

Safety Data Sheet
in accordance with HSNO

Printing date 22.09.2020

Version number 1

Revision: 22.09.2020

1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** ***Proxyl Medium, Coarse (New Formula)***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** *Paste for professional tooth cleaning*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*Ivoclar Vivadent AG
Bendererstrasse 2
9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
Tel: +423 235 35 35 / Fax: +423 235 33 60*
- **Importer:**
*Ivoclar Vivadent Ltd.
12 Omega St, Rosedale, Auckland
New Zealand
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990*
- **Further information obtainable from:**
*Regulatory Affairs
sds@ivoclarvivadent.com*
- **Emergency telephone number:** 0800 764 766 (*National Poison Centre - 24 hours / 7 days*)

2 Hazards identification

- **Classification of the substance or mixture**
Acute Tox. 5 H333 May be harmful if inhaled.

- **Label elements**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms** *Void*
- **Signal word** *Warning*
- **Hazard statements**
May be harmful if inhaled.
- **Precautionary statements**
IF INHALED: Call a POISON CENTER/doctor if you feel unwell.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

3 Composition/Information on ingredients

- **Chemical characterisation:** *Mixtures*
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

· **Dangerous components:**

CAS: 56-81-5	glycerol	25-50%
EINECS: 200-289-5		

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CAS: 13463-67-7 EINECS: 236-675-5	titanium dioxide Acute Tox. 5, H333	<2.5%
CAS: 151-21-3 EINECS: 205-788-1	sodium dodecyl sulphate Flam. Sol. 1, H228; Acute Tox. 3, H311; Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335	<2.5%
CAS: 7681-49-4 EINECS: 231-667-8	sodium fluoride Acute Tox. 3, H301; Skin Irrit. 2, H315; Eye Irrit. 2, H319	<2.5%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**
Supply fresh air or oxygen; call for doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**
Rinse opened eye for several minutes under running water. Then consult a doctor.
Mechanical effects only.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** CO₂, powder or water spray. Fight larger fire with alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.

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For use in dentistry only.

Prevent formation of aerosols.

- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 56-81-5 glycerol

WES	Long-term value: 10 mg/m ³ mist
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- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
 - Usual hygienic measures for dental practice and dental laboratories.
 - Keep away from foodstuffs, beverages and feed.
 - Wash hands before breaks and at the end of work.
 - Avoid contact with the eyes and skin.
 - Do not inhale gases / fumes / aerosols.
- **Respiratory protection:** Use respiratory protective device against the effects of fumes/dust/aerosol.
- **Protection of hands:** Not required.
- **Material of gloves -**
- **Penetration time of glove material -**
- **Eye protection:** Not required.

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Pasty
Colour:	Different according to colouring
Odour:	like peppermint
Odour threshold:	Not determined.
- **pH-value:** Not determined.
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.

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· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Partly miscible.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:** No further relevant information available.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---|--|
| · UN-Number | Void |
| · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · ADR/RID/ADN, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · ADR/RID/ADN, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **New Zealand Inventory of Chemicals**

CAS: 7631-86-9	silicon dioxide, chemically prepared
CAS: 50-70-4	D-glucitol
CAS: 1332-09-8	Bismehl

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CAS: 56-81-5	glycerol
CAS: 87-99-0	xylitol
CAS: 9004-32-4	Carboxymethylcellulose-Natriumsalz
CAS: 13463-67-7	titanium dioxide
CAS: 2379-74-0	C.I. Vat Red 1 Kuepenfarbstoff
CAS: 1328-53-6	C.I. Pigment Green 7
CAS: 147-14-8	Phthalocyanine Blue
CAS: 7681-49-4	sodium fluoride
CAS: 7732-18-5	water, distilled, conductivity or of similar purity

· **HSNO Approval numbers**

CAS: 151-21-3	sodium dodecyl sulphate	HSR003122
CAS: 7681-49-4	sodium fluoride	HSR003112

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms** Void

· **Signal word** Warning

· **Hazard statements**

May be harmful if inhaled.

· **Precautionary statements**

IF INHALED: Call a POISON CENTER/doctor if you feel unwell.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is covered by Regulation (EU) 2017/745 on Medical Devices (MDR).

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H228 Flammable solid.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H333 May be harmful if inhaled.

H335 May cause respiratory irritation.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Sol. 1: Flammable solids – Category 1

Acute Tox. 4: Acute toxicity - oral – Category 4

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Acute Tox. 3: Acute toxicity - dermal – Category 3
Acute Tox. 5: Acute toxicity - inhalation – Category 5
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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