

1. Product identification/preparation/company undertaking

Product details

Product no.: 81260
Trade name: BISICO Softbase Primer
Trade number: 13860
Use or preparation: Dental-Soft-Reliner
Manufacturer/supplier: BISICO Bielefelder Dentsilicone GmbH & Co. KG
 Johanneswerkstraße 3
 D-33611 Bielefeld
Emergency information: Tel.: +49 521 8016800
 Fax: +49 521 8016801

2. Hazards identification

Classification of the substance or mixture:

Classification according to Regulation (EC) 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

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.

Label elements

Labeling according to Regulation (EC) 1272/2008:

Hazard pictograms:



Signal word: Danger

Hazard statements: H225 Highly flammable liquid and vapour
 H319 Causes serious eye irritation
 H336 May cause drowsiness or dizziness

Precautionary statements: P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

<p>Other hazards:</p> <p>Results of PBT and vPvB assessment:</p>	<p>PBT: not applicable</p> <p>vPvB: not applicable</p>
<p>3. <u>Composition/Information of Ingredients</u></p> <p><u>Chemical characterization:</u></p> <p>Description:</p> <p>Hazardous components:</p>	<p>Solution of polyacrylate in ethylacetate</p> <p>CAS-No. [141-78-6], EC-No. 2005-500-4 Ethylacetate GHS02, GHS07, H225, H319, H336</p>
<p>4. <u>First-aid measures</u></p> <p>General information:</p> <p>after skin contact:</p> <p>after inhalation:</p> <p>after eye contact:</p> <p>after swallowing:</p>	<p>no special measures required</p> <p>wash with plenty of water and soap</p> <p>fresh air</p> <p>Rinse opened eye for several minutes under running water and consult a doctor</p> <p>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>
<p>5. <u>Fire fighting measures</u></p> <p>Extinguishing media:</p> <p>Special hazards arising from the substance or mixture:</p> <p>Protective equipment:</p>	<p>CO2, powder, water spray.</p> <p>Use extinguishing method and media suitable to surrounding fire.</p> <p>No further relevant information available</p> <p>Wear self-contained respiratory protective equipment</p>
<p>6. <u>Accidental release measures</u></p> <p>Personal precautions, protective equipment and emergency procedures:</p> <p>Environmental precautions:</p> <p>Methods for cleaning up:</p> <p>Reference to other sections:</p>	<p>Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms</p> <p>Do not allow to enter drains/surface water/ ground-water.</p> <p>Absorb with liquid binding material. Clean up affected area.</p> <p>See Section 7 for information on safe handling See Section 8 for information on personal protection equipment See Section 13 for disposal information</p>

<p>7.</p>	<p><u>Handling and storage</u></p> <p>Handling:</p> <p>Precautions for safe handling:</p> <p>Information about fire and explosion protection:</p> <p>Storage:</p> <p>Requirements at storerooms and containers:</p> <p>Further information on storage conditions:</p> <p>Specific end uses:</p>	<p>This product should only be supplied or handled to dentists or dental technicians or upon their instructions.</p> <p>Observe normal care for working with chemicals</p> <p>No special measures required</p> <p>Store only in the original containers</p> <p>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.</p> <p>No further relevant information available</p>
<p>8.</p>	<p><u>Exposure controls/personal protection</u></p> <p>Components with limits of values to be supervised at the workplace:</p> <p>Additional information:</p> <p>Personal protective equipment:</p> <p>General measures of protection and hygiene:</p> <p>Hand protection:</p> <p>Eye protection:</p> <p>Respiratory protection:</p>	<p><u>CAS-No.</u> : [141-78-6]</p> <p><u>Name:</u> Ethylacetate</p> <p><u>Art:</u> TRGS900</p> <p><u>Value/Unit:</u> 400 ml/m³ or 1500 mg/m³</p> <p>The lists valid during the making were used as basis.</p> <p>-</p> <p>The usual precautionary measures are to be adhered to when handling chemicals. Keep away from foodstuffs and beverages. Avoid contact with eyes or skin</p> <p>Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.</p> <p>safety glasses</p> <p>Required, when aerosols are generated</p>
<p>9.</p>	<p><u>Physical and chemical properties</u></p> <p>Appearance:</p> <p>Form:</p> <p>Color:</p> <p>Odor:</p> <p>Safety relevant basic data</p>	<p>liquid</p> <p>slightly yellow</p> <p>sweetish</p> <p><u>Value</u> <u>Unit</u> <u>Method</u></p>

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. 0,9 (20°C) g/cm ³		
Vapor pressure:	n.d.		
Solubility in/miscibility with:			
Water:	soluble		
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: Heat, direct sunlight and radical starters. The product is stable by proper use. Avoid contact with alkali metals, hydrids, strong oxidizing agents, radical initiators.

Hazardous decomposition products: No information available.

11. Toxicological information

Acute toxicity:

Ethylacetate:

LD ₅₀ (oral, rat)	5600 mg/kg
LD ₅₀ (dermal, rabbit)	>18000 mg/kg
LD ₅₀ (inhal., rat)	5,86 mg/l (8h)

Primary irritation:

skin: repeated exposure may cause skin dryness or cracking

eye: strong irritating effect

Inhalation and swallowing: irritation of mucous membranes, loss of appetite, headache, drowsiness

Additional toxicological information: Allergic reactions to acrylates 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.

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
General information:	Do not flush into surface water or sanitary sewer system
13. <u>Disposal consideration</u>	
Product:	
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
14. <u>Transport information</u>	
Land transport ADR/RID and GGVS/GGVE (Germany):	UN 1173 ETHYLACETAT, 3, II
Sea transport IMDG:	UN 1173 ETHYLACETAT, 3, II
Air transport ICAO-TI and IATA-DGR:	UN 1173 ETHYLACETATE, 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.	
15. <u>Regulatory information</u>	
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. <u>Other information:</u>	
Changes compared with the previous version:	Adaptation according to 1907/2006/EG, Article 31
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.	
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