

VANNINI DENTAL INDUSTRY

Safety Data Sheet PROTESIL PUTTY

Revision nr. 2

Dated 31/10/2017

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

1.1. Product identifier

Code: 056004, 056024, 056002, U056004
Product name: PROTESIL PUTTY

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

Intended use: For professional use only. Condensation silicone for dental impression.

1.3. Details of the supplier of the safety data sheet.

Name: Vannini Dental Industry S.r.l.
Full address: Via di Campigliano 55/a
District and Country: 50012 Grassina (FI)
Italy
tel. +39 055 644698
fax +39 055 644697

e-mail address of the competent person.

responsible for the Safety Data Sheet. info@vanninidental.com

1.4. Emergency telephone number.

For urgent inquiries refer to. 0039 055644698

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

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

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	x = Conc. %	Classification 1272/2008 (CLP)
ETHYL ACETATE		
CAS 141-78-6	$0 \leq x < 0,2$	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336, EUH066
EC 205-500-4		
INDEX 607-022-00-5		
Reg. no. 01-2119475103-46-XXXX		
PROPIONIC ACID		
CAS 79-09-4	$0 \leq x < 0,2$	Flam. Liq. 3 H226, Skin Corr. 1B H314, STOT SE 3 H335
EC 201-176-3		
INDEX 607-089-00-0		

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

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

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SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Excess pressure may form in containers exposed to fire at a risk of explosion. 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. If the product is flammable, use explosion-proof equipment. 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.

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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.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

See section 1.2.

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
DNK	Danmark	Graensevaerdier per stoffer og materialer
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2015
FIN	Suomi	HTP-arvot 2012. Haitallisiksi tunnetut pitoisuudet - Sosiaali- ja terveystieteiden tutkimuskeskus julkaisuja 2012:5
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GBR	United Kingdom	EH40/2005 Workplace exposure limits
GRC	Ελλάδα	ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ -ΤΕΥΧΟΣ ΠΡΩΤΟ Αρ. Φύλλου 19 - 9 Φεβρουαρίου 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

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EU	OEL EU	Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 91/322/EEC.				
	TLV-ACGIH	ACGIH 2016				

PROPIONIC ACID								
Threshold Limit Value								
Type	Country	TWA/8h		STEL/15min				
		mg/m3	ppm	mg/m3	ppm			
MAK	DEU	31	10	62	20	INHAL		
TLV	DNK	30	10	60	20	INHAL		
VLA	ESP	31	10	62	20	INHAL		
VLEP	FRA	31	10	62	20	INHAL		
MAK	SWE	30	10	45	15	INHAL		
OEL	EU	31	10	62	20	INHAL		
Predicted no-effect concentration - PNEC								
Normal value in fresh water				0,5	mg/l			
Normal value in marine water				0,05	mg/l			
Normal value for fresh water sediment				1,86	mg/kg			
Normal value for marine water sediment				0,186	mg/kg			
Normal value for water, intermittent release				5	mg/l			
Normal value of STP microorganisms				5	mg/l			
Normal value for the terrestrial compartment				0,1258	mg/kg			
Health - Derived no-effect level - DNEL / DMEL								
	Effects on consumers			Effects on workers				
Route of exposure								
Inhalation					62 mg/m3	62 mg/m3	31 mg/m3	31 mg/m3
Skin							260 mg/kg/day	132 mg/kg/day

ETHYL ACETATE						
Threshold Limit Value						
Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
TLV	CZE	700		900		
AGW	DEU	1500	400	3000	800	
MAK	DEU	1500	400	3000	800	
TLV	DNK	540	150			
VLA	ESP	1460	400			
HTP	FIN	1100	300	1800	500	
VLEP	FRA	1400	400			
WEL	GBR		200		400	
TLV	GRC	1400	400			
OEL	NLD	550		1100		
TLV	NOR	550	150			
NDS	POL	200		600		
MAK	SWE	500	150	1100	300	
OEL	EU	734	200	1468	400	
TLV-ACGIH		1441	400			

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Predicted no-effect concentration - PNEC						
Normal value in fresh water		0,26	mg/l			
Normal value in marine water		0,026	mg/l			
Normal value for fresh water sediment		1,25	mg/kg			
Normal value for marine water sediment		0,125	mg/kg			
Normal value for the terrestrial compartment		0,24	mg/kg			
Health - Derived no-effect level - DNEL / DMEL						
Route of exposure		Effects on consumers	Effects on workers			
Inhalation			1468 mg/m3	1468 mg/m3	734 mg/m3	734 mg/m3
Skin					VND	63 mg/kg bw/d

Legend:

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

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

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.

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 I 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).

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 EXPOSURE CONTROLS

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

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SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	paste
Colour	yellow
Odour	peach
Odour threshold	Not available
pH	Not applicable
Melting point / freezing point	Not available
Initial boiling point	Not available
Boiling range	Not available
Flash point	Not available
Evaporation Rate	Not available
Flammability of solids and gases	not applicable
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	Not available
Solubility	insoluble in water
Partition coefficient: n-octanol/water	Not applicable
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Explosive properties	Not available
Oxidising properties	Not available

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

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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

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 toxicological effects

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

Interactive effects

Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture: Not classified (no significant component)

LD50 (Oral) of the mixture: Not classified (no significant component)

LD50 (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

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

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Does not meet the classification criteria for this hazard class

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

ETHYL ACETATE	
EC50 - for Crustacea	560 mg/l/48h (Daphnia magna, MSDS supplier).
EC50 - for Algae / Aquatic Plants	1200 mg/l/72h (Selenastrum, MSDS supplier).
LC10 for Fish	350 mg/l/96h (Oncorhynchus mykiss (rainbow trout), MSDS supplier).

PROPIONIC ACID	
LC50 - for Fish	> 10000 mg/l/96h (DIN 38412, Leuciscus idus, ECHA dossier).
EC50 - for Crustacea	> 500 mg/l/48h (EU Method C.2, Daphnia magna, ECHA dossier).

12.2. Persistence and degradability

ETHYL ACETATE	
Solubility in water	> 10000 mg/l
Rapidly degradable	

PROPIONIC ACID	
Rapidly degradable	

12.3. Bioaccumulative potential

ETHYL ACETATE	
Partition coefficient: n-octanol/water	0,68
BCF	30

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 greater than 0,1%.

12.6. Other adverse effects

Information not available

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SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

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

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

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Not applicable

14.7. Transport in bulk according to Annex II of Marpol 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 - Directive 2012/18/EC: 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)

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

Substances subject to authorisation (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

Information not available

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:

Flam. Liq. 2	Flammable liquid, category 2
Flam. Liq. 3	Flammable liquid, category 3

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Skin Corr. 1B	Skin corrosion, category 1B
Eye Irrit. 2	Eye irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
EUH066	Repeated exposure may cause skin dryness or cracking.
EUH210	Safety data sheet available on request.

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 (EC) 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
 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
 11. Regulation (EU) 2016/918 (VIII 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
 - IFA GESTIS website

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- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) – Italy

Note for users:

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC.

This safety data sheet has been created on a voluntary basis.

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.

Changes to previous review:

The following sections were modified:

01 / 02 / 03 / 04 / 05 / 06 / 08 / 09 / 10 / 11 / 12 / 14 / 15 / 16.