Safety Information Sheet for Medical Devices
following 1907/2006/EG, Article 31

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This product is a medical device as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/745 (MDR), which is invasive or used in direct physical contact with the human body. For this product a safety data sheet is not legally required. The provision of this document is on a voluntary basis.

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

1.1 Product identifier
Trade name:
OmniCite 2.0

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified uses:
Dental product.

Restrictions on use:
This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

1.3 Details of the supplier of the safety information sheet

Manufacturer/supplier:	**Distributor:**
SanaPro Dental GmbH	Omnident Dental-Handelsgesellschaft mbH
Stresemannstrasse 46	Gutenbergring 5
27570 Bremerhaven, Germany	63110 Rodgau Nieder-Roden, Germany
dentalproducts@sanapro.dental	info@omnident.de

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Medical devices as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/245, which are invasive or used in direct physical contact with the human body are exempt from labeling requirements of Regulation (EC) No. 1272/2008 (CLP/GHS). Although not required, classification and labeling are indicated as follows:

Classification:
Skin irritation, Category 2; H315 Causes skin irritation.
Eye irritation, Category 2; H319 Causes serious eye irritation.
Skin Sensitization, Category 1; H317 May cause allergic skin reaction.

2.2 Label elements
CLP Regulation (EC) No. 1272/2008

Signal word:
Warning.

Hazard pictograms:



GHS07

Hazard statements:

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H317	May cause allergic skin reaction.

Precautionary statements:

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.

2.3 Other hazards
Results of PBT and vPvB assessment:

PBT:	not applicable.
vPvB:	not applicable.

SECTION 3: Composition/information on ingredients

3.1 Substances
Not applicable.

3.2 Mixtures
Chemical characterization (description):
Hydrophilic methacrylates, modified acrylic acids, ethanol, photo initiators.

Hazardous components:

CAS 868-77-9	2-Hydroxyethyl-methacrylate	GHS07, H315, H319, H317
CAS 64-17-5	Ethanol	GHS02, H225

SECTION 4: First aid measures

4.1 Description of first aid measures
General information:
Seek medical advice, if symptoms occur, which can be caused by the product.

after skin contact:
Wash with plenty of water and soap.

after inhalation:
Fresh air.

after eye contact:
Rinse opened eye for several minutes under running water and consult a doctor.

after swallowing:
Consult a doctor.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Extinguishing media:
CO_2, extinguishing powder, water spray. Use extinguishing method and media suitable to surrounding fire.

5.2 Special hazards arising from the substance or mixture
No further relevant information available.

Protective equipment:
Wear self-contained respiratory protective equipment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions:
Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms.

6.2 Environmental precautions
Do not allow to enter drains/surface water/ ground-water.

6.3 Methods and material for containment and cleaning up
Absorb with liquid binding material. Clean up affected area. Ensure fresh air.

6.4 Reference to other sections
See Section 7: Handling and storage
See Section 8: Exposure controls/personal protection
See Section 13: Disposal considerations

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Handling:
This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Information for safe handling:
Observe normal care for working with chemicals.

Information about fire and explosion protection:
Keep away from heat and fire. Take measure to prevent electrostatic charge.

7.2 Conditions for safe storage, including any incompatibilities
Storage:
Store at a dry place. Store tightly closed. Storage temperature < 25°C.

Requirements at storerooms and containers:
Store only in the original containers.

Information about storage in one common storage facility:
Store away from food stuffs.

Further information on storage conditions:
None.

Storage class:
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7.3 Specific end use(s)
No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Additional information on the design of technical systems:
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Components with limits of values to be supervised at the workplace:

CAS-No.	name	art		value	unit
64-17-5	Ethanol	TRGS 900		200	ml/m³ (ppm)
			or	380	mg/m³

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

8.2 Exposure controls
Personal protective equipment:
General protective and hygienic measures:
Normal hygienic measures. The usual precautionary measures are to be adhered to when handling chemicals. Keep away from foodstuffs and beverages. Avoid contact with eyes or skin.

Respiratory protection:
Required, when aerosols are generated.

Hand protection:
Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection:
Safety glasses.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
Appearance:

Form:	liquid
Color:	colorless
Odor:	characteristic

Change in condition:

Melting point/melting range:	not applicable

Boiling point/boiling range:	not applicable
Flash point:	not applicable
Ignition temperature:	no information available
Danger of explosion:	no information available
Density:	1.05 (20°C) g/cm^3
Vapor pressure:	not determined
pH:	1.5 – 2.5
Solubility in/miscibility with:	
Water:	soluble
Content of solvents:	
Organic solvents:	ethanol

SECTION 10: Stability and reactivity

10.1 Reactivity
Expected to be non-reactive under normal conditions of use.

10.2 Chemical stability
The product is stable by proper use and storage.
Reaction with light (risk of polymerization).

10.4 Conditions to avoid
Heat, sunlight, amines, peroxi compounds, polymerisation initiators, acids, bases, oxidizing agents.

10.6 Hazardous decomposition products
No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Acute toxicity (ethanol):
LD50 (oral, rat) 10470 mg/kg.

Acute toxicity (2-Hydroxyethyl-methacrylate):
LD50 (oral, rat) 5050 mg/kg.

Primary irritation:
Skin: irritant.

Eye: irritant.

Sensitization: sensitization by skin contact possible.

Additional toxicological information:
Allergic reactions to the product after long-term exposure are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

SECTION 12: Ecological information

General information:
Avoid transfer into environment.

Classification hazardous to water:
Water hazard class 1 (self-classification): slightly hazardous to water.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Recommendation:
Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

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

SECTION 14: Transport information

Land transport ADR/RID and GGVSE (Germany):
No subject to transport regulations.

Sea transport IMDG Code:
No subject to transport regulations.

Air transport ICAO-TI and IATA-DGR:
No subject to transport regulations.

The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national deviations in other countries are not considered.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
National regulations:
Water hazard class 1 (self-classification): slightly hazardous to water.

15.2 Chemical safety assessment
A chemical safety assessment has not been carried out.

SECTION 16: Other information

For invasive medical devices or medical devices in direct contact with the human body, the Medical Device Regulation does not require a safety data sheet. The safe use of the product is indicated in the instructions for use and/or the labeling.

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties.
Users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.