Safety data sheet

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

1.1. Product identifier

Product name

GHENESYL REGULAR BODY
GHENESYL HEAVY BODY
GHENESYL LIGHT BODY
GHENESYL SUPERLIGHT BODY

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

Intended use

Silicone for dental impression.
Addition curing.

Uses advised against

No use advised against.

1.3. Details of the supplier of the safety data sheet

Name

Full address

District and Country

LASCOD SPA
Via Luigi Longo, 18
50019 Sesto Fiorentino (FI)
ITALY
tel. +39 055/4215768
fax +39 055/4210421

e-mail address of the competent person responsible for the Safety Data Sheet

ricerca@lascod.it

1.4 Details of Distributor

Ultimate Dental Supplies
660A South Rd
MOORABBIN VIC 3189
Tel: 03 9532 1799

Email: info@ultimatedental.com.au
www.ultimatedental.com.au

1.5 Emergency phone number:

13 11 26
Poisons Hotline 24hours/7 days

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).
However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments.
Hazard classification and indication:

2.2. Label elements.

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

Hazard pictograms: --

Signal words: --

Hazard statements:

EUH210 Safety data sheet available on request.

Precautionary statements:

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2.3. Other hazards.

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

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 1272/2008 (CLP).
DIATOMACEOUS EARTH soda ash flux-calcined		
CAS. 68855-54-9 EC. 272-489-0 INDEX. - Reg. no. 01-2119488518-22	10 - 20	STOT RE 2 H373

Note: Diatomaceous earth, soda ash flux-calcined.
This product contains cristobalite (respirable fraction) (CAS 14464-46-1) in concentration between 1 and 10 %; cristobalite (respirable fraction) is classified as STOT RE1.

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. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.
INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorized by a doctor.

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

For symptoms and effects caused by the contained substances, see chap. 11.

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 EXTINGUISHINGEQUIPMENT
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).

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. Check incompatibility for container material in section 7. 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).

Information not available.

SECTION 8. Exposure controls/personal protection.

8.1. Control parameters.

Regulatory References:

CZE	Česká Republika	Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany zdraví při práci

DEU	Deutschland	MAK-und BAT-Werte-Liste 2012
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2015
EST	Eesti	Töökeskkonna keemiliste ohutegurite piirnormid 1. Vastu võetud 18.09.2001 nr 293 RT I 2001, 77, 460 - Redaktsiooni jõustumise kp: 01.01.2008
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GRB	United Kingdom	EH40/2005 Workplace exposure limits
LTU	Lietuva	DĖL LIETUVOS HIGIENOS NORMOS HN 23:2007 CHEMINIŲ MEDŽIAGŲ 2007 m. spalio 15 d. Nr. V-827/A1-287
LVA	Latvija	Ķīmisko vielu aroda ekspozīcijas robežvērtības (AER) darba vides gaisā 2012
NLD	Nederland	Databank of the social and Economic Concil of Netherlands (SER) Values, AF 2011:18
NOR	Norge	Veiledning om Administrative normer for forurensning i arbeidsatmosfære
POL	Polska	ROZPORZĄDZENIE MINISTRA PRACY I POLITYKI SPOŁECZNEJ z dnia 16 grudnia 2011r
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
	TLV-ACGIH	ACGIH 2014

CRISTOBALITE

Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
TLV	CZE	0,1				
MAK	DEU	0,15				
VLA	ESP	0,05				
TLV	EST	0,05				
VLEP	FRA	0,05				RESP.
WEL	GRB	0,3				
RD	LTU	0,05				
RV	LVA	0,05				
OEL	NLD	0,075				RESP.
TLV	NOR	0,05				RESP.
NDS	POL	2				INHAL.
NDS	POL	0,3				RESP.
MAK	SWE	0,05				RESP.
TLV-ACGIH		0,025				

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. 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 (see standard EN 374).
The following should be considered when choosing work glove material: 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.

SKIN PROTECTION
Wear category III professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC 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).

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
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 B 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 EXPOSURECONTROLS.

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.

Appearance	fluid paste
Colour	Green
Odour	none.
Odour threshold.	Not available.
pH.	Not available.
Melting point / freezing point.	Not available.

Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	360 °C.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	1,17 Kg/L.
Solubility	insoluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	150°C.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidising properties	Not oxidant.

9.2. Other information.

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 toxicological effects.

Data available for the mixture:

ACUTE TOXICITY: no data available.
SKIN CORROSION/IRRITATION: no data available.
SERIOUS EYE DAMAGE/IRRITATION: no data available.
RESPIRATORY OR SKIN SENSITISATION: no data available.
GERM CELL MUTAGENICITY: no data available.
CARCINOGENICITY: no data available.
REPRODUCTIVE TOXICITY: no data available.
STOT-SINGLE EXPOSURE: no data available.
STOT-REPEATED EXPOSURE: the mixture is not classified in this hazard class because the product is in a physical state that prevents the crystalline silica (cristobalite) to become respirable.
ASPIRATION HAZARD: no data available.

Data available for the substances in the mixture:

CRISTOBALITE (respirable fraction)
STOT-REPEATED EXPOSURE: causes lung damage in case of prolonged or repeated exposure by inhalation, classification available in the SDS of the supplier.

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.

Diatomaceous earth, soda ash flux-calcined.

LC50 - for Fish.	exceeds the maximum level of solubility of the substance, Oncorhynchus mykiss, OECD 203
EC50 - for Crustacea.	exceeds the maximum level of solubility of the substance, Daphnia magna, OECD 202
EC50 - for Algae / Aquatic Plants.	exceeds the maximum level of solubility of the substance, Desmodesmus subspicatus, OECD 201

12.2. Persistence and degradability.

DIATOMACEOUS EARTH, SODA ASH FLUX-CALCINED
The product contains exclusively inorganic compounds non-biodegradable (data available in the SDS of the supplier).

12.3. Bioaccumulative potential.

DIATOMACEOUS EARTH, SODA ASH FLUX-CALCINED
The product does not contain any substances expected to be bioaccumulating.

12.4. Mobility in soil.

DIATOMACEOUS EARTH, SODA ASH FLUX-CALCINED
Mobility: not relevant due to the physical state of the product. The product is insoluble in water.

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 greater than 0,1%.

12.6. 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.

14.1. UN 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. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code.

Information not relevant.

SECTION 15. Regulatory information.

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

Seveso category. None.

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

None

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisarion (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 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.

German regulation on the classification of substances hazardous to water (VwVwS 2005).

WGK 1: Low hazard to waters

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

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

STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
H373	May cause damage to organs through prolonged or repeated exposure.

Classification according to Regulation (EC) n. 1272/2008	Classification procedure
STOT RE 2,H373	Not classified as dangerous on the basis of expert judgement

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 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 NUMBER: 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: EC Regulation 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 STEL: Short-term exposure limit
- TWA: Time-weighted average 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 (EU) 1907/2006 (REACH) of the European Parliament
2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 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
- 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
- ECHA website

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.