observed.

The following restrictions are applicable according to Annex XVII to Regulation (EC) No. 1907/2006 of REACH

3. Liquid substances or mixtures which are regarded as dangerous set out in Annex I to Regulation (EC) No 1272/2008	Eugenia Caryophyllus Bud Oil, Eugenol, Eugenyl Acetate, Beta-Caryophyllene, Isoeugenol, α -Humulene
3a. Substances or mixtures meeting the criteria for any of the following hazard classes or categories listed in Annex I to Regulation (EC) No 1272/2008: Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8, type A and B, 2.9 , 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15	
3.b. Substances or mixtures meeting the criteria for any of the following hazard classes or categories listed in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development , 3.8 effects other than narcotic effects, 3.9 and 3.10	Eugenia Caryophyllus Bud Oil, Eugenol, Eugenyl Acetate, Beta-Caryophyllene, Isoeugenol, α -Humulene
3.c. Substances or mixtures meeting the criteria for any of the following hazard classes or categories listed in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1	

National inventories

State	List	Status
AU	AICS	the substance is entered
CA	DSL	the substance is entered
CN	IECSC	the substance is entered
EU	ECSI	the substance is entered
EU	REACH Reg.	the substance is entered
NZ	NZIoC	the substance is entered
PH	PICCS	the substance is entered
TR	CICR	the substance is entered
TW	TCS	the substance is entered

Legend

AICS	Australian Inventory of Chemical Substances
CICR	Chemical Inventory and Control Regulation
DSL	Domestic Substances List (DSL)
ECSI	EC list of substances (EINECS, ELINCS, NLP)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
NZIoC	New Zealand Inventory of Chemicals



PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg.	REACH registered substances
TCSI	Taiwan Chemical Substance Inventory

15.2. Chemical Safety Assessment

A chemical safety assessment has not been prepared for this substance.

16. Other information

Shelf life	30 months from the date of manufacture.
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Classification and procedure used to obtain the classification of mixtures according to Regulation (EC) No 1272/2008 [CLP]

Classification procedure

The method for classifying mixtures is based on the constituents of the mixture (additivity formula).

Classification and procedure used to obtain the classification of mixtures according to Regulation (EC) No 1272/2008 [CLP]

Specifying the changes	:	Change of product name, Classification, Allergens based on new gas-chromatographic analysis and new amendments to Regulation 1272/2008
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Abbreviations and acronyms:

Abbr.	Description of used abbreviations
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement on the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement on the International Carriage of Dangerous Goods by Road)
Asp Tox 1	Inhalation hazard
BCF	bioconcentration factor
BOD	Biochemical Oxygen Demand
CAS	Chemical Abstracts Service (prepares the most comprehensive list of chemicals)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (Classification, Labelling and Packaging)
CMR	Carcinogenic, mutagenic and toxic for reproduction (substance)
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR))
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. EC50 refers to the concentration of the test substance causing a 50 % change in response (e.g. in growth) over a specified time interval
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, the concentration of test substance that causes a 50 %



	reduction in growth (EbC50) or growth rate (ErC50) relative to the control
Eye Dam.	Serious eye damage
Eye irrit.	Eye irritation
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" ", developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
LD50	Lethal Dose 50 % LD50 refers to the dose of a test substance causing 50% lethality over a specified time interval
log KOW	n-octanol/water
NLP	A substance that no longer has the properties of a polymer
PBT	Persistent, bioaccumulative and toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulation on Carriage of Dangerous Goods by Rail)
Skin Corr.	Skin corrosive
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitization
STOT SE	Specific target organ toxicity — single exposure
SVHC	Substance of Very High Concern
vPvB	very Persistent and very Bioaccumulative
EO No.	(EINECS, ELINCS и NLP-list) is the source for the seven-digit EC number, identifier of substances in the commercial network within the EU (European Union)
Index No.	the index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
VOC	Volatile Organic Compounds

Main references and sources of data in the literature

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
Regulation (EC) No 1907/2006 (REACH) as amended by 2020/878/EU.

Road, rail and inland water transport of dangerous goods (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA)

- Regulation (EC) No 1907/2006 (REACH), as amended by (EU) 2020/878
- Regulation (EC) No 1272/2008 (CLP, EC GHS)

	List of relevant phrases (code and full text as defined in Section 2 and 3)
Code	Text
H302	Harmful if swallowed
H304	May be fatal if swallowed and enters the respiratory tract
H315	Causes skin irritation



H317	May cause allergic skin reaction
H319	Causes serious eye irritation
H335	May cause respiratory tract irritation.
EUH208	Contains Eugenol, Isoeugenol, Beta-Caryophyllene, Eugenyl Acetate. May cause allergic reaction.
List of instructions for safe treatment, used in the safety document	
P102	Keep away from children
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P241	Use explosion-proof electrical/ventilation/lighting/.../equipment.
P262	Do not get in eyes, on skin, or on clothing.
P264	Wash hands thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release in the environment
P280	Use protective gloves/protective clothing/protective goggles/protective facial mask.
P363	Wash contaminated clothing before reuse
P301 + P310	IF SWALLOWED: Immediately call the TOXICOLOGY CENTRE or a physician.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/take a shower.
P305 +P351 + P338	If contact with eyes: Rinse thoroughly with water for several minutes. Remove the contact lenses if there are such and if possible. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P302 + P352	IF ON SKIN: Wash with plenty of water and soap.
P331	Do NOT induce vomiting.
P333 + P313	In case of skin irritation or skin rash: Seek medical advice / assistance.
P501	Dispose of the content / container in an approved for disposal place in compliance with the local and national regulations.

Other information

: In accordance with general product specification:
The information in this material safety data sheet is meant to represent typical data/analysis for this product and was obtained from current and reliable sources.
To the best of our knowledge, data is accurate and based on our knowledge and information, at the time of publication.
The information presented is intended only as a guidance for proper and safe use, handling, storage, transportation and disposal, and should not be considered a guarantee /expressed or implied / or a quality specification with respect to the correctness or accuracy.



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It is responsibility of the user to determine any safe conditions for use of this product, and to assume responsibility for any loss, injury, damage or expenses resulting from the improper use of this product.

The information relates to the specific product only and is not valid when used in combination with other materials or in any process, unless specified in the text.

The information provided does not constitute a delivery contract; regarding any specification or a given application, the buyer must determine for himself the requirements and recommendations for use of the product.

Disclaimer :

The data in this Safety Ordinance correspond to the fair presentation of our experience at the time of printing. The information should give you basic guidelines for safe handling of this product, specified in the Safety Ordinance, regarding its storage, processing, transport and disposal. Data cannot be assigned to other products.

If the product is mixed or processed with other materials, or if it is subject to processing, the data in this Safety Ordinance cannot be assigned to the new material unless expressly stated otherwise.

The information provided is intended only as a guide to safe handling, use, processing, storage, transportation, disposal and release and should not be considered a warranty or quality specification.

Due to the many factors beyond our control in the use of this product, we cannot accept responsibility for accidents, mishaps, loss or damage caused by its use.

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LIST OF ALLERGEN SUBSTANCES / ANNEX III TO REGULATION (EC) NO 1223/2009

Customer: „ALTEYA ORGANICS LLC, 1 Rose Field St., 6167, village of Yagoda, Stara Zagora Region
salesbg@alteya.com, http://alteya.com, +359 700 15 502

Name of product: Organic Clove Oil (Eugenia Caryophyllus Bud Oil)

	NAME OF SUBSTANCES	REMARK	CAS №	EINECS №	NATURAL %	SYNTHETIC %	TOTAL %
1	AMYL CINNAMAL	H317; H411	122-40-7	204-541-5	-	-	-
2	AMYLCINNAMYL ALCOHOL	H315; H317	101-85-9	202-982-8	-	-	-
3	ANISE ALCOHOL	H302; H318 H317	105-13-5	203-273-6	-	-	-
4	BENZYL ALCOHOL	H332; H302	100-51-6	202-859-9	-	-	-
5	BENZYL BENZOATE	H302	120-51-4	204-402-9	-	-	-
6	BENZYL CINNAMATE	H317; H411	103-41-3	203-109-3	-	-	-
7	BENZYL SALICYLATE	H317; H411	118-58-1	204-262-9	-	-	-
8	CINNAMAL	H312; H315 H317	104-55-2	203-213-9	-	-	-
9	CINNAMYL ALCOHOL	H317	104-54-1	203-212-3	-	-	-
10	CITRAL	H315; H317	5392-40-5	226-394-6	-	-	-
11	CITRONELLOL	H315; H317 H411	106-22-9	203-375-0	-	-	-
12	COUMARIN	H302; H317	91-64-5	202-086-7	-	-	-
13	EUGENOL	H319; H317	97-53-0	202-589-1	72,0 – 88,0	-	72,0 – 88,0
14	FARNESOL	H315; H319	4602-84-0	225-004-1	-	-	-
15	ALPHA-ISOMETHYL IONONE	H412	127-51-5	204-846-3	-	-	-
16	GERANIOL	H315; H317	106-24-1	203-377-1	-	-	-
17	HEXYL CINNAMAL	H317;	101-86-0	202-983-3	-	-	-
18	HYDROXYCITRONELLAL	H319; H317	107-75-5	203-518-7	-	-	-
19	ISOEUGENOL	H312; H302 H319; H315 H317	97-54-1	202-590-7	0,05 – 0,2	-	0,05 – 0,2
20	BUTYLPHENYL METHYLPROPIONAL (LILIAL)	H317	80-54-6	201-289-8	-	-	-
21	LIMONENE	H226; H315 H317; H411	5989-27-5	227-813-5	-	-	-
22	LINALOOL	H315	78-70-6	201-134-4	-	-	-
23	HYDROXYISOHEXYL 3- CYCLOHEXENE CARBOXALDEHYDE (LYRAL)	H317	31906-04-4	250-863-4	-	-	-
24	METHYL 2-OCTYNOATE	H302; H317	111-12-6	203-836-6	-	-	-
25	EVERNIA FURFURACEA LICHEN EXTRACT (TREEMOSS EXTRACT)	H317	90028-67-4	289-860-8	-	-	-
26	EVERNIA PRUNASTRI (OAK MOSS)	H317	90028-68-5	289-861-3	-	-	-
27	BETA-CARYOPHYLLENE	H304; H317	99-86-5	202-795-1	3,0 – 8,0	-	3,0 – 8,0
28	EUGENYL ACETATE	H302; H315; H317	93-28-7	202-235-6	5,0 – 15,0	-	5,0 – 15,0

According to Regulation EO 1223/2009 is hereby amended as follows:

The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds:—
0,001 % in “leave-on” products, (and)— **0,01 %** in “rinse-off” products