



Safety data sheet

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

1.1. Product identifier

Code: **056021**
Product name: **PROTESIL GEL CATALYST**

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

Intended use: Condensation silicone for laboratory and clinic use.

1.3. Details of the supplier of the safety data sheet

Name: **VANNINI DENTAL INDUSTRY SRL**
Full address: **Via di Campigliano 55/A – 50012 Grassina Bagno a Ripoli – FI– Italy**
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E-mail: info@vanninidental.com

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

Jaime Sandoval

1.4. Emergency telephone number

For urgent inquiries refer to

CAV Italia: Centro Antiveleni di Milano: 02 66101029; Centro Antiveleni di Pavia: 0382 24444; Centro Antiveleni di Bergamo: 800 883300; Centro Antiveleni di Firenze: 055 7947819; Centro Antiveleni di Roma: 06 3054343; Centro Antiveleni di Roma: 06 49978000; Centro Antiveleni di Napoli: 081 7472870

Servicio de Información Toxicológica (España): + 34 91 562 04 20 (24h/365 días)

Numéro ORFILA (INRS-France): + 33 (0)1 45 42 59 59 (24h/ 7 jours sur 7)

UK Emergency number: 844 892 0111 (24 hours)

Deutschland Notruf: BERLIN Tel.: 030/19240; HOMBURG Tel.: 06841/19240; BONN Tel.: 0228/19240; MAINZ Tel.: 06131/19240; ERFURT Tel.: 0361/730 730; MÜNCHEN Tel.: 089/19240; FREIBURG Tel.: 0761/19240; NÜRNBERG Tel.: 0911/398-2451; GÖTTINGEN Tel.:0551/19 240

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 EC Regulation 1907/2006 and subsequent amendments. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments.

Hazard classification and indication:

Flam. Liq. 3: **H226**
Repr. 2: **H361d**



STOT RE 2
Eye Irrit. 2

H373
H319

2.1.2. 67/548/EEC and 1999/45/EC Directives and following amendments and adjustments.

Danger Symbols:

Xn

R phrases:

10-48/22-Repr. Cat. 3 63

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

2.2. Label elements.

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



Signal words:

Warning

H226 Flammable liquid and vapour.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H319 Causes serious eye irritation.
EUH208 Contains:
d-CARVONE

May produce an allergic reaction.

P201 Obtain special instructions before use.
P280 Wear protective gloves / protective clothing / eye protection / face protection.
P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P308+P313 IF exposed or concerned: Get medical advice/attention.

Contains: DIOCTYLTIN OXIDE

2.3. Other hazards.

Information not available.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 67/548/EEC.	Classification 1272/2008 (CLP).
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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. 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.

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. 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:

United Kingdom	EH40/2005 Workplace exposure limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended).
Éire	Code of Practice Chemical Agent Regulations 2011.
OEL EU	Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC.
TLV-ACGIH	ACGIH 2012

ETHYL SILICATE

Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
OEL	IRL	85	10	255	30
TLV-ACGIH		85	10		

Predicted no-effect concentration - PNEC.

Normal value for the terrestrial compartment	0,05	mg/kg
Normal value in fresh water	10	mg/l
Normal value in marine water	0,019	mg/l
Normal value for fresh water sediment	0,83	mg/kg
Normal value for marine water sediment	0,083	mg/kg
Normal value of STP microorganisms	4000	mg/l

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Skin.	VND	3 mg/kg/d	VND	3 mg/kg/d	VND	56 mg/kg/d	VND	56 mg/kg/d

TRIMETHOXYVINYL SILANE

Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm

Predicted no-effect concentration - PNEC.

Normal value in fresh water	3,4	mg/l
Normal value in marine water	0,034	mg/l

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation.	VND	93,4 mg/m3	VND	1,04 mg/m3			VND	4,9 mg/m3
Skin.	VND	26,9 mg/kg/d	VND	0,3 mg/kg/d			VND	0,69 mg/m3



DIOCTYL TIN OXIDE

Threshold Limit Value.

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm			
Predicted no-effect concentration - PNEC.						0,0000018	mg/l	
Normal value in fresh water						0,000018	mg/l	
Normal value in marine water						0,0000018	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.			VND	0,0005 mg/kg/d				
Inhalation.			VND	0,0009 mg/m3		VND		0,004 mg/m3
Skin.			VND	0,025 mg/kg/d		VND		0,05 mg/kg/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 protection equipment, make sure that the workplace is well aired through effective local aspiration. Personal protection equipment must comply with the rules in force indicated below.

HAND PROTECTION

Protect hands with category II (ref. Directive 89/686/EEC and standard EN 374) work gloves, such as those in PVC, neoprene, nitril or equivalent. The following should be considered when choosing work glove material: degradation, breakage times and permeation. Work glove resistance to preparations should be checked before use, as it can be unpredictable. Gloves` limit depends on the duration of exposure.

EYE PROTECTION

Wear protective airtight goggles (ref. standard EN 166).

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (ref. Directive 89/686/CEE and standard EN 344). Wash body with soap and water after removing overalls.

RESPIRATORY PROTECTION

If the threshold value (if available) for one or more of the substances present in the preparation for daily exposure in the workplace or to a fraction established by the company`s prevention and protection service is exceeded, wear a mask with an A or universal filter, the class (1, 2 or 3) of which must be chosen according to the limit concentration of use (ref. standard EN 141).

The use of respiratory tract protection equipment, such as masks like that indicated above, is necessary to reduce worker exposure in the absence of technical measures. The protection provided by masks is in any case limited.

If the substance in question is odourless or its olfactory threshold is higher than the relative exposure limit and in the event of an emergency, or when exposure levels are unknown or the concentration of oxygen in the workplace is less than 17% volume, wear self-contained, open-circuit compressed air breathing apparatus (ref. standard EN 137) or fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece (ref. standard EN 138).

An emergency eye washing and shower system must be provided.

The product must be used in well-aired environments fitted with strong localised aspiration systems, otherwise to use the personal protection equipment indicated.

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.



Exposure levels must be kept as low as possible to avoid significant build-up in the organism; consequently, personal protective equipment must be managed so as to guarantee maximum protection (e.g. by reducing the replacement times for used PPE).

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.

Appearance	gel
Colour	light blue
Odour	mint
Odour threshold.	Not available.
pH.	Not available.
Melting point / freezing point.	Not available.
Initial boiling point.	108 °C.
Boiling range.	Not available.
Flash point.	32 °C.
Evaporation Rate	NA
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.	Not available.
Solubility	insoluble in water
Partition coefficient: n-octanol/water	NA
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.

The vapours may also form explosive mixtures with the air.



10.4. Conditions to avoid.

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

10.5. Incompatible materials.

Information not available.

10.6. Hazardous decomposition products.

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

SECTION 11. Toxicological information.

11.1. Information on toxicological effects.

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.

This product must be handled carefully because of its possible teratogenic effects, which may be toxic and damage the foetus development.

This product may cause functional disorders or morphological mutations after repeated or prolonged exposure and/or may accumulate inside the human body and is thus graded as dangerous.

Acute effects: stinging eyes. Symptoms may include: rubescence, edema, pain and lachrymation.

Vapour inhalation may moderately irritate the upper respiratory tract. Contact with skin may cause slight irritation.

Ingestion may cause health problems, including stomach pain and sting, nausea and sickness.

DIOCTYL TIN OXIDE

LD50 (Oral). > 2500 mg/kg (rat, MSDS supplier)

Repeated dose toxicity: affected organ Thymus (OECD 422, GLP, rat, dossier ECHA)

Toxicity to reproduction: positive (OECD 422, GLP, rat, dossier ECHA)

ETHYL SILICATE

LC50 (Inhalation). < 16 mg/l/4h (OECD 403, rat, 4h, MSDS supplier)

TRIMETHOXYVINYL SILANE

LD50 (Oral). 7120 mg/kg (OECD 401, rat, MSDS supplier)

LD50 (Dermal). 3540 mg/kg (rabbit, MSDS supplier)

LC50 (Inhalation). 16,8 mg/l/4h (OECD 403, rat, 4h, dossier ECHA)

SECTION 12. Ecological information.

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

12.1. Toxicity.

TRIMETHOXYVINYL SILANE

EC50 (48h) - for Crustacea

168,7 mg/l Daphnia

12.2. Persistence and degradability.

ETHYL SILICATE

Rapidly biodegradable.

TRIMETHOXYVINYL SILANE



Rapidly biodegradable.

DIOCTYL TIN OXIDE

NOT rapidly biodegradable.

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 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.

Avoid littering. Do not contaminate soil, sewers and waterways.

CONTAMINATED PACKAGING

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

SECTION 14. Transport information.

These goods must be transported by vehicles authorized to the carriage of dangerous goods according to the provisions set out in the current edition of the Code of International Carriage of Dangerous Goods by Road (ADR) and in all the applicable national regulations. These goods must be packed in their original packagings or in packagings made of materials resistant to their content and not reacting dangerously with it. People loading and unloading dangerous goods must be trained on all the risks deriving from these substances and on all actions that must be taken in case of emergency situations.

Road and rail transport:



ADR/RID Class:	3	UN:	1993
Packing Group:	III		
Label:	3		
Limited Quantity:	3L, 30 kg		
Proper Shipping Name:	FLAMMABLE LIQUID, N.O.S. (ethyl silicate, vinyltrimethoxyvinylsilane)		

Carriage by sea (shipping):



IMO Class:	3	UN:	1993
Packing Group:	III		
Label:	3		



EMS: F-E, S-E
Marine Pollutant. NO
Proper Shipping Name: FLAMMABLE LIQUID, N.O.S. (ethyl silicate, vinyltrimethoxyvinylsilane)

Transport by air:



IATA: 3 UN: 1993
Packing Group: III
Label: 3
Cargo:
Packaging instructions: Y341 Maximum quantity: 0,5L, 1L
Pass.:
Packaging instructions: Y341 Maximum quantity: 0,5L, 1L
Proper Shipping Name: FLAMMABLE LIQUID, N.O.S. (ethyl silicate, vinyltrimethoxyvinylsilane)

SECTION 15. Regulatory information.

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

Seveso category. 6

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

Product.

Point. 3 - 40

Contained substance.

Point. 20 DIOCTYL TIN OXIDE

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 689/2008:

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.

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. 3	Flammable liquid, category 3
Repr. 2	Reproductive toxicity, category 2
Acute Tox. 4	Acute toxicity, category 4
STOT RE 1	Specific target organ toxicity - repeated exposure, category 1
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
Eye Irrit. 2	Eye irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
H226	Flammable liquid and vapour.
H361d	Suspected of damaging the unborn child.
H332	Harmful if inhaled.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

R10	FLAMMABLE.
R20	HARMFUL BY INHALATION.
R36/37	IRRITATING TO EYES AND RESPIRATORY SYSTEM.
R48/22	HARMFUL: DANGER OF SERIOUS DAMAGE TO HEALTH BY PROLONGED EXPOSURE IF SWALLOWED.
R48/25	TOXIC: DANGER OF SERIOUS DAMAGE TO HEALTH BY PROLONGED EXPOSURE IF SWALLOWED.
Repr. Cat. 3	Reproductive toxicity, development, category 3.
R63	POSSIBLE RISK OF HARM TO THE UNBORN CHILD.

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.

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. Regulation (EC) 286/2011 (II Atp. CLP) of the European Parliament
8. The Merck Index. - 10th Edition
9. Handling Chemical Safety
10. Niosh - Registry of Toxic Effects of Chemical Substances
11. INRS - Fiche Toxicologique (toxicological sheet)
12. Patty - Industrial Hygiene and Toxicology
13. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
14. 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.

Changes to previous review:

The following sections were modified:

02 / 03 / 04 / 08 / 11 / 12 / 16.