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	**Ghenesyl putty soft - Normal set / Fast set**

1.2. Relevant identified uses of the substance or mixture and uses advised against			
Identified Uses	Industrial	Professional	Consumer
Addition silicone for dental impressions.	-		-
Uses Advised Against			
All uses not indicated in the identified uses.			

1.3. Details of the supplier of the safety data sheet		
Name	LASCOD S.p.A.	Australian Distributor Ultimate Dental Supply
Full address	VIA LUIGI LONGO 18	660A South Rd MOORABBIN VIC 3189
District and Country	50019 SESTO FIORENTINO (FI)	03 9532 1799 info@ultimatedental.com.au
	Italy	
	tel. +39 055 421 5768	
e-mail address of the competent person		
responsible for the Safety Data Sheet	info@lascod.it	
Supplier:	LASCOD S.p.A.	

1.4. Emergency telephone number	Australian Emergency phone number
For urgent inquiries refer to	13 11 26 - Poisons Hotline - 24/7

(AT): +43 14064343 - (BE): +32 070245245 - (BG): +359 29154233 - (CY): 1401
(DK): +45 82121212 - (ES): +34 915620420 - (HR): +385 12348342
(EE): +372 7943794, 16662 - (FI): +358 800 147111 - (FR): +33 (0) 145425959
(DE): 112 - (EL): +30 2107793777 - (IE): +353 (01) 8092166 - (IS): +354 5432222, 112
(LV): +371 67042473, 112 - (LT): +370 (85) 2362052 - (LU): +352 80025500
(MT): 2545 0000 - (NO): +47 22591300 - (NL): +31 (0) 887558000 - (PL): 112
(PT): +351 800250250 - (CZ): +420 224919293 - (RO): +40 212308000
(SK): +421 254774166 - (SI): 112 - (SE): 112 - (HU):+36 80201199

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).
This mixture contains elastomers. It presents a danger to human health through inhalation of dust contained in one or more filler ingredients. However, the mixture of elastomers, in the form in which it is made available (malleable or pourable paste), does not allow the emission of dust, therefore the danger due to inhalation is no longer present.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

2.2. Label elements

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

Hazard pictograms:	None					

Signal words:	None

Hazard statements:	None

Precautionary statements:	None

2.3. Other hazards

There is no exposure to free crystalline silica during normal use of this product.

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.
The product does not contain substances with endocrine disrupting properties in concentration ≥ 0.1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)	
CRISTOBALITE			
INDEX -	30 ≤ x < 50	STOT RE 1 H372	
EC 238-455-4			
CAS 14464-46-1			

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, if the situation allows you to carry out the operation easily. Wash immediately and abundantly with water for at least 15 minutes, opening the eyelids wide. If symptoms occur, consult a doctor.
SKIN: Remove all contaminated clothing immediately. Wash immediately and thoroughly with running water (and soap if possible). If symptoms occur, consult a doctor.
INGESTION: Do not induce vomiting unless expressly authorized by your doctor. Do not give anything by mouth if the person is unconscious. If symptoms occur, consult a doctor.
INHALATION: Move the subject to fresh air, away from the accident site. If symptoms occur, consult a doctor.

Rescuer protection
Wear the PPE required as per section 8.

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

Organ symptoms may occur due to prolonged and repeated exposure.

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

If symptoms appear or persist following exposure, consult a doctor immediately.

Means to have available in the workplace for specific and immediate treatment
Running water for skin and eye washing.

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING MEANS
The extinguishing media are: carbon dioxide, foam, chemical powder. For product leaks and spills that have not ignited, water spray can be used to disperse flammable vapors and protect those trying to stop the leak.
UNSUITABLE EXTINGUISHING MEANS
Do not use water jets. Water is not effective in extinguishing fire, however, it can be used to cool closed containers exposed to flame, preventing explosions and explosions.

5.2. Special hazards arising from the substance or mixture

DANGERS DUE TO EXPOSURE IN THE EVENT OF FIRE
Avoid breathing combustion products.

5.3. Advice for firefighters

SPECIFIC PROTECTIVE EQUIPMENT: wear self-contained breathing apparatus and integral heat- and flame-resistant protective suits.

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.
Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.
Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Refer to the uses identified in section 1.2. For applications other than those described, contact the supplier.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory references:

EU	OEL EU	Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.

CRISTOBALITE							
Threshold Limit Value							
Type	Country	TWA/8h		STEL/15min		Remarks / Observations	
		mg/m3	ppm	mg/m3	ppm		
OEL	EU	0,1				RESP	

Legend:
(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

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.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

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, permeability time.
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.

SKIN PROTECTION
Wear category III 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 ISO 16321).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

RESPIRATORY PROTECTION
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. Use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387).
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	paste	
Colour	orange	
Odour	mint	
Melting point / freezing point	not available	Reason for missing data:not relevant for the characterization of the product
Initial boiling point	not available	Reason for missing data:not relevant for the characterization of the product
Flammability	not flammable	
Lower explosive limit	not applicable	Reason for missing data:the substance/mixture is a solid
Upper explosive limit	not applicable	Reason for missing data:the substance/mixture is a solid
Flash point	not applicable	Reason for missing data:the substance/mixture is a solid
Auto-ignition temperature	not applicable	Reason for missing data:the substance/mixture is a solid
Decomposition temperature	not available	Reason for missing data:not relevant for the characterization of the product
pH	not available	Reason for missing data:not relevant for the characterization of the product
Kinematic viscosity	not applicable	Reason for missing data:the substance/mixture is a solid
Solubility	not available	Reason for missing data:not relevant for the characterization of the product
Partition coefficient: n-octanol/water	not applicable	Reason for missing data:the product is a mixture
Vapour pressure	not available	Reason for missing data:not relevant for the characterization of the product
Density and/or relative density	1,64 g/cm3	
Relative vapour density	not applicable	Reason for missing data:the substance/mixture is a solid
Particle characteristics	not available	Reason for missing data:not relevant for the characterization of the product

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

No known incompatible materials.

10.6. Hazardous decomposition products

The product does not decompose under normal conditions of use and storage.

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.
It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

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
The most likely routes of exposure are dermal and oral

Delayed and immediate effects as well as chronic effects from short and long-term exposure
Refer to section 4.2

Interactive effects
None known

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)

SKIN CORROSION / IRRITATION
Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION
Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION
Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY
Does not meet the classification criteria for this hazard class

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
Causes damage to organs

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

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Information not available

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 ≥ 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 authorized 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

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

Product

Point	3	

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 ≥ 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:

STOT RE 1	Specific target organ toxicity - repeated exposure, category 1	
H372	Causes damage to organs through prolonged or repeated exposure.	

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)
- 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
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- 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
- vPvM: Very persistent and very mobile
- 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
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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)
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- 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.
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.