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

· 1.1 Product identifier

· Trade name: Ionofil Plus liquid

- 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 filling material
- $\cdot$  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

Eye Irrit. 2 H319 Causes serious eye irritation.

- · 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
- Causes serious eye irritation.
- · Precautionary statements
- Wear eye protection / face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor.

If eye irritation persists: Get medical advice/attention.

· 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:

CAS: 87-69-4 (+)-tartaric acid EINECS: 201-766-0

*Eye Dam. 1, H318* 10-25%

### **SECTION 4: First aid measures**

- · 4.1 Description of first aid measures
- · After inhalation: Seek medical treatment in case of complaints.
- After skin contact: Immediately wash with water and soap and rinse thoroughly.

· After eye contact:

- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- 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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#### • **4.3 Indication of any immediate medical attention and special treatment needed** No further relevant information available.

# **<u>SECTION 5: Firefighting measures</u>**

· 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.
- · 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
- 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: 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: Keep container tightly sealed.

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. Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.
- · Protection of hands: Not required.
- · Material of gloves Not applicable.

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· Eye protection: Safety glasses

SECTION 9: Physical and chemical properties		
• 9.1 Information on basic physical and chemical properties		
· General Information		
· Appearance:		
Form:	Fluid	
Colour:	Colourless	
· Odour:	Acidic	
• Odour threshold:	Not determined.	
· pH-value at 20 °C:	1.2	
· Change in condition		
Melting point/Melting range:	Undetermined.	
<b>Boiling point/Boiling range:</b>	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 explosion hazard.	
· Density at 20 °C:	1 g/cm <sup>3</sup>	
· Relative density	Not determined.	
· Vapour density	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
water:	Fully miscible.	
· Partition coefficient (n-octanol/water): Not determined.		
· 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 Based on available data, the classification criteria are not met.

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- · Serious eye damage/irritation
- Causes serious eye irritation.
- · 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.
- $\cdot$  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:

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.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

## **SECTION 14: Transport information**

• 14.1 UN-Number	Attention: special provisions A197 IATA, 375 ADR and/or IMDG-Code paragraph 2.10.2.7 may be applied during transport.
	-
$\cdot$ 14.2 UN proper shipping name	-
· 14.3 Transport hazard class(es)	-
· 14.4 Packing group	-
· 14.5 Environmental hazards:	Not applicable.
· Marine pollutant:	No
$\cdot$ 14.6 Special precautions for user	Not applicable.
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• 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not

Not applicable.

### **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: 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 Eye Dam. 1: Serious eye damage/eye irritation – Category 1 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
\* Data compared to the previous version altered. (Contd. of page 4)

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