VANNINI DENTAL INDUSTRY

# Safety Data Sheet
# PROTESIL CATALYST GEL LAB

## Revision nr. 2
## Dated 08/11/2023

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

**1.1. Product identifier**

Mixture identification:

Product Name: PROTESIL CATALYST GEL LAB

Code: 056025 - 057021 - 057022 - 057023

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

For professional use only. Catalyst for condensation silicone for the dental lab.

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

Name
Vannini Dental Industry S.r.l.
Via di Campigliano 55/a
50012 Grassina (FI)
Italy
tel. +39 055-644698

Competent person responsible for the safety data sheet:
info@vanninidental.com

**1.4. Emergency telephone number**

UK Emergency number: 999 (24 hours)

## SECTION 2: Hazards identification

**2.1. Classification of the substance or mixture**

EC regulation criteria 1272/2008 (CLP)

Skin Irrit. 2, H315 Causes skin irritation.
STOT RE 2, H373 May cause damage to organs (blood) through prolonged or repeated exposure if swallowed.

Adverse physicochemical, human health and environmental effects:

No other hazards

**2.2. Label elements**

Hazard pictograms:



Warning

Hazard statements:

H315 Causes skin irritation.
H373 May cause damage to organs (blood) through prolonged or repeated exposure if swallowed.

Precautionary statements:

P264 Wash hands thoroughly after handling.
P280 Wear protective gloves.
P314 Get medical advice/attention if you feel unwell.

Special Provisions:

None

Contains

Tetrakis(2-butoxyethyl)orthosilicate

Special provisions according to Annex XVII of REACH and subsequent amendments:
None

**2.3. Other hazards**
No PBT, vPvB or endocrine disruptor substances present in concentration >= 0.1%
Other Hazards:
No other hazards

## SECTION 3: Composition/information on ingredients

**3.1. Substances**
Not Applicable

**3.2. Mixtures**
Hazardous components within the meaning of the CLP regulation and related classification:

| Qty | Name | Ident. Number | Classification |
|---|---|---|---|
| >= 25% - < 30% | Tetrakis(2-butoxyethyl) orthosilicate | CAS: 18765-38-3<br>EC: 242-560-0<br>REACH No.: 01-21207615 33-55-XXXX | STOT RE 2 H373 May cause damage to organs (blood) through prolonged or repeated exposure if swallowed.<br>Skin Irrit. 2 H315 Causes skin irritation. |
| >= 3% - < 5% | Dioctyltin oxide | CAS: 870-08-6<br>EC: 212-791-1<br>REACH No.: 01-21199712 68-27-XXXX | STOT SE 2 H371 May cause damage to organs (immune system) if swallowed. |

## SECTION 4: First aid measures

**4.1. Description of first aid measures**
In case of skin contact:
Immediately take off all contaminated clothing.
Areas of the body that have - or are only even suspected of having - come into contact with the product must be rinsed immediately with plenty of running water and possibly with soap.
Wash thoroughly the body (shower or bath).
Remove contaminated clothing immediatley and dispose off safely.
After contact with skin, wash immediately with soap and plenty of water.
In case of eyes contact:
After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an opthalmologist immediately.
Protect uninjured eye.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
In case of Ingestion:
Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.
In case of Inhalation:
Remove casualty to fresh air and keep warm and at rest.

**4.2. Most important symptoms and effects, both acute and delayed**
None

**4.3. Indication of any immediate medical attention and special treatment needed**
In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).
Treatment:
None

## SECTION 5: Firefighting measures

**5.1. Extinguishing media**

Suitable extinguishing media:
Water.
Carbon dioxide (CO2).
Extinguishing media which must not be used for safety reasons:
None in particular.

**5.2. Special hazards arising from the substance or mixture**

Do not inhale explosion and combustion gases.
Burning produces heavy smoke.

**5.3. Advice for firefighters**

Use suitable breathing apparatus .
Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Move undamaged containers from immediate hazard area if it can be done safely.

## SECTION 6: Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**

For non emergency personnel:
Wear personal protection equipment.
Remove persons to safety.
See protective measures under point 7 and 8.
For emergency responders:
Wear personal protection equipment.

**6.2. Environmental precautions**

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.
Retain contaminated washing water and dispose it.
In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.
Suitable material for taking up: absorbing material, organic, sand

**6.3. Methods and material for containment and cleaning up**

Wash with plenty of water.

**6.4. Reference to other sections**

See also section 8 and 13

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling**

Avoid contact with skin and eyes, inhalation of vapours and mists.
Don't use empty container before they have been cleaned.
Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.
See also section 8 for recommended protective equipment.
Advice on general occupational hygiene:
Contamined clothing should be changed before entering eating areas.
Do not eat or drink while working.

**7.2. Conditions for safe storage, including any incompatibilities**

Keep away from food, drink and feed.
Incompatible materials:
See section 10.5.
Instructions as regards storage premises:
Adequately ventilated premises.

**7.3. Specific end use(s)**

See section 1.2.

## SECTION 8: Exposure controls/personal protection

**8.1. Control parameters**

PROTESIL CATALYST GEL LAB

Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3

| OEL Type | TWA | | Duration | STEL | | Duration | Notes | Country |
|---|---|---|---|---|---|---|---|---|
| No data available | | | | | | | | |

Dioctyltin oxide - CAS: 870-08-6

| OEL Type | TWA | | Duration | STEL | | Duration | Notes | Country |
|---|---|---|---|---|---|---|---|---|
| AGW | 0.01 mg/m3 | 0.002 ppm | 8h | 0.02 mg/m3 | 0.004 ppm | 15min | Inhalable fraction and vapour | GERMANY |

DNEL Exposure Limit Values

Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3

Consumer: 12.5 mg/kg bw/d - Exposure: Human Oral - Frequency: Long Term, systemic effects
Consumer: 10.9 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic effects
Worker Professional: 44 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic effects
Consumer: 12.5 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects
Worker Professional: 25 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

Dioctyltin oxide - CAS: 870-08-6

Consumer: 0.0005 mg/kg bw/d - Exposure: Human Oral - Frequency: Long Term, systemic effects
Consumer: 0.025 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects
Consumer: 0.0009 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

PNEC Exposure Limit Values

Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3

Target: Fresh Water - Value: 10 mg/l
Target: Marine water - Value: 1 mg/l
Target: Freshwater sediments - Value: 63.6 mg/kg
Target: Marine water sediments - Value: 6.4 mg/kg
Target: Microorganisms in sewage treatments - Value: 463 mg/l
Target: Soil (agricultural) - Value: 0.57 mg/kg

**8.2. Exposure controls**

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.

Eye protection:

Wear airtight protective goggles (EN 166).

Protection for skin:

Wear professional overalls and safety footwear (EN 14605).

Protection for hands:

Permeation resistant gloves A H J in PVA or fluorinated rubber (EN 374).

The following should be considered when choosing work glove material (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.

Respiratory protection:

Mask with a type AP filter
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 (e.g. TLV-TWA).

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

| Properties | Value | Method: | Notes |
|---|---|---|---|
| Physical state: | Putty | -- | -- |
| Colour: | Red | -- | -- |
| Odour: | Characteristic | -- | -- |
| Melting point/freezing point: | Not available | -- | -- |
| Boiling point or initial boiling point and boiling range: | Not available | -- | -- |
| Flammability: | Not available | -- | -- |
| Lower and upper explosion limit: | Not available | -- | -- |
| Flash point: | >100 ° C | EN ISO 3679 | -- |
| Auto-ignition temperature: | Not available | -- | -- |
| Decomposition temperature: | Not available | -- | -- |
| pH: | Not Relevant | -- | -- |
| Kinematic viscosity: | Not available | -- | -- |
| Solubility in water: | Insoluble | -- | -- |
| Solubility in oil: | Not available | -- | -- |
| Partition coefficient n-octanol/water (log value): | Not Relevant | -- | -- |
| Vapour pressure: | Not available | -- | -- |
| Density and/or relative density: | 0.95 g/cm3 (@23°C) | -- | -- |
| Relative vapour density: | Not available | -- | -- |
| Particle characteristics: | | | |
| Particle size: | Not available | -- | -- |

### 9.2. Other information

No other relevant information

## SECTION 10: Stability and reactivity

**10.1. Reactivity**
Stable under normal conditions
**10.2. Chemical stability**
Stable under normal conditions
**10.3. Possibility of hazardous reactions**
The vapours may also form explosive mixtures with the air.
**10.4. Conditions to avoid**
Avoid moisture and high temperature.
**10.5. Incompatible materials**
Water
Avoid contact with strong oxidizing materials.
**10.6. Hazardous decomposition products**
May develop: 2-Butoxyethanol.

## SECTION 11: Toxicological information

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

Toxicological information of the product:
PROTESIL CATALYST GEL LAB
a) acute toxicity
Not classified

b) skin corrosion/irritation
The product is classified: Skin Irrit. 2 H315
c) serious eye damage/irritation
Not classified

d) respiratory or skin sensitisation
Not classified

e) germ cell mutagenicity
Not classified

f) carcinogenicity
Not classified

g) reproductive toxicity
Not classified

h) STOT-single exposure
Not classified

i) STOT-repeated exposure
The product is classified: STOT RE 2 H373
j) aspiration hazard
Not classified

Toxicological information of the main substances found in the product:
Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3
a) acute toxicity:
Test: LD50 - Route: Skin - Species: Rat > 2000 mg/kg - Source: (OECD TG 402, MSDS supplier).

Test: LD50 - Route: Oral - Species: Rat > 2000 mg/kg - Source: (OECD TG 401, MSDS supplier).

b) skin corrosion/irritation:

Species: Rabbit - Skin Irritant - Source: (OECD 404, MSDS supplier).

c) serious eye damage/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met - Source: (OECD 405, MSDS supplier).

d) respiratory or skin sensitisation:

Test: Skin Sensitization - Species: Rat - Based on available data, the classification criteria are not met - Source: (OECD 406, Buehler test, MSDS supplier).

e) germ cell mutagenicity:

Test: In vitro - Negative - Source: (OECD 471, 490, OECD 473, MSDS supplier).

g) reproductive toxicity:

Route: Oral - Species: Rat - Based on available data, the classification criteria are not met - Source: (OECD 422, MSDS supplier).

i) STOT-repeated exposure:

Test: NOAEL - Route: Oral - Species: Rat 25 mg/kg - Notes: Target organ: blood. - Positive - Source: (OECD 422, MSDS supplier).

Dioctyltin oxide - CAS: 870-08-6

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Rat > 2500 mg/kg - Source: (MSDS supplier)

**11.2. Information on other hazards**

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration >= 0.1%

## SECTION 12: Ecological information

**12.1. Toxicity**

Adopt good working practices, so that the product is not released into the environment.

PROTESIL CATALYST GEL LAB

Not classified for environmental hazards

Based on available data, the classification criteria are not met

Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3

a) Aquatic acute toxicity:

Endpoint: LC50 - Species: Fish > 201 mg/l - Duration h: 96h (Danio rerio, MSDS supplier).

Endpoint: EC50 - Species: Daphnia > 90 mg/l - Duration h: 48h (Daphnia magna, MSDS supplier).

b) Aquatic chronic toxicity:

Endpoint: NOEC - Species: Fish > 100 mg/l - Duration h: 21d (Danio rerio, MSDS supplier).

Endpoint: NOEC - Species: Daphnia 100 mg/l - Duration h: 21d (Daphnia magna, MSDS supplier).

Dioctyltin oxide - CAS: 870-08-6

a) Aquatic acute toxicity:

Endpoint: EC50 - Species: Daphnia > 0.21 mg/l - Duration h: 48h (Daphnia magna, Immobilisation Test, MSDS supplier).

Endpoint: LC50 - Species: Fish > 0.09 mg/l - Duration h: 96h (Brachydanio rerio, MSDS supplier).

Endpoint: EC50 - Species: .Bacteria > 1000 mg/l - Duration h: 3h (Activated Sludge, Respiration Inhibition Test), MSDS supplier

**12.2. Persistence and degradability**

Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3

Biodegradability: Readily biodegradable

Dioctyltin oxide - CAS: 870-08-6

Biodegradability: Non-readily biodegradable

**12.3. Bioaccumulative potential**
Not available
**12.4. Mobility in soil**
Not available
**12.5. Results of PBT and vPvB assessment**
vPvB Substances: None - PBT Substances: None
**12.6. Endocrine disrupting properties**
No endocrine disruptor substances present in concentration >= 0.1%
**12.7. Other adverse effects**
None

## SECTION 13: Disposal considerations

**13.1. Waste treatment methods**
Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force.

## SECTION 14: Transport information

**14.1. UN number or ID number**
Not classified as dangerous in the meaning of transport regulations.
**14.2. UN proper shipping name**
Not available
**14.3. Transport hazard class(es)**
Not available
**14.4. Packing group**
Not available
**14.5. Environmental hazards**
ADR-Enviromental Pollutant: No
IMDG-Marine pollutant: No
**14.6. Special precautions for user**
Not available
**14.7. Maritime transport in bulk according to IMO instruments**
Not Applicable

## SECTION 15: Regulatory information

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**
Dir. 98/24/EC (Risks related to chemical agents at work)
Dir. 2000/39/EC (Occupational exposure limit values)
Regulation (EC) n. 1907/2006 (REACH)
Regulation (EC) n. 1272/2008 (CLP)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) n. 2020/878
Regulation (EU) n. 286/2011 (ATP 2 CLP)
Regulation (EU) n. 618/2012 (ATP 3 CLP)
Regulation (EU) n. 487/2013 (ATP 4 CLP)
Regulation (EU) n. 944/2013 (ATP 5 CLP)
Regulation (EU) n. 605/2014 (ATP 6 CLP)
Regulation (EU) n. 2015/1221 (ATP 7 CLP)
Regulation (EU) n. 2016/918 (ATP 8 CLP)
Regulation (EU) n. 2016/1179 (ATP 9 CLP)
Regulation (EU) n. 2017/776 (ATP 10 CLP)
Regulation (EU) n. 2018/669 (ATP 11 CLP)
Regulation (EU) n. 2018/1480 (ATP 13 CLP)
Regulation (EU) n. 2019/521 (ATP 12 CLP)

Regulation (EU) n. 2020/217 (ATP 14 CLP)
Regulation (EU) n. 2020/1182 (ATP 15 CLP)
Regulation (EU) n. 2021/643 (ATP 16 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:
Restriction 3

Restrictions related to the substances contained:
Restriction 20
Restriction 75

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1
None

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)
WGK1 - Slightly hazardous for water

Lagerklasse according to TRGS 510:
LGK 10: Combustible liquids

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
Dioctyltin oxide.

California Proposition 65
Substance(s) listed under California Proposition 65:
None.

**15.2. Chemical safety assessment**

No Chemical Safety Assessment has been carried out for the mixture.
Substances for which a Chemical Safety Assessment has been carried out:
Dioctyltin oxide

## SECTION 16: Other information

| Hazard class and hazard category | Code | Description |
|---|---|---|
| Skin Irrit. 2 | 3.2/2 | Skin irritation, Category 2 |
| STOT SE 2 | 3.8/2 | Specific target organ toxicity - single exposure, Category 2 |
| STOT RE 2 | 3.9/2 | Specific target organ toxicity - repeated exposure, Category 2 |

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

| Classification according to Regulation (EC) Nr. 1272/2008 | Classification procedure |
|---|---|
| Skin Irrit. 2, H315 | Calculation method |
| STOT RE 2, H373 | Calculation method |

This document was prepared by a competent person who has received appropriate training.
Main bibliographic sources:
ECHA – European Chemical Agency

GESTIS - Information system on hazardous substances of the German Social Accident Insurance
IARC – International Agency for Research on Cancer
IPCS INCHEM – International Programme on Chemical Safety
ISS – Istituto Superiore di Sanità
PubChem - open chemistry database at the National Institutes of Health (NIH)

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.
It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.
This MSDS cancels and replaces any preceding release.

| | |
|---|---|
| ADR: | European Agreement concerning the International Carriage of Dangerous Goods by Road. |
| ATE: | Acute Toxicity Estimate |
| ATEmix: | Acute toxicity Estimate (Mixtures) |
| CAS: | Chemical Abstracts Service (division of the American Chemical Society). |
| CLP: | Classification, Labeling, Packaging. |
| DNEL: | Derived No Effect Level. |
| EINECS: | European Inventory of Existing Commercial Chemical Substances. |
| GefStoffVO: | Ordinance on Hazardous Substances, Germany. |
| GHS: | Globally Harmonized System of Classification and Labeling of Chemicals. |
| IATA: | International Air Transport Association. |
| IATA-DGR: | Dangerous Goods Regulation by the "International Air Transport Association" (IATA). |
| ICAO: | International Civil Aviation Organization. |
| ICAO-TI: | Technical Instructions by the "International Civil Aviation Organization" (ICAO). |
| IMDG: | International Maritime Code for Dangerous Goods. |
| INCI: | International Nomenclature of Cosmetic Ingredients. |
| KSt: | Explosion coefficient. |
| LC50: | Lethal concentration, for 50 percent of test population. |
| LD50: | Lethal dose, for 50 percent of test population. |
| PNEC: | Predicted No Effect Concentration. |
| RID: | Regulation Concerning the International Transport of Dangerous Goods by Rail. |
| STEL: | Short Term Exposure limit. |
| STOT: | Specific Target Organ Toxicity. |
| TLV: | Threshold Limiting Value. |
| TWA: | Time-weighted average |
| WGK: | German Water Hazard Class. |