

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

Date of issue: 08.06.2020 Printing date: 11.06.2020

1. Identification of the substance/mixture and of the company/undertaking **Product Identifier** Trade name: Löffelplatten LC Use of the preparation: Dental product Details of the supplier of the safety data sheet: Manufacturer/supplier: Distributor: First Scientific Dental GmbH Plandent OY Asentajankatu 6 25335 Elmshorn FI-00880 Helsinki - Finland Germany info@first-scientific.de Emergency telephone number: +49 4121 483-0 2. Hazards identification Classification of the substance or mixture: Classification according to Regulation (EC) No 1272/2008: Skin Irrit. 2, H315 Causes skin irritation Eye Irrit. 2, H319 Causes serious eye irritation STOT SE 3, H335 May cause respiratory irritation 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 Warning Hazard statements H315 Causes skin irritation H319 Causes serious eve irritation H335 May cause respiratory irritation **Precautionary statements** 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. Other hazards Results of PBT and vPvB assessment **PBT:** not applicable vPvB: not applicable

Version: 1



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2. Composition/Information on Ingradiante			
3. Composition/Information on Ingredients			
Chemical characterization:			
Description:			
Light curing custom tray material based on esters of acrylic acids and glass fillers Hazardous components:			
607-133-00-9 (Index No.) Acrylic acid ester GHS07, H315, H319, H335			
4. 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: If symptoms persist, consult a physician.			
5. Fire fighting measures			
Extinguishing media:			
CO2, powder, water spray, foam.			
Use extinguishing method and media suitable to surrounding fire.			
Special hazards arising from the substance or mixture No further relevant information available			
Protective equipment Wear self-contained respiratory protective equipment			
6. Accidental release measures			
Personal precautions, protective equipment and emergency procedures:			
Environmental precautions:			
Do not allow to enter drains/surface water/ ground-water.			
Methods for cleaning up:			
Take-up mechnaically. Clean up affected area.			
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			
7. Handling and storage			
Handling:			
This product should only be supplied or handled to dentists or dental technicians or upon their			
instructions.			
Precautions for safe handling: Observe normal care for working with chemicals			
Information about fire and explosion protection: -			
Storage: Store at a dry place, protected from light. Storage temperature <25°C.			
Requirements at storerooms and containers: Store only in the original containers			
Further information on storage conditions:			
Store away from food stuffs.			
Specific end uses: No further relevant information available			



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8. Exposure controls/personal protection			
Components with limits of values to be supervised at the workplace:			
The product does not contain any relevant quantities of materials with critical values that have to			
be monitored at the workplace			
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: -			
9. Physical and chemical properties			
Information on basic physical and chemical prop	perties		
Appearance			
Form:	kneadable stiff paste		
Color:	various		
Odor:	characteristic		
	<u>Value Unit Method</u>		
Safety relevant basic data			
Melting point/melting range:	n.a.		
Boiling point/boiling range:	n.a.		
Flash point:	n.d.		
Ignition temperature:	no information available		
Danger of explosion:	none (non volatile)		
Density:	1.84 g/cm3		
Vapor pressure:	n.a.		
pH:	neutral		
Solubility in/miscibility with:	partially in isopropyal alcohole, soluble in ethyl		
	acetate		
Water:	insoluble		
Content of solvents:			
Organic solvents:	none		
10. <u>Stability and reactivity</u>			
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.			
Hazardous decomposition products: none by proper use.			



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11. Toxicological information		
Acute toxicity:		
no data available		
Primary irritation:		
skin: irritant		
eye: irritant		
Sensitization: sensitization by skin contact possible		
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		
General information: Do not allow to enter drains/surface water/ ground-water.		
Classification of water endangerment: WGK=2 (self estimation).		
13. Disposal considerations		
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. Transport information		
Land transport ADR/RID and GGVS/GGVE (Germany): no subject to transport regulations		
Sea transport IMDG: no subject to transport regulations		
Air transport ICAO-TI and IATA-DGR: no subject to transport regulations		
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:		
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.		