

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/15/2026

Reviewed on 06/15/2026

1 Identification

- **Product identifier**

- **Trade name:** Ionolux AC

- **Information:**

This product is a medical device within the meaning of the US Federal Food, Drug and Cosmetic Act, the Canadian Medical Devices Regulations (CMDR) SOR/98-282 and the Canadian Food and Drugs Act R.S.S., 1985, c. F-27, which is used invasively or in contact with the body. It is therefore exempt from the classification and labeling requirements of the US Hazard Communication Standard (HCS), WHMIS, the Canadian Hazardous Products Act (HPA) and the Canadian Hazardous Products Regulations Act (HPR).

A safety data sheet is not required by law for this product. This information is provided on a voluntary basis.

- **Application of the substance / the mixture**

Resin-reinforced, light-curing, radiopaque glass ionomer restorative material.

- **Uses advised against** No further relevant information available.

- **Details of the supplier of the safety data sheet**

- **Manufacturer/Supplier**

VOCO GmbH

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2 Hazard(s) identification

- **Classification of the substance or mixture**

This product is a medical device within the meaning of the US Federal Food, Drug and Cosmetic Act, the Canadian Medical Devices Regulations (CMDR) SOR/98-282 and the Canadian Food and Drugs Act R.S.S., 1985, c. F-27, which is used invasively or in contact with the body. It is therefore exempt from the classification and labeling requirements of the US Hazard Communication Standard (HCS), WHMIS, the Canadian Hazardous Products Act (HPA) and the Canadian Hazardous Products Regulations Act (HPR).

The classification criteria of Regulation (EC) No 1272/2008 are not directly applicable to this product, but are considered by us as an orienting basis for assessment. The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes. The following hazards based on the classification criteria of Regulation (EC) No 1272/2008 for humans and the environment cannot be excluded:

The product is classified according to the Globally Harmonized System (GHS).



GHS07

Eye Irritation 2A H319 Causes serious eye irritation.

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

- **Additional information:**

This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.

Health effects are based on the unmixed/uncured material.

Under FDA regulations this product is classified as a medical device.

Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

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- **Label elements**

- **GHS label elements**

This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d).

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS07

- **Hazard statements**

Causes serious eye irritation.

May cause an allergic skin reaction.

- **Precautionary statements**

Wear protective gloves / eye protection.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

- **Other hazards** Use only for intended scope of application.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable

- **vPvB:** Not applicable

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture of non-hazardous substances.

- **Dangerous components:**

	Polyacrylic acid solution	5-10%
	⚠ Eye Irritation 2A, H319	
CAS: 868-77-9	2-hydroxyethyl methacrylate	5-10%
	⚠ Skin Irritation 2, H315; Eye Irritation 2A, H319; Sensitization - Skin 1, H317	
CAS: 72869-86-4	Urethane dimethacrylate	2.5-5%
	⚠ Sensitization - Skin 1B, H317	
CAS: 1830-78-0	Glycerindimethacrylate	2.5-5%
	⚠ Eye Irritation 2A, H319	

- **Additional information:**

Further information on ingredients can be found in the instructions for use.

In case of known hypersensitivity to the ingredients mentioned in the instructions for use, do not use the product.

4 First-aid measures

- **Description of first aid measures**

- **General information:** No special measures required.

- **After inhalation:** Supply fresh air; consult doctor 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.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **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:** Ensure adequate ventilation.
- **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.
- **Protective Action Criteria for Chemicals**

· PAC-1:

CAS: 868-77-9	2-hydroxyethyl methacrylate	33 mg/m ³
CAS: 72869-86-4	Urethane dimethacrylate	88 mg/m ³

· PAC-2:

CAS: 868-77-9	2-hydroxyethyl methacrylate	170 mg/m ³
CAS: 72869-86-4	Urethane dimethacrylate	970 mg/m ³

· PAC-3:

CAS: 868-77-9	2-hydroxyethyl methacrylate	1000 mg/m ³
CAS: 72869-86-4	Urethane dimethacrylate	5800 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Observe the instructions for use! This contains the relevant application and safety information for the use of this product.
No special precautions are necessary if used correctly.
For dental use only.
- **Information about protection against explosions and fires:** No special measures required.
- **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:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.

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- **Control parameters**
- **Components 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 that were valid during the creation were used as basis.
Due to the proportions contained in relation to the amount of product during application and the way it is the product, monitoring of specific, workplace-related limit values is not applicable.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
In the context of the use of this product, the hygiene standards customary and general in dental practice, such as hand, mouth and eye protection, must be applied.
- **Protection of hands:** Single-use gloves.
- **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 resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Eye protection:** Not required

9 Physical and chemical properties

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

Form:	Solid
Color:	According to product specification
Odor:	Characteristic
Odor threshold:	Not determined
- **pH-value:** Not applicable
- **Change in condition**

Melting point/Melting range:	Undetermined
Boiling point/Boiling range:	Undetermined
- **Flash point:** Not applicable
- **Flammability:** Not determined
- **Decomposition temperature:** Not determined
- **Ignition temperature:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Density:** Not determined
- **Relative density** Not determined
- **Vapor density** Not applicable
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with**

Water:	Insoluble.
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- **Partition coefficient (n-octanol/water):** Not determined
- **Viscosity:**

Dynamic:	Not applicable
Kinematic:	Not applicable

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· **Other information** *No further relevant information available.*

10 Stability and reactivity

- **Reactivity** *No further relevant information available.*
- **Chemical stability**
- **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:** *No dangerous decomposition products known.*

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Sensitization:** *Sensitization possible through skin contact.*
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant
- **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*
- **Behavior in environmental systems:**
- **Bioaccumulative potential** *No further relevant information available.*
- **Mobility in soil** *No further relevant information available.*
- **Additional ecological information:** *Not applicable.*
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow product to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable*
- **vPvB:** *Not applicable*

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	Void
· DOT, ADR, IMDG, IATA	1
· ADN	
· UN proper shipping name	-
· DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	-
· Class	Void
· Packing group	-
· DOT, ADR, IMDG, IATA	Void
· Environmental hazards:	Not applicable
· Special precautions for user	Not applicable
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable
· UN "Model Regulation":	Void

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
 Regulation (EU) 2017/745
 Medical Devices Regulation
 Directive 93/42/EEC concerning medical devices
 US Federal Food, Drug and Cosmetic Act
 Canadian Medical Devices Regulations
- **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

One or more substances contained in this material are not listed on the TSCA Inventory.
 Contact manufacturer or supplier for more information.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed

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· **Carcinogenicity categories**· **EPA (Environmental Protection Agency)**

None of the ingredients are listed

· **TLV (Threshold Limit Value)**

CAS: 128-37-0 Butylated hydroxytoluene

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients are listed

16 Other information

The product to which this data sheet is assigned is a medical device within the meaning of the US Federal Food, Drug and Cosmetic Act (FFDCA), the Canadian Medical Devices Regulations (CMDR) SOR/98-282 and the Canadian Food and Drugs Act R.S.S., 1985, c. F-27 and to the EU Medical Devices Regulation EU 2017/745, that is used invasively or in contact with the body. Invasive medical devices or medical devices in direct physical contact are exempt from the requirements for classification and labelling according to Hazard Communication Standard (HCS), WHMIS, Canadian Hazardous Products Act (HPA) and Canadian Hazardous Products Regulations Act (HPR) and also to Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d). The Medical Devices Regulation does not require a safety data sheet for invasive medical devices or medical devices in direct body contact, as the safe use of the product is indicated in the instructions for use and/or the labelling. Nevertheless, we provide a data sheet in order to provide as transparent a source as possible for the assessment of hazards to humans and the environment.

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.

Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

· **Department issuing SDS:** Knowledge Communication Department

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· **Date of preparation / last revision** 06/15/2026 / 1

· **Abbreviations and acronyms:**

Skin Irritation 2: Skin corrosion/irritation – Category 2

Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

Sensitization - Skin 1: Skin sensitisation – Category 1

Sensitization - Skin 1B: Skin sensitisation – Category 1B