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1. Identification of the substance/mixture and of the company/undertaking **Product Identifier** Trade name: Harvard Ionoglas Fill Extra – Liquid Harvard Ionoglas Fill Extra OptiCaps[®] – Liquid Use of the preparation: Dental product Details of the supplier of the safety data sheet: Manufacturer/supplier: Harvard Dental International GmbH, Margaretenstraße 2-4. 15366 Hoppegarten, Germany info@harvard-dental-international.de **Emergency telephone number:** + 49 (0) 30 99 28 978-0 (Quality Management) 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 eye 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

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3. <u>Composition/Information on Ingredients</u>					
Chemical characterization: Mixture					
Description of the mixture: Aqueous solution of polyarylic acids					
Hazardous components:					
CAS-Nr. 9003-01-4 Polyacrylic acid GHS07, H315, H319, H335					
4. <u>First-aid measures</u>					
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: supply with fresh air					
after eye contact: rinse opened eye for several minutes under running water and consult a doct	after eye contact: rinse opened eye for several minutes under running water and consult a doctor				
after swallowing: seek medical advice if problems persist.					
5. <u>Fire fighting measures</u>	5. <u>Fire fighting measures</u>				
Extinguishing media:					
CO ₂ , powder, water spray.					
Use extinguishing method and media suitable to surrounding fire	Use extinguishing method and media suitable to surrounding fire				
Special hazards arising from the substance or mixture No further relevant information					
available	available				
Protective equipment Wear self-contained respiratory protective equipment					
6. <u>Accidental release measures</u>					
Personal precautions, protective equipment and emergency procedures: not necessary					
Environmental precautions:					
Do not allow to enter drains/surface water/ ground-water.					
Methods for cleaning up:					
Absorb with liquid binding material. 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. <u>Handling and storage</u>					
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: No special measures required					
Storage:					
Requirements at storerooms and containers: Store only in the original containers					
Further information on storage conditions: Store at dry place, at room temperature (< 25°C,					
78°F). Store away from food stuffs. Always store with lid on					
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 contains no relevant quantities of components with limit values to be supervised at the workplace. Additional information: The lists valid during the making were used as basis Personal protective equipment: General protective gloves. Hand protective gloves. Due to missing tests no recommendation to the glove material can be given for the product. Eye protection: Required, when aerosols are generated Goner colorless Odor: faint odor Value Unit Method Safety relevant basic data Melting point/melting range: n.a. Boiling point/boiling range: a			
The product contains no relevant quantities of components with limit values to be supervised at the workplace. Additional information: The lists valid during the making were used as basis Personal protective equipment: General protective and hygienic measures are to be adhered to when handling chemicals. Keep away from foodstuffs and beverages. Hand protection Protection: safety glasses Respiratory protection: Required, when aerosols are generated 9. Physical and chemical properties Appearance Form: Golor: G	8. Exposure controls/personal protection		
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Possibility of hazardous reactions: No dangerous reaction known Conditions to avoid: No further relevant information available	materials e.g. peroxides.		
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Incompatible materials: No further relevant information available			

Hazardous decomposition products: No dangerous decomposition products known.

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11. <u>Toxicological information</u>			
Acute toxicity:			
Primary irritation:			
skin: may cause skin irritation			
eye: irritating effect			
Sensitization: no sensitizing effects known			
Additional toxicological information:			
Allergic reation by chronic exposure to product 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 allow undiluted product or large quantities of it into surface water			
or sanitary sewer system			
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. <u>Transport information</u>			
Land transport ADR/RID and GGVS/GGVE (Germany)			
Not classified as dangerous goods in the meaning of transport regulations			
Sea transport IMDG			
Not classified as dangerous goods in the meaning of transport regulations			
Air transport ICAO-TI and IATA-DGR			
Not classified as dangerous goods in the meaning of transport regulations			
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 REACH-regulation (EC) No. 1907/2006, 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			

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.