VANNINI DENTAL INDUSTRY

Safety Data Sheet
PROTESIL ELASTIC-RAPID

Revision nr. 4
Dated 15/09/2023

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

1.1. Product identifier

Mixture identification:

Product Name: PROTESIL ELASTIC-RAPID

Code: 005002 - 005001 - 005004

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

For professional use only. Alginate for dental impression.

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)

STOT RE 2, H373 May cause damage to organs (lungs) through prolonged or repeated exposure if inhaled.

Adverse physicochemical, human health and environmental effects:

No other hazards

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 pictograms:



Warning

Hazard statements:

H373 May cause damage to organs (lungs) through prolonged or repeated exposure if inhaled.

Precautionary statements:

P260 Do not breathe dust.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314 Get medical advice/attention if you feel unwell.

Special Provisions:

None

Contains

Cristobalite

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

2.3. Other hazards

Classification of the mixture is based on the results of an in vitro assay conducted in accordance with the guidelines provided by OCSE (OECD Test Guideline 437 resp. EU Method B.47 – Bovine Corneal Opacity and Permeability (BCOP) Test Method) and GLP certified - Good Laboratory Practices. For more information refer to section 11.

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
>= 5% - < 8%	Cristobalite	CAS: 14464-46-1 EC: 238-455-4	STOT RE 1 H372 Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled.
>= 1% - < 3%	Dipotassium exafluorotitanate	CAS: 16919-27-0 EC: 240-969-9 REACH No.: 01-21199782 68-20-XXXX	Acute Tox. 4 H302 Harmful if swallowed. Eye Dam. 1 H318 Causes serious eye damage. Acute Toxicity Estimate: ATE - Oral 324 mg/kg bw
>= 0,5% - < 2,5%	Paraffin oil	CAS: 8042-47-5 EC: 232-455-8 REACH No.: 01-21194870 78-27-XXXX	Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.

Substances in nanoform:
>= 1% - < 3% Dipotassium exafluorotitanate
REACH No.: 01-2119978268-20-XXXX, CAS: 16919-27-0, EC: 240-969-9

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:
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 with plenty of water and soap.
Wash thoroughly the body (shower or bath).
Remove contaminated clothing immediatley and dispose off safely.
In case of eyes contact:
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
In case of Ingestion:

Do NOT induce vomiting.

In case of Inhalation:

If breathing is irregular or stopped, administer artificial respiration.

In case of inhalation, consult a doctor immediately and show the packing or label.

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.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Provide adequate ventilation.

Use appropriate respiratory protection.

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.

Use localized ventilation system.

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 ELASTIC-RAPID
Cristobalite - CAS: 14464-46-1

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
EU	0.1 mg/m3		8h				Respirable	
TLV	0.1 mg/m3		8h				Respirable	ITALY
ACGIH	0.025 mg/m3		8h				(R), A2 - Pulm fibrosis, lung cancer	

Dipotassium exafluorotitanate - CAS: 16919-27-0

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
No data available								

Paraffin oil - CAS: 8042-47-5

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
AGW	5 mg/m3		8h	20 mg/m3		15min	Respirable	GERMANY
MAK	5 mg/m3		8h	20 mg/m3		15min	Respirable	GERMANY
TLV	5 mg/m3		8h	10 mg/m3		15min		ROMANIA
MAK	5 mg/m3		8h				Inhalable	SWITZERLAND

DNEL Exposure Limit Values

Dipotassium exafluorotitanate - CAS: 16919-27-0

Worker Professional: 5.2 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, local effects

Worker Professional: 5.2 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic effects
Worker Professional: 5.2 mg/m3 - Exposure: Human Inhalation - Frequency: Short Term, systemic effects
Worker Professional: 75 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects
Worker Professional: 75 mg/kg bw/d - Exposure: Human Dermal - Frequency: Short Term, systemic effects
Consumer: 37.5 mg/kg bw/d - Exposure: Human Dermal - Frequency: Short Term, systemic effects
Consumer: 37.5 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

Paraffin oil - CAS: 8042-47-5

Consumer: 93 mg/kg/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects
Consumer: 35 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic effects
Consumer: 40 mg/kg/d - Exposure: Human Oral - Frequency: Long Term, systemic effects
Worker Professional: 220 mg/kg/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects
Worker Professional: 160 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

PNEC Exposure Limit Values

Dipotassium exafluorotitanate - CAS: 16919-27-0

Target: Fresh Water - Value: 0.131 mg/l
Target: Marine water - Value: 0.131 mg/l
Target: Freshwater sediments - Value: 24.45 03
Target: Marine water sediments - Value: 4.89 03
Target: Microorganisms in sewage treatments - Value: 1.5 mg/l
Target: Soil (agricultural) - Value: 19.1 mg/kg
Target: intermittent release - Value: 0.108 mg/l

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:

Protect hands with work gloves (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:

Use respiratory protection where ventilation is insufficient or exposure is prolonged.
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:	Dust	--	--
Colour:	Pink	--	--
Odour:	strawberry	--	--
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:	Not available	--	--
Auto-ignition temperature:	Not available	--	--
Decomposition temperature:	Not available	--	--
pH:	Not available	--	--
Kinematic viscosity:	Not available	--	--
Solubility in water:	Partially soluble	--	--
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or relative density:	Not available	--	--
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

None

10.4. Conditions to avoid

Stable under normal conditions.

10.5. Incompatible materials

None in particular.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

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

Toxicological information of the product:

PROTESIL ELASTIC-RAPID

a) acute toxicity

Not classified

b) skin corrosion/irritation

Not classified

c) serious eye damage/irritation

Not classified

Test: In vitro - (INTERNAL TEST Bridging Principle, OECD 437 resp. EU Method B.47, GLP, in vitro, study report 2014).

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:

Cristobalite - CAS: 14464-46-1

i) STOT-repeated exposure:

Route: Inhalation - Notes: Silicosis, pulmonary fibrosis; Target organ: lungs - Source: (MSDS supplier).

Dipotassium exafluorotitanate - CAS: 16919-27-0

a) acute toxicity

ATE - Oral 324 mg/kg bw

Test: LD50 - Route: Oral - Species: Rat 324 mg/kg - Source: (OECD 401, ECHA dossier).

b) skin corrosion/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met - Source: (OECD 404, MSDS supplier).

c) serious eye damage/irritation:

Species: Rabbit - Eye Corrosive - Source: (OECD 405, MSDS supplier).

d) respiratory or skin sensitisation:

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

e) germ cell mutagenicity:

Test: In vitro - Species: Salmonella Typhimurium - Negative - Source: (OECD 471, MSDS supplier).

Test: In vitro - Positive - Source: (OECD 487, MSDS supplier).

Test: In vitro - Negative - Source: (OECD 476, MSDS supplier).
Test: In vivo - Species: Rat - Negative - Source: (OECD 474, MSDS supplier).

Paraffin oil - CAS: 8042-47-5

a) acute toxicity:

Test: LC50 - Route: Inhalation - Species: Rat > 5 mg/l - Duration: 4h - Source: (OECD 403, ECHA dossier).
Test: LD50 - Route: Skin - Species: Rabbit > 2000 mg/kg - Source: (similar or equvalent to OECD 402, ECHA dossier).
Test: LD50 - Route: Oral - Species: Rat > 5000 mg/kg - Source: (similar or equivalent to OECD 401, ECHA dossier).

j) aspiration hazard:

Positive - 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 ELASTIC-RAPID

Not classified for environmental hazards
Based on available data, the classification criteria are not met

Dipotassium exafluorotitanate - CAS: 16919-27-0

a) Aquatic acute toxicity:

Endpoint: LC50 - Species: Fish 172 mg/l - Duration h: 96h (OECD 203, Danio rerio, ECHA dossier).
Endpoint: EC50 - Species: Daphnia 48.2 mg/l - Duration h: 48h (OECD 203, Daphnia magna, ECHA dossier).
Endpoint: IC50 - Species: Algae 10.81 mg/l - Duration h: 72h (OECD 201, Pseudokirchneriella subcapitata, ECHA dossier).
Endpoint: NOEC - Species: Algae 1.31 mg/l (OECD 201, Pseudokirchneriella subcapitata, ECHA dossier).

12.2. Persistence and degradability

Cristobalite - CAS: 14464-46-1

Biodegradability: Non-readily biodegradable

Dipotassium exafluorotitanate - CAS: 16919-27-0

Biodegradability: Non-readily biodegradable

Paraffin oil - CAS: 8042-47-5

Biodegradability: Persistent and Biodegradable

12.3. Bioaccumulative potential

Cristobalite - CAS: 14464-46-1

Not bioaccumulative

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
Restriction 40

Restrictions related to the substances contained:
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)

Lagerklasse according to TRGS 510:
LGK 10: Combustible liquids

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
None.

California Proposition 65
Substance(s) listed under California Proposition 65:
Cristobalite - Listed as carcinogen.

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:
Dipotassium exafluorotitanate

SECTION 16: Other information

Hazard class and hazard category	Code	Description
Acute Tox. 4	3.1/4/Oral	Acute toxicity (oral), Category 4
Asp. Tox. 1	3.10/1	Aspiration hazard, Category 1
Eye Dam. 1	3.3/1	Serious eye damage, Category 1
STOT RE 1	3.9/1	Specific target organ toxicity - repeated exposure, Category 1
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
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)

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 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.

Safety Data Sheet
PROTESIL ELASTIC-RAPID

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.