Printing date 26.01.2017

Version number 13

Revision: 26.01.2017

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

· 1.1 Product identifier

- · Trade name: Clean Joy
- 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Prophylaxis paste for professional tooth cleaning and polishing
- \cdot 1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier: VOCO GmbH Anton-Flettner-Str. 1-3 D-27472 Cuxhaven

• Further information obtainable from: Scientific department tel. +49 (0)4721-719-0

• 1.4 Emergency telephone number: Poison Control Center Mainz +49 (0)6131-19240

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

 \cdot Classification according to Regulation (EC) No 1272/2008

Skin Sens. 1 H317 May cause an allergic skin reaction.

· 2.2 Label elements

- · Labelling according to Regulation (EC) No 1272/2008
- As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- · Hazard pictograms GHS07
- · Hazard statements
- May cause an allergic skin reaction.
- · Precautionary statements
- *Wear protective gloves / protective clothing.*
- If skin irritation or rash occurs: Get medical advice/attention.
- Dispose of contents/container in accordance with local/regional/national/international regulations.

· 2.3 Other hazards Use only for intended scope of application

- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

| · Dangerous compon | ents: | | |
|-------------------------------------|-------------------------------------------|-----------------------------------------------------------------------------------------|--------|
| CAS: 61789-40-0 931-296-8 | Tensid TB | Eye Dam. 1, H318 | ≤2.5% |
| | peppermint aroma | Asp. Tox. 1, H304 Aquatic Chronic 2, H411 Skin Irrit. 2, H315; Skin Sens. 1, H317 | ≤ 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 informat | ion · For the wording of the listed hazar | d phrases refer to section 16 | |

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

SECTION 4: First aid measures

• 4.1 Description of first aid measures

- · General information: No special measures required.
- After inhalation: Seek medical treatment in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.

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Trade name: Clean Joy

- · After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

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

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures Not required.

· 6.2 Environmental precautions:

ready-made-solution:

- No special measures required.
- \cdot 6.3 Methods and material for containment and cleaning up:
- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- 6.4 Reference to other sections No dangerous substances are released. See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

 \cdot 7.1 Precautions for safe handling

For dental use only.

No special measures required.

- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: See storage instructions on package

• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

• Additional information: The lists valid during the making were used as basis.

· 8.2 Exposure controls

- · Personal protective equipment:
- · General protective and hygienic measures: Usual protective and hygienic measures for dental practice.

· Respiratory protection: Not required.

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| acci | raing to 1907/2000/EC, Article 51 | |
|----------------------------------------|-------------------------------------|---------------------|
| rinting date 26.01.2017 | Version number 13 | Revision: 26.01.201 |
| rade name: Clean Joy | | |
| | | (Contd. of page 2 |
| · Protection of hands: | | |
| Protective gloves | | |
| • Material of gloves Not applicable. | | |
| | | |
| SECTION 9: Physical and ch | emical properties | |
| • 9.1 Information on basic physical a | und chemical properties | |
| · General Information | | |
| · Appearance: | | |
| Form: | Fluid | |
| Colour: | According to product specification | |
| · Odour: | Characteristic Not determined. | |
| · Odour threshold: | Noi delerminea. | |
| · pH-value at 20 °C: | 7.5 | |
| · Change in condition | | |
| Melting point/Melting range: | Undetermined. | |
| Boiling point/Boiling range: | Undetermined. | |
| · Flash point: | Not applicable. | |
| · Flammability (solid, gaseous): | Not applicable. | |
| · Decomposition temperature: | Not determined. | |
| · Self-igniting: | Product is not selfigniting. | |
| • Danger of explosion: | Product does not present an explosi | ion hazard. |
| · Density: | Not determined. | |
| · Relative density | Not determined. | |
| · Vapour density | Not determined. | |
| · Evaporation rate | Not determined. | |
| · Solubility in / Miscibility with | | |
| water: | Not miscible or difficult to mix. | |
| · Partition coefficient (n-octanol/wat | | |
| · Viscosity: | | |
| Dynamic: | Not determined. | |
| Kinematic: | Not determined. | |
| | | |

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

• 9.2 Other information

• Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

No further relevant information available.

• 10.3 Possibility of hazardous reactions No dangerous reactions known.

• 10.4 Conditions to avoid No further relevant information available.

• 10.5 Incompatible materials: No further relevant information available.

• 10.6 Hazardous decomposition products: No dangerous decomposition products known.

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Trade name: Clean Joy

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation
- May cause an allergic skin reaction.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- *Reproductive toxicity Based on available data, the classification criteria are not met.*
- STOT-single exposure Based on available data, the classification criteria are not met.
- $\cdot \textit{STOT-repeated exposure} \textit{ Based on available data, the classification criteria are not met.}$
- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· 12.1 Toxicity

- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- General notes: Not known to be hazardous to water.
- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- Recommendation Smaller quantities can be disposed of with household waste.
- · Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.

| · 14.1 UN-Number | | |
|-----------------------------------|------|--|
| · ADR, ADN, IMDG, IATA | Void | |
| · 14.2 UN proper shipping name | - | |
| · ADR, ADN, IMDG, IATA | Void | |
| · 14.3 Transport hazard class(es) | - | |
| · ADR, ADN, IMDG, IATA | | |
| · Class | Void | |
| · 14.4 Packing group | - | |
| · ADR, IMDG, IATA | Void | |
| · 14.5 Environmental hazards: | | |
| • Marine pollutant: | No | |

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Safety data sheet according to 1907/2006/EC, Article 31

Not applicable.

Not applicable.

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Trade name: Clean Joy

 14.6 Special precautions for user
 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

· UN "Model Regulation":

SECTION 15: Regulatory information

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

Void

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.

· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

SECTION 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.

· Department issuing SDS: Scientific department

· Contact: Tel.: +49 (0)4721-719-0 · 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 GHS: Globally Harmonised System of Classification and Labelling of Chemicals 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 Acute Tox. 3: Acute toxicity – Category 3 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 Skin Sens. 1: Skin sensitisation – Category 1 Asp. Tox. 1: Aspiration hazard – Category 1 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2 • * Data compared to the previous version altered.

Printing date 15.12.2016

Version number 10

Revision: 15.12.2016

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

· 1.1 Product identifier

· Trade name: Grandio Seal

- 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture fissure sealant
- \cdot 1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier: VOCO GmbH Anton-Flettner-Str. 1-3 D-27472 Cuxhaven

• Further information obtainable from: Scientific department tel. +49 (0)4721-719-0

• 1.4 Emergency telephone number: Poison Control Center Mainz +49 (0)6131-19240

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

 \cdot Classification according to Regulation (EC) No 1272/2008

Skin Sens. 1 H317 May cause an allergic skin reaction.

· 2.2 Label elements

- · Labelling according to Regulation (EC) No 1272/2008
- As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- · Hazard pictograms GHS07
- · Hazard statements

May cause an allergic skin reaction.

- · Precautionary statements
- *Wear protective gloves / protective clothing.*

If skin irritation or rash occurs: Get medical advice/attention.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· 2.3 Other hazards Use only for intended scope of application

- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

| · Dangerous compone | ents: | |
|---------------------|-------------------------------------------------------------|--------|
| | Triethylene glycol dimethacrylate | 10-25% |
| EINECS: 203-652-6 | Skin Sens. 1, H317 | |
| | fumed silica | 5-10% |
| | Acute Tox. 2, H330 | |
| CAS: 1565-94-2 | BIS GMA | 2.5-5% |
| | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 |] |

SECTION 4: First aid measures

• 4.1 Description of first aid measures

· General information: No special measures required.

• After inhalation: Seek medical treatment in case of complaints.

• After skin contact: Generally the product does not irritate the skin.

• After eye contact: Rinse opened eye for several minutes under running water.

• After swallowing: If symptoms persist consult doctor.

• 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

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Revision: 15.12.2016

Trade name: Grandio Seal

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• **4.3 Indication of any immediate medical attention and special treatment needed** No further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

• Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures Not required.

• 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

No special measures required.

· 6.3 Methods and material for containment and cleaning up: Pick up mechanically.

• 6.4 Reference to other sections No dangerous substances are released.

SECTION 7: Handling and storage

- \cdot 7.1 Precautions for safe handling
- For dental use only. No special measures required.
- Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

- · Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: See storage instructions on package
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

• Additional information about design of technical facilities: No further data; see item 7.

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:
- The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:
- The usual precautionary measures are to be adhered to when handling chemicals.
- · Respiratory protection: Not required.
- Protection of hands:



· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the

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Trade name: Grandio Seal

(Contd. of page 2) resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

| SECTION 9: Physical and | l chemical properties |
|---------------------------------------------------------------------------------------|-----------------------------------------------|
| • 9.1 Information on basic physic • General Information | cal and chemical properties |
| · Appearance: | |
| Form: | Viscous |
| Colour: | According to product specification |
| · Odour: | Characteristic |
| · pH-value: | Not determined. |
| • Change in condition Melting point/Melting range: Boiling point/Boiling range: | |
| · Flash point: | Not applicable. |
| · Self-igniting: | Product is not selfigniting. |
| • Danger of explosion: | Product does not present an explosion hazard. |
| · Density: | Not determined. |
| · Solubility in / Miscibility with water: | Not miscible or difficult to mix. |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| • 9.2 Other information | No further relevant information available. |

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

- · Acute toxicity Based on available data, the classification criteria are not met.
- Primary irritant effect:
- · Skin corrosion/irritation

Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured • *Serious eye damage/irritation Based on available data, the classification criteria are not met.*

· Respiratory or skin sensitisation

May cause an allergic skin reaction.

- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- *Reproductive toxicity Based on available data, the classification criteria are not met.*
- STOT-single exposure Based on available data, the classification criteria are not met.

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Trade name: Grandio Seal

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- \cdot **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- $\cdot \textit{Aspiration hazard Based on available data, the classification criteria are not met.}$

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- 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.

- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

| SECTION 14: Transport information | tion | |
|----------------------------------------------------------------------|------------------------------------|--|
| · 14.1 UN-Number · ADR, ADN, IMDG, IATA | Void | |
| · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA | Void | |
| · 14.3 Transport hazard class(es) | | |
| · ADR, ADN, IMDG, IATA · Class | Void | |
| · 14.4 Packing group · ADR, IMDG, IATA | Void | |
| · 14.5 Environmental hazards: · Marine pollutant: | No | |
| · 14.6 Special precautions for user | Not applicable. | |
| · 14.7 Transport in bulk according to Ann Marpol and the IBC Code | ex II of Not applicable. | |
| · UN ''Model Regulation'': | Void | |

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Printing date 15.12.2016

Version number 10

Revision: 15.12.2016

Trade name: Grandio Seal

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SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

SECTION 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.

· Department issuing SDS: Scientific department

· Contact: Tel.: +49 (0)4721-719-0

• 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

- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- 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
- Acute Tox. 2: Acute toxicity Category 2
- Skin Irrit. 2: Skin corrosion/irritation Category 2 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- Skin Sens. 1: Skin sensitisation Category 1
- * Data compared to the previous version altered.

Printing date 08.09.2016

Version number 21

Revision: 08.09.2016

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

· 1.1 Product identifier

· Trade name: VOCO Profluorid Varnish

- 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- Application of the substance / the mixture Dental varnish
- \cdot 1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier: VOCO GmbH Anton-Flettner-Str. 1-3 D-27472 Cuxhaven

• Further information obtainable from: Scientific department tel. +49 (0)4721-719-0

• 1.4 Emergency telephone number: Poison Control Center Mainz +49 (0)6131-19240

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 3 H226 Flammable liquid and vapour.

Acute Tox. 4 H302 Harmful if swallowed.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008

As a medical device the product is not subject to labelling regulations under 1272/2008/EC. • Hazard pictograms GHS02, GHS07

- · Hazard statements
- Flammable liquid and vapour.
- Harmful if swallowed.
- Harmful to aquatic life with long lasting effects.
- · Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

- Avoid breathing vapours.
- Wear protective gloves / eye protection.
- Wear protective clothing.

IF SWALLOWED: Call a doctor if you feel unwell.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· 2.3 Other hazards

Material should only be used with extreme caution in individuals who may not have control over their swallowing reflex (e.g. pre-school children and the disabled). Use only for intended scope of application

- Results of PBT and vPvB assessment
- *PBT:* Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

| CAS: 64-17-5 EINECS: 200-578-6 | Flam. Liq. 2, H225 | 10-25% |
|-----------------------------------|--------------------|---------------|
| EIII 200 270 0 | (Conto | 1. on page 2) |

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Trade name: VOCO Profluorid Varnish

| | | (Conto | 1. of page 1) |
|-------------------|---|-----------------------------------------|---------------|
| | • | Acute Tox. 3, H301 | 2.5-5% |
| EINECS: 231-667-8 | | Skin Irrit. 2, H315; Eye Irrit. 2, H319 | |

SECTION 4: First aid measures

• 4.1 Description of first aid measures

- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing:

Swallowing of larger amounts can lead to nausea, vomiting and/or diarrhoea. Call for a doctor immediately.

- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

- \cdot Suitable extinguishing agents:
- CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- 5.3 Advice for firefighters No further relevant information available.

SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.

• 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

- · 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 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.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling For dental use only.
- · Information about fire and explosion protection: Keep ignition sources away Do not smoke.

· 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Do not store together with acids.
- · Further information about storage conditions:
- See storage instructions on package
- Keep container tightly sealed.

• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

• Additional information about design of technical facilities: No further data; see item 7.

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GB

Printing date 08.09.2016

Version number 21

Revision: 08.09.2016

(Contd. of page 2)

Trade name: VOCO Profluorid Varnish

· 8.1 Control parameters

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

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

• Additional information: The lists valid during the making were used as basis.

· 8.2 Exposure controls

· Personal protective equipment:

- \cdot General protective and hygienic measures:
- The usual precautionary measures are to be adhered to when handling chemicals.
- · Respiratory protection: Not required.
- **Protection of hands:** Not required.

· Material of gloves Not applicable.

| SECTION 9: Physical | and chemical properties |
|----------------------------|-------------------------|
|----------------------------|-------------------------|

| 0.1 Information on basic physic | and a homical properties |
|---------------------------------------------------------------------------------|-----------------------------------------------|
| 9.1 Information on basic physi General Information | cai ana chemicai properiles |
| · Appearance: | |
| Form: | Fluid |
| Colour: | Colourless |
| · Odour: | Fruit-like |
| · pH-value: | Not determined. |
| · Change in condition | |
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |
| · Flash point: | 36 °C |
| · Self-igniting: | Product is not selfigniting. |
| · Danger of explosion: | Product does not present an explosion hazard. |
| · Density at 20 °C: | 1.02 g/cm ³ |
| · Solubility in / Miscibility with | |
| water: | Not miscible or difficult to mix. |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| 9.2 Other information | No further relevant information available. |

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions Contact with acids releases toxic gases.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

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SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- Acute toxicity
- Harmful if swallowed.
- · LD/LC50 values relevant for classification:

7681-49-4 sodium fluoride

Oral LD50 52 mg/kg (rat)

- · Primary irritant effect:
- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- $\cdot \textit{Reproductive toxicity Based on available data, the classification criteria are not met.}$
- $\cdot \textit{STOT-single exposure Based on available data, the classification criteria are not met.}$
- $\cdot \textit{STOT-repeated exposure Based on available data, the classification criteria are not met.}$
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 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.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.

| SECTION 14: Transport informa | nion | |
|--------------------------------|------------------------------|--|
| · 14.1 UN-Number | | |
| · ADR, IMDG, IATA | UN1170 | |
| · 14.2 UN proper shipping name | | |
| ADR | 1170 ETHANOL (ETHYL ALCOHOL) | |
| ·IMDG | ETHANOL (ETHYL ALCOHOL) | |

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|-------------------------------------------------|-----------------------------------------|
| ·IATA | ETHANOL |
| · 14.3 Transport hazard class(es) | |
| · ADR, IMDG, IATA | |
| e | |
| · Class | 3 Flammable liquids. |
| · Label | 3 |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | III |
| · 14.5 Environmental hazards: | |
| • Marine pollutant: | No |
| · 14.6 Special precautions for user | Warning: Flammable liquids. |
| · Danger code (Kemler): | 30 |
| • EMS Number: | F-E,S-D |
| · Stowage Category | A |
| \cdot 14.7 Transport in bulk according to Ann | |
| Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | |
| · ADR | |
| · Limited quantities (LQ) | 5L |
| · Transport category | 3 |
| • Tunnel restriction code | D/E |
| · UN "Model Regulation": | UN 1170 ETHANOL (ETHYL ALCOHOL), 3, III |

SECTION 15: Regulatory information

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

· Directive 2012/18/EU

- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category P5c FLAMMABLE LIQUIDS

 \cdot Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t

• Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t

• REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

SECTION 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.

· Department issuing SDS: Scientific department

· Contact: Tel.: +49 (0)4721-719-0

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
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 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)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 Additional Canadian Additional Canadian Additional Canadian Additional Society
 PBT: Persistent, Bioaccumulative and Toxic
 Additional Canadian Additional Canadian Additional Canadian Additional Society
 PBT: Persistent, Bioaccumulative and Toxic
 Particular Societa Particular Societa Particular Societa Particular Par

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Trade name: VOCO Profluorid Varnish

vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2 Flam. Liq. 3: Flammable liquids – Category 3 Acute Tox. 3: Acute toxicity – Category 4 Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3 • * Data compared to the previous version altered. (Contd. of page 5)

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

· 1.1 Product identifier

- · Trade name: Remin Pro
- 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Remineralisation paste
- \cdot 1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier: VOCO GmbH Anton-Flettner-Str. 1-3 D-27472 Cuxhaven

• Further information obtainable from: Scientific department tel. +49 (0)4721-719-0

• 1.4 Emergency telephone number: Poison Control Center Mainz +49 (0)6131-19240

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

• Classification according to Regulation (EC) No 1272/2008 The product is not classified according to the CLP regulation.

· 2.2 Label elements

- · Labelling according to Regulation (EC) No 1272/2008
- As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- · Hazard pictograms Void
- · Hazard statements Void
- · 2.3 Other hazards Use only for intended scope of application
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components: Void

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- General information: No special measures required.
- · After inhalation: Seek medical treatment in case of complaints.
- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 4.3 Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.

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· 5.3 Advice for firefighters

· Protective equipment: No special measures required.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 6.2 Environmental precautions:

Do not allow to enter sewers/ surface or ground water.

- No special measures required.
- · 6.3 Methods and material for containment and cleaning up: No special measures required.
- · 6.4 Reference to other sections No dangerous substances are released.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- Information about fire and explosion protection: No special measures required.

· 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

- · Requirements to be met by storerooms and receptacles: See storage instructions on package
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

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

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · Respiratory protection: Not required.
- · Protection of hands: Not required.
- *Material of gloves* Not applicable.
- Eye protection: Not required.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

Pasty

- · General Information
- · Appearance:
- Form: Colour:

Colour: White • Odour: Characteristic

• *pH-value:* Not determined.

· Change in condition

Melting point/Melting range: Undetermined. Boiling point/Boiling range: Undetermined.

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|-----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|------------|
| · Flash point: | Not applicable. | |
| · Self-igniting: | Product is not selfigniting. | |
| · Danger of explosion: | Product does not present an explosion hazard. | |
| · Density: | Not determined. | |
| · Solubility in / Miscibility with water: | Fully miscible. | |
| Viscosity: Dynamic: Kinematic: 9.2 Other information | Not determined. Not determined. No further relevant information available. | |

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

· Acute toxicity Based on available data, the classification criteria are not met.

· Primary irritant effect:

· Skin corrosion/irritation Based on available data, the classification criteria are not met.

• Serious eye damage/irritation Based on available data, the classification criteria are not met.

- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.

· Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· 12.1 Toxicity

- Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:

· General notes: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Trade name: Remin Pro

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· 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

• *Recommendation Smaller quantities can be disposed of with household waste*.

· Uncleaned packaging:

• *Recommendation: Disposal must be made according to official regulations.*

SECTION 14: Transport information

| · 14.1 UN-Number | | |
|-------------------------------------------------------|-----------------|--|
| · ADR, ADN, IMDG, IATA | Void | |
| | , | |
| 14.2 UN proper shipping name | | |
| · ADR, ADN, IMDG, IATA | Void | |
| , , , , | | |
| 14.3 Transport hazard class(es) | | |
| · ADR, ADN, IMDG, IATA | | |
| ·Class | Void | |
| Chu55 | 1014 | |
| · 14.4 Packing group | | |
| · ADR, IMDG, IATA | Void | |
| | , | |
| 14.5 Environmental hazards: | | |
| • Marine pollutant: | No | |
| • | | |
| 14.6 Special precautions for user | Not applicable. | |
| · 14.7 Transport in bulk according to Annex II of | | |
| Marpol and the IBC Code | Not applicable. | |
| Murpoi unu ine IBC Code | Νοι αρρικασιε. | |
| · UN "Model Regulation": | Void | |
| | | |

SECTION 15: Regulatory information

· Directive 2012/18/EU

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

SECTION 16: Other information

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- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative

 \cdot * Data compared to the previous version altered.

^{· 15.1} Safety, health and environmental regulations/legislation specific for the substance or mixture