

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

Date of issue: 18.08.2025
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Version: 1

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:

LC HAFTOPAQUE 1K METAPHOR OPAQUERS

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:

S&C Polymer Silicon- und Composite Spezialitäten GmbH
Robert-Bosch-Strasse 2
25335 Elmshorn, Germany
info@sc-polymer.com

Australian Distributor:

Ultimate Dental Supply
660A South Rd, Moorabbin Vic 3189
03 9532 1799
info@ultimatedental.com.au

1.4 Emergency telephone number

+49 4121 483-0

Australian Emergency No.

13 11 26 Poisons Hotline 24/7

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:

Flammable liquid, Category 2, H225 Highly flammable liquid and vapour.

Skin irritation, Category 2; H315 Causes skin irritation.

Skin sensitization, Category 1; H317 May cause allergic skin reaction.

Specific target organ toxicity – single exposure (STOT SE), Category 3; H335 May cause respiratory irritation.

2.2 Label elements

CLP Regulation (EC) No. 1272/2008

Signal word:

Danger.

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Hazard pictograms:



GHS02



GHS07

Hazard statements:

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause allergic skin reaction.
H335	May cause respiratory irritation.

Precautionary statements:

P280	Wear protective gloves/protective clothing/eye protection/face protection.
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):

Methacrylates, pigments and initiators.

Hazardous components:

CAS-No. 80-62-6	Methyl methacrylate	GHS02, GHS07, H225, H315, H317, H335
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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 with plenty of water and consult a doctor.

after swallowing:

Drink plenty of water. Consult a doctor.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Extinguishing media:

CO₂, 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 2 – 8 °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.

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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
80-62-6	Methyl methacrylate	TRGS 900	50	ml/m ³ (ppm)
		or	210	mg/m ³

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:	- 48 °C
Boiling point/boiling range:	100 °C
Flash point:	10 °C
Ignition temperature:	no information available

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Danger of explosion:	lower limit of explosion: 1.7 vol % upper limit of explosion: 12.5 vol %
Density:	~ 1 (20°C) g/cm ³
Vapor pressure:	not determined
Solubility in/miscibility with:	
Water:	slightly soluble
Content of solvents:	
Organic solvents:	none

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.

10.4 Conditions to avoid

Heat, sunlight, peroxides, metal powder, reducing agents, radical initiators. Do not use rubber or various plastics as working materials.

10.6 Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

LD50 (oral, rat): 7870 mg/kg.

LD50 (dermal, rabbit): > 5000 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.

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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):

UN 1247 METHYLMETHACRYLAT, MONOMER, STABILISIERT, 3, II.

Sea transport IMDG Code:

UN 1247 METHYL METHACRYLATE, MONOMER, STABILIZED, 3, II.

EmS: F-E S-D

Air transport ICAO-TI and IATA-DGR:

UN 1247 METHYL METHACRYLATE, MONOMER, STABILIZED, 3, II.

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.