

Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878 and to Annex II to UK REACH

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

1.1. Product identifier

Product name **ENDO N2 liquido**

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

Intended use **Cement for the definitive filling of the canals of vital and gangrenous teeth**

Identified Uses	Industrial	Professional	Consumer
Cement for the definitive filling of the canals of vital and gangrenous teeth - Medical device	-	✓	-

1.3. Details of the supplier of the safety data sheet

Name **Ghimas S.p.a.**
Full address **Via Domenico Cimarosa, 85**
District and Country **40033 Casalecchio di Reno (BO)**
Tel. 051 575353

e-mail address of the competent person responsible for the Safety Data Sheet **info@ghimas.it**

1.4. Emergency telephone number

For urgent inquiries refer to **Tel. 051 575353 (office hours)**

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Eye irritation, category 2	H319	Causes serious eye irritation.
Skin sensitization, category 1B	H317	May cause an allergic skin reaction.

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:



Signal words: **Warning**

ENDO N2 liquido

Revision nr. 1
Dated 26/05/2023
First compilation
Printed on 26/05/2023
Page n. 2/14

Hazard statements:

H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

Precautionary statements:

P280 Wear protective gloves / eye protection / face protection.
P261 Avoid breathing dust / fume / gas / mist / vapours / spray.
P333+P313 If skin irritation or rash occurs: Get medical advice / attention.
P337+P313 If eye irritation persists: Get medical advice / attention.
P302+P352 IF ON SKIN: Wash with plenty of water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Contains: Eugenol
citronellol

Linalyl acetate

Geraniol

dl-linalool;

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration \geq 0.1%.

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
Eugenol		
INDEX -	$74 \leq x < 78$	Eye Irrit. 2 H319, Skin Sens. 1B H317
EC 202-589-1		
CAS 97-53-0		
dl-linalool;		
INDEX 603-235-00-2	$0,6 \leq x < 0,7$	Eye Irrit. 2 H319, Skin Irrit. 2 H315, Skin Sens. 1B H317
EC 201-134-4		
CAS 78-70-6		
Geraniol		
INDEX -	$0,5 \leq x < 0,6$	Eye Dam. 1 H318, Skin Irrit. 2 H315, Skin Sens. 1 H317
EC 203-377-1		
CAS 106-24-1		
Linalyl acetate		

ENDO N2 liquido

Revision nr. 1
Dated 26/05/2023
First compilation
Printed on 26/05/2023
Page n. 3/14

INDEX - 0,25 ≤ x < 0,3 Eye Irrit. 2 H319, Skin Irrit. 2 H315, Skin Sens. 1B H317

EC 204-116-4

CAS 115-95-7

citronelloI

INDEX - 0,25 ≤ x < 0,3 Eye Irrit. 2 H319, Skin Irrit. 2 H315, Skin Sens. 1 H317

EC 203-375-0

CAS 106-22-9

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.

INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

ENDO N2 liquido

Revision nr. 1
Dated 26/05/2023
First compilation
Printed on 26/05/2023
Page n. 5/14

Oral	3 mg/kg bw/d	
Inhalation	5,22 mg/m3	21,2 mg/m3
Skin	3 mg/kg bw/d	6 mg/kg bw/d

Geraniol

Predicted no-effect concentration - PNEC		
Normal value in fresh water	10,8	ug/l
Normal value in marine water	1,08	ug/l
Normal value for fresh water sediment	115	ug/l
Normal value for marine water sediment	11,5	ug/l
Normal value of STP microorganisms	700	ug/l

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers			Effects on workers				
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation			11,8 mg/m3	47,8 mg/m3			11,8 mg/m3	161,6 mg/m3
Skin			11,8	7,5 mg/kg bw/d				12,5 mg/kg bw/d

citronellol

Predicted no-effect concentration - PNEC		
Normal value in fresh water	2,4	ug/L
Normal value in marine water	24	ug/L
Normal value for fresh water sediment	25,6	ug/L
Normal value for marine water sediment	2,56	ug/L
Normal value of STP microorganisms	580	mg/l

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers			Effects on workers				
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral								47,8 mg/kg bw/d
Inhalation	10 mg/m3		10 mg/m3	47,8 mg/m3	10 mg/m3		10 mg/m3	161,6 mg/m3
Skin	2,95 mg/cm2			196,4 mg/kg bw/d	2,96 mg/cm2			327,4 mg/kg bw/d

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

Protect hands with category III work gloves.

The following should be considered when choosing work glove material (see standard EN 374): compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

ENDO N2 liquido

Revision nr. 1
Dated 26/05/2023
First compilation
Printed on 26/05/2023
Page n. 6/14

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	liquid	
Colour	yellowish	
Odour	characteristic	
Melting point / freezing point	not available	
Initial boiling point	not available	
Flammability	not available	
Lower explosive limit	not available	
Upper explosive limit	not available	
Flash point	> 60 °C	
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	not available	
Kinematic viscosity	not available	
Solubility	not available	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	1,52-1,528	
Relative vapour density	not available	
Particle characteristics	not applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Information not available

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

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

Information not available

ENDO N2 liquido

Revision nr. 1
Dated 26/05/2023
First compilation
Printed on 26/05/2023
Page n. 8/14

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	Not classified (no significant component)
ATE (Dermal) of the mixture:	Not classified (no significant component)

Eugenol

LD50 (Oral):	2000 mg/kg rat
--------------	----------------

dl-linalool;

LD50 (Dermal):	5610 mg/kg rabbit
LD50 (Oral):	2200 mg/kg topo

Geraniol

LD50 (Dermal):	5000 mg/kg rabbit
LD50 (Oral):	3600 mg/kg rat

Linalyl acetate

LD50 (Dermal):	> 5000 mg/kg
LD50 (Oral):	14500 mg/kg

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

ENDO N2 liquido

Revision nr. 1
Dated 26/05/2023
First compilation
Printed on 26/05/2023
Page n. 9/14

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

SECTION 12. Ecological information

12.1. Toxicity

Linalyl acetate

LC50 - for Fish 116 mg/l/96h

citronellol

LC50 - for Fish 14,66 mg/l/96h

EC50 - for Crustacea 17,48 mg/l/48h

EC50 - for Algae / Aquatic Plants 2,4 mg/l/72h

ENDO N2 liquido

Revision nr. 1
Dated 26/05/2023
First compilation
Printed on 26/05/2023
Page n. 10/14

Geraniol
LC50 - for Fish 3,2 mg/l/96h

Eugenol
LC50 - for Fish 13 mg/l/96h
EC50 - for Crustacea 1,13 mg/l/48h
EC50 - for Algae / Aquatic Plants 24 mg/l/72h
Chronic NOEC for Algae / Aquatic Plants 23 mg/l

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number or ID number

not applicable

ENDO N2 liquido

Revision nr. 1
Dated 26/05/2023
First compilation
Printed on 26/05/2023
Page n. 11/14

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

<u>Product</u>	
Point	3 - 40

<u>Contained substance</u>	
Point	75

ENDO N2 liquido

Revision nr. 1
Dated 26/05/2023
First compilation
Printed on 26/05/2023
Page n. 12/14

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage \geq than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
Skin Sens. 1	Skin sensitization, category 1
Skin Sens. 1B	Skin sensitization, category 1B
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)

ENDO N2 liquido

Revision nr. 1
Dated 26/05/2023
First compilation
Printed on 26/05/2023
Page n. 13/14

- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
 4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
 13. Regulation (EU) 2017/776 (X Atp. CLP)
 14. Regulation (EU) 2018/669 (XI Atp. CLP)
 15. Regulation (EU) 2019/521 (XII Atp. CLP)
 16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
 17. Regulation (EU) 2019/1148
 18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
 19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
 20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
 21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
 22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - IFA GESTIS website
 - ECHA website
 - Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.
Provide appointed staff with adequate training on how to use chemical products.

ENDO N2 liquido

Revision nr. 1

Dated 26/05/2023

First compilation

Printed on 26/05/2023

Page n. 14/14

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.