

Safety Data Sheet

according to 1907/2006/EC, Article 31

Revision Date: 17.01.2023
Date of Print: 17.01.2023

Version: 2

1. Product identification/preparation/company undertaking

Product details

Trade name: OPTISOFT PRIMER

Use or preparation: Denture relining

Manufacturer:

SanaPro Dental GmbH
27570 Bremerhaven
Germany
dentalproducts@sanapro.dental

Distributor:

IDS Spa
Via S. Cristoforo, 28/10
17100 Savona – Italy
www.idsdental.it

2. Hazards identification

Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008:

Carcinogenicity, Category 2, H351 Suspected of causing cancer

Information concerning particular hazards for human and environment:

The product has to be labeled due to the calculation procedure of the „General classification guideline for preparations of the EU“ in the latest valid version.

Label elements:

Labeling according to Regulation (EC) 1272/2008:

Hazard pictograms



Signal word

Warning

Hazard statements

H351 Suspected of causing cancer

Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray

P262 Do not get in eyes, on skin or on clothing.

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

P281 Use personal protective equipment as required.

Labeling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

Other hazards

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

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3. Composition/Information of Ingredients
<p>Chemical characterization: Description: Solution of polyacrylate in dichloromethane Hazardous components: CAS-No. [75-09-2] EC-No. 200-838-9 Dichloromethane GHS08, H351</p>
4. First-aid measures:
<p>After inhalation: fresh air. Consult a physician. After skin contact: wash with plenty of water. Remove contaminated clothing. Consult a physician. After eye contact: rinse with plenty of water with the eyelid held wide open. Consult an ophthalmologist if necessary. After swallowing: Caution if victim vomits. Risk of aspiration. Keep airways free. Call a physician immediately. Drink plenty of water. Subsequently administer: activated charcoal (20-40g in 10% slurry).</p>
5. Fire fighting measures
<p>Extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Not combustible. Vapours are heavier than air. Protective equipment: Do not stay in dangerous zone without suitable chemical protection clothing and self-containing breathing apparatus.</p>
6. Accidental release measures
<p>Personal precautions: Do not inhale vapors/aerosols. Ensure supply of fresh air in enclosed rooms. Environmental precautions: Observe local by laws. Do not allow to enter sewerage system. Methods for cleaning up: Wipe out with absorbent material. Forward of disposal. Clean up affected area. Additional information: none</p>
7. Handling and storage
<p>Handling: The product should only be supplied or handled to dentists or dental technicians or upon their instructions Information for safe handling: Work under hood. Do not inhale substance/mixture. Avoid generation of vapors/aerosols. Recommendation for fire and explosion protection: No special measures required Storage: Tightly closed. Protected from light. store in well ventilated place (< 25 °C). Requirements at storerooms and containers: Store only in the original containers. Requirements for storage with other products: Keep away from food stuffs Further information on storage conditions: none</p>

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8. Exposure controls/personal protection

Components with limits of values to be supervised at the workplace:

CAS-No.	name	art	value	unit
[75-09-2]	dichloromethane	TRGS900	75	ml/m ³
			or 260	mg/m ³

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

Personal protective equipment: The usual precautionary measures are to be adhered to when handling chemicals. Change contaminated clothes. After finishing of work wash hands.

General measures of protection and hygiene: Do not eat, drink or smoke during handling; avoid contact with eyes or skin.

Respiratory protection: Required when vapors/aerosols are generated.

Protection of hands: Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: Glasses recommended.

9. Physical and chemical properties

Appearance:

Form: Liquid

Color: yellowish

Odor: sweetish

Value	Unit	Method
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Information on change in the physical state

Melting point/melting range: ca. -95 °C

Boiling point/boiling range: ca. 40 °C

Flash point: n.a.

Autoignition temperature: No information available

Danger of explosion: Lower limit of explosion 13 % Kühn-

Upper limit of explosion 22 % Birett

Density: ca. 1.30 (20°C) g/cm³

Vapor pressure: n.d. mbar

Viscosity: Slightly viscous

pH: neutral

Solubility in/miscibility with: Soluble in toluene, slightly in petrol ether

Water: insoluble

Content of solvents:

Organic solvents: dichloromethane

Water: None

Content of solids: None

10. Stability and reactivity

Conditions to avoid:

Avoid heat. The product is stable by proper use. >120 °C thermal decomposition occurs.

Avoid contact with alkali metals alkaline earth metals, metals in powder form

Hazardous decomposition products: In case of fire: phosgene, hydrochloric acid

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11. Toxicological information

Acute toxicity: LD₅₀ (oral, Rat) 1600 mg/kg.

Primary irritation:

skin: Repeated or prolonged exposure may cause skin irritation or dermatitis, due to degreasing properties of the product.

eye: Slight irritation. Risk of corneal clouding.

inhalation: Mucosal irritations; inebriation, narcosis, unconsciousness.

Sensitization of product: Not observed.

Additional toxicological information:

The following applies to halogenated hydrocarbons in general: systemic effect: narcosis, cardiovascular, disorders. Toxic effect on liver, kidneys.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12. Ecological information

General information: Do not allow to come in the environment or sewerage system

Classification of water endangerment: WGK 2 (German regulation) hazardous for water

13. Disposal consideration

Product:

Recommendation: Use proper landfill disposal or incineration in accordance with local, state and federal regulations

Uncleaned packaging:

Recommendation: Handle contaminated packaging in the same way as the substance itself.

14. Transport information

Land transport ADR, RID: UN 1593 DICHLOROMETHANE, 6.1, III

Maritime transport: IMDG-Code: UN 1593 DICHLOROMETHANE, 6.1, III;

EmS: F-A S-A

Air transport ICAO-TI/IATA-DGR: UN 1593 DICHLOROMETHANE, 6.1, III

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.

15. Regulatory information

Classification according to EC-guidelines:

The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16. Other information:

Changes compared with the previous version:

Distributor address added

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. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.