

According to REACH (article 32)

Ozonia 3000 SESAME Ozonized Sesame Seeds Oil Version: 1

Date of compilation: 25/11/2020 Printing: 25/11/2020

Ozonized Sesame Seeds Oil

For this product, it is not necessary to fill out a safety date sheet because it is not classified as hazardous product.

With this **Safety Information Sheet**, Innovares wishes to communicate to its customers "the information required to allow the identification of the application of the application of appropriate risk management measures".

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier: Ozonia 3000 SESAME - Ozonized Sesame Seeds Oil

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

Relevant uses: Raw materials for the cosmetics and pharmaceuticals industries. Uses advised against: All uses not specified in this section or in section 7.3.

1.3 Details of the supplier of the safety data sheet:

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Naples - Tel: 081 7472870 (CAV Ospedale Cardarelli) Foggia - Tel.: 800 183459 (CAV Az. Osp. Univ. Foggia) Verona - Tel.: 800 011858 (CAV Ospedale Integrata)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture:

CLP Regulation (EC) n° 1272/2008:

The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.

2.2 Label elements:

CLP Regulation (EC) n° 1272/2008:

None

2.3 Other hazards:

Product fails to meet PBT/vPvB criteria.

Sesame oil is treated with ozone, which, reacting chemically with the oil itself, is no longer detectable in the finished product and therefore the "danger" of its original state cannot be attributed to the final product.

The non-irritability of the product has been demonstrated with patch tests.

SECTION 3: Composition/information on ingredients

3.1 Substance:

Non-applicable

3.2 Mixture:



According to REACH (article 32)

Ozonia 3000 SESAME Ozonized Sesame Seeds Oil

Version: 1

Date of compilation: 25/11/2020 Printing: 25/11/2020

Chemical description: Solution

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification		
CAS: 8008-74-0	Ozonized Sesame seed oil (Pedaliaceae seed oil), product with ozone (1)		
EC: 232-370-6 REACH: non applicabile	Regulation 1272/2008		95 - <100
CAS: 10191-41-0	3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol ⁽¹⁾		
EC: 233-466-0 REACH: 01-2120086658-39-XXXX	Regulation 1272/2008	Skin Sens. 1B: H317 - Warning	0,01 - <0,1
CAS: 137-66-6	6-O-palmitoylascorbic acid ⁽¹⁾		
EC: 205-305-4 REACH: 01-2120769098-41-XXXX	Regulation 1272/2008	Aquatic Chronic 3: H412	0,01 - <0,1

⁽¹⁾ Voluntarily-listed substance failing to meet any of the criteria set out in Regulation (EU) No. 2015/830

SECTION 4: First aid measures

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

This product is not classified as hazardous when in contact with the skin. However, in case of skin contact it is recommended to remove contaminated clothes and shoes, rinse the skin or if necessary shower the affected person thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

By eye contact:

This product does not contain substances classified as hazardous for eye contact. Rinse eyes thoroughly for at least 15 minutes with lukewarm water, ensuring that the person affected does not rub or close their eyes.

By ingestion/aspiration:

In case of consumption, seek immediate medical assistance showing the SDS for the product.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

SECTION 5: Firefighting Measures

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, manipulation and use, but the product contains flammable substances. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use full jet water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

To obtain more information on the hazards of the substances consult sections 8, 11, 12, 15 and 16.

^{*}Sesame oil with presence of hydroperoxide groups in the fatty acid of triglyceride, for addition reaction in the unsaturated fatty acids double bound after the treatment with ozone.



According to REACH (article 32)

Ozonia 3000 SESAME Ozonized Sesame Seeds Oil

Version: 1

Date of compilation: 25/11/2020 Printing: 25/11/2020

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

6.2 Environmental precautions:

Avoid spillage into the aquatic environment as it contains substances potentially dangerous for this. Contain the product absorbed in hermetically sealed containers. In the case of serious spillage into the aquatic environment notify the relevant authority.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, handling and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

Store in a cool, dry, well-ventilated location. Storage at 4°C (not exceed 23-25°C)

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace



According to REACH (article 32)

Ozonia 3000 SESAME Ozonized Sesame Seeds Oil

There are no occupational exposure limits for the substances contained in the product

DNEL (Workers):

Non-applicable

DNEL (General population):

Non-applicable

PNEC:

Non-applicable

8.2 Exposure controls:

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

HANDS PROTECTION

Non-applicable.

RESPIRATORY PROTECTION

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

OCULAR AND FACIAL PROTECTION

Non-applicable

BODY PROTECTION

Non-applicable

ENVIRONMENTAL EXPOSURE CONTROL

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20°C:

Appearance:

Colour:

Odour:

Odour threshold:

Liquid

Not available

Light Yellow

Characteristic

Non-applicable *

Volatility:

Boiling point at atmospheric pressure:

Vapour pressure at 20°C:

Vapour pressure at 50°C:

Non-applicable *

Non-applicable *

Evaporation rate at 20°C:

Non-applicable *

Product description:

Density at 20°C:

Relative density at 20°C:

Dynamic viscosity at 20°C:

Non-applicable *
980 kg/m³

0,98

Kinematic viscosity at 20 °C:

Kinematic viscosity at 20 °C:

Kinematic viscosity at 40 °C:

Concentration:

PH:

Non-applicable *

Non-applicable *

Vapour density at 20 °C:

Non-applicable *

Version: 1

Date of compilation: 25/11/2020

Printing: 25/11/2020



According to REACH (article 32)

Da

Date of compilation: 25/11/2020 Printing: 25/11/2020

Version: 1

Ozonia 3000 SESAME Ozonized Sesame Seeds Oil

Partition coefficient n-octanol/water 20 °C:

Solubility in water at 20 °C:

Non-applicable *

Non-applicable *

Non-applicable *

Non-applicable *

Non-applicable *

Non-applicable *

Melting point/freezing point:

Explosive properties:

Non-applicable *

Non-applicable *

Non-applicable *

Non-applicable *

Non-applicable *

Flammability:

Flash Point: Not Flammable (> 60°C)

Flammability (solid, gas):

Autoignition temperature:

Lower flammability limit:

Upper flammability limit:

Non-applicable *

Non-applicable *

Non-applicable *

Explosive:

Lower explosive limit:

Upper explosive limit::

Non-applicable *
Non-applicable *

9.2 Other information:

Surface tension at 20 °C:

Refraction index:

Non-applicable *

Non-applicable *

SECTION 10: Stability and reactivity

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the donditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

None in particular.

10.5 Incompatible materials:

Avoid strong acids and bases.

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO2), carbon monoxide and other organic compounds.

SECTION 11: Toxicological information

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available.

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3.

^{*}Not relevant due to the nature of the product, not providing information property of its hazards.

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According to REACH (article 32)

Ozonia 3000 SESAME
Ozonized Sesame Seeds Oil

Date of compilation: 25/11/2020 Printing: 25/11/2020

Version: 1

B- Inhalation (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- C- Contact with the skin and the eyes (acute effect):
- Contact with the skin: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3.
- D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):
- Carcinogenicity: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous with carcinogenic effects. For more information see section 3.

IARC: Non-applicable

- Mutagenicity: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous with mutagenic effects. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- E- Sensitizing effects:
- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: Prolonged contact with the skin can result in episodes of allergic contact dermatitis.
- F- Specific target organ toxicity (STOT) single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

- G- Specific target organ toxicity (STOT)-repeated exposure:
- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3.

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
2,5,7,8-3,4-diidro-tetrametil-2- (4,8,12-trimethyltridecyl) -2H-benzopiran-6-olo	DL50 oral	>2000 mg/kg	
CAS: 10191-41-0	DL50 dermal	>2000 mg/kg	
EC: 233-466-0	CL50 inhalation	>20 mg/L	
Acido 6-O-palmitoilascorbico	DL50 oral	25000 mg/kg	Торо
CAS: 137-66-6	DL50 dermal	>2000 mg/kg	
EC: 205-305-4	CL50 inhalation	Non applic.	

Acute Toxicity Estimate (ATE mix):

ATE mix		Ingredient(s) of unknown toxicity	
Oral	>2000 mg/kg (Calculation metho))	Non-applicable	
Dermal	>2000 mg/kg (Calculation method)	Non-applicable	
Inhalation	>20 mg/L (4h) (Calculation method)	Non-applicable	

SECTION 12: Ecological information

The experimental information related to the eco-toxicological properties of the product itself is not available.

12.1 Toxicity:

Identification		Acute toxicity	Species	Genus
Acido 6-O-palmitoilascorbico	LC50	10 – 100 mg/L (96 h)		Pesce
CAS: 137-66-6	EC50	10 – 100 mg/L		Crostaceo
EC: 205-305-4	EC50	10 – 100 mg/L		Alga



According to REACH (article 32)

Ozonia 3000 SESAME Ozonized Sesame Seeds Oil Version: 1

Date of compilation: 25/11/2020 Printing: 25/11/2020

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Identification	Bioaccumulation potential	
Acido 6-O-palmitoilascorbico	BCF	180
CAS: 137-66-6	Log POW	6
EC: 205-305-4	Potential	Alto

12.4 Mobility in soil:

Identificazione	Absorption/desorption		Volatility	
Acido 6-O-palmitoilascorbico	Кос	450	Henry	1,419E-2 Pa*m³/mol
CAS: 137-66-6	Conclusion	Non applicabile	Dry soil	No
EC: 205-305-4	Surface tension	Non applicabile	Moist soil	No

12.5 Results of PBT and vPvB assessment:

Product fails to meet PBT/vPvB criteria

12.6 Other adverse effects:

Not described

SECTION 13: Disposal considerations

13.1 Waste treatment methods:

Code	Description	Waste class (Reg. UE n.1357/2014)
	It is not possible to assign a specific code, as it depends on the intended use by the user	Non dangerous

Type of waste (Regulation (EU) No 1357/2014):

Non-applicable

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: Transport information

Refers to ADR 2019, RID 2019, IMDG 39-18 e ICAO/IATA 2020:

This product is not regulated for transportation (ADR/RID, IMDG, IATA)

14.1 UN number: Non-applicable

14.2 UN proper shipping name: Non-applicable

14.3 Transport hazard class: Non-applicable

14.4 Packaging group: Non-applicable

14.5 Environmental hazards: Non-applicable

14.6 Special precautions for user: Non-applicable



According to REACH (article 32)

Ozonia 3000 SESAME Ozonized Sesame Seeds Oil Version: 1

Date of compilation: 25/11/2020 Printing: 25/11/2020

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Non-applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Seveso III:

Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH,

etc):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: Other information

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (Regulation (EC) No 2015/830)

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

Non-applicable

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Aquatic Chronic 3: H412 - Harmful to aquatic life with long lasting effects

Skin Sens. 1B: H317 - May cause an allergic skin reaction

Classification procedure:

Non-applicable

Advice related to training:

Minimal training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

http://echa.europa.eu

http://eur-lex.europa.eu

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50 EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient



According to REACH (article 32)

Ozonia 3000 SESAME **Ozonized Sesame Seeds Oil**

Koc: Partition coefficient of organic carbon

Date of compilation: 25/11/2020

Printing: 25/11/2020

Version: 1

Product safety information sheet prepared in accordance with Article 32 of Regulation (EC) 1907/2006 (REACH); this document does not constitute a Safety Data Sheet under Article 31 of Regulation (EC) No. 1907/2006, as a Safety Data Sheet is not mandatory for this product

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.