

Safety Data Sheet
according to 1907/2006/EC, Article 31

Date of issue: 18.08.2014

Version: 4

Printing date: 18.08.2014

1. Identification of the substance/mixture and of the company/undertaking

Product Identifier

Trade name: H-Nano SEAL

Use of the preparation: Dental product

Details of the supplier of the safety data sheet:

Manufacturer/supplier:

HEYDENT GmbH

Viktor Frankl Str. 20

86916 Kaufering

Germany

+49 8191 9737805

info@ heydent.com

2. Hazards identification

Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008:

Flam. Liq. 2, H225 Highly flammable liquid and vapour

Eye Irrit. 2, H319 Causes serious eye irritation

STOT SE 3, H336 May cause drowsiness or dizziness

Classification according to Directive 67/548/EEC or Directive 1999/45/EC:

F Highly flammable

Xi Irritant

R11-36-66-67 Highly flammable. Irritating to eyes. Repeated exposure may cause skin dryness or cracking. Vapours may cause drowsiness and dizziness.

Information concerning particular hazards for human and environment:

The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

Classification system:

The classification corresponds to actual EU-lists, and completed with details from technical literature and company data.

Label elements

Labeling according to Regulation (EC) 1272/2008:

Hazard pictograms



Signal word

Danger

Labeling according to 67/548/EEC or 1999/45/EC:

F Highly flammable

Xi Irritant

R11-36-66-67 Highly flammable. Irritating to eyes. Repeated exposure may cause skin dryness or cracking. Vapours may cause drowsiness and dizziness.

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 dangerous substance Directive 1999/45/EWG.

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3. Composition/Information on Ingredients						
<p>Chemical characterization:</p> <p>Description of the mixture: Solution of siliconepolyacrylate, nano-fluorapatite, nano-calciumfluoride in ethylacetate</p> <p>Hazardous components:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">CAS-No. [141-78-6], EC-No. 2005-500-4</td> <td style="width: 33%;">Ethylacetate</td> <td style="width: 33%;">R11-36-66-67</td> </tr> <tr> <td></td> <td></td> <td>GHS02, GHS07, H225, H319, H336</td> </tr> </table>	CAS-No. [141-78-6], EC-No. 2005-500-4	Ethylacetate	R11-36-66-67			GHS02, GHS07, H225, H319, H336
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		GHS02, GHS07, H225, H319, H336				
4. First-aid measures						
<p>General information: no special measures required</p> <p>after skin contact: wash with plenty of water and soap</p> <p>After inhalation: fresh air</p> <p>after eye contact: Rinse opened eye for several minutes under running water and consult a doctor</p> <p>after swallowing: Caution if victim vomits. Risk of aspiration. Keep airways free. Consult a physician. Subsequently administer: activated charcoal (20 – 40 g in 10% slurry). Laxative: Sodium sulfate (1 tablespoon/ ¼ l water)</p>						
5. Fire fighting measures						
<p>Extinguishing media: CO2, powder, foam. Use extinguishing method and media suitable to surrounding fire.</p> <p>Special hazards arising from the substance or mixture No further relevant information available</p> <p>Protective equipment Wear self-contained respiratory protective equipment</p>						
6. Accidental release measures						
<p>Personal precautions, protective equipment and emergency procedures: Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms</p> <p>Environmental precautions: Do not allow to enter drains/surface water/ ground-water.</p> <p>Methods for cleaning up: Absorb with liquid binding material. Clean up affected area.</p> <p>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</p>						
7. Handling and storage						
<p>Handling: This product should only be supplied or handled to dentists or dental technicians or upon their instructions.</p> <p>Precautions for safe handling: Observe normal care for working with chemicals</p> <p>Information about fire and explosion protection: No special measures required</p> <p>Storage: Requirements at storerooms and containers: Store only in the original containers Further information on storage conditions: Store in well ventilated place at 15 °C to 25 °C, protected from light. Store away from food stuffs. Store tightly closed. Keep away from heat and sources of ignition. Specific end uses: No further relevant information available</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
[141-78-6]	Ethylacetate	TRGS900	400	ml/m3
		or	1500	mg/m3

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

Personal protective equipment:**General protective and 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

Hand protection

Protective gloves.

Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: safety glasses

Respiratory protection: Required, when aerosols are generated

9. Physical and chemical properties**Information on basic physical and chemical properties****Appearance**

Form:	liquid		
Color:	slightly yellow		
Odor:	sweetish		
	Value	Unit	Method

Safety relevant basic data

Melting point/melting range:

n.a.

Boiling point/boiling range:

approx. 77 °C

Flash point:

-4 °C DIN 51755

Ignition temperature:

no information available

Danger of explosion:

Lower limit of explosion 2.1 Vol% Kühn-

Upper limit of explosion 11.5 Vol% Birett

Density:

ca. 0,90 (20°C) g/cm³

Vapor pressure:

n.d.

Solubility in/miscibility with:

Soluble in acetone, benzene

Water:

none

Content of solvents:

Organic solvents:

Ethylacetate

10. Stability and reactivity**Thermal decomposition / conditions to be avoided**

Possibility of hazardous reactions: no information available

Conditions to avoid: Sensitive to moisture, strong oxidizing agents

Hazardous decomposition products: No information available.

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11. Toxicological information
<p>Acute toxicity: (ethylacetate)</p> <p>LD50 (oral, rat) 5600 mg/kg LD50 (dermal, rabbit) >18000 mg/kg LD50 (inhal., rat) 1600 ppm (V)/8h</p> <p>Primary irritation:</p> <p>skin: repeated exposure may cause skin dryness or cracking eye: irritating effect</p> <p>Inhalation and swallowing: irritation of mucous membranes, loss of appetite, headache, drowsiness</p> <p>Additional toxicological information:</p> <p>When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.</p>
12. Ecological information
<p>Toxicity:</p> <p>Aquatic toxicity: No further relevant information available</p> <p>Persistence and degradability: No further relevant information available</p> <p>Behavior in environmental systems:</p> <p>Bioaccumulative potential No further relevant information available</p> <p>Mobility in soil No further relevant information available</p> <p>General information: Do not flush into surface water or sanitary sewer system</p>
13. Disposal considerations
<p>Product:</p> <p>Recommendation:</p> <p>Use proper landfill disposal or incineration in accordance with local, state and federal regulations.</p> <p>Uncleaned packaging:</p> <p>Recommendation: Disposal must be made according to official regulations</p>
14. Transport information
<p>Land transport ADR/RID and GGVS/GGVE (Germany): UN 1173 ETHYLACETAT, 3, II</p> <p>Sea transport IMDG: UN 1173 ETHYL ACETATE, 3, II</p> <p>EmS F-E S-D</p> <p>Air transport ICAO-TI and IATA-DGR: UN 1173 ETHYL ACETATE, 3, II</p> <p>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.</p>
15. Regulatory information
<p>Classification according to EC-guidelines:</p> <p>The product is a medical device according to EC-directive 93/42 EEC.</p> <p>Chemical safety assessment:</p> <p>A Chemical Safety Assessment has not been carried out.</p>
16. Other information:
<p>Changes compared with the previous version:</p> <p>Adaptation according to 1907/2006/EG, Article 31</p> <p>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.</p>