

Safety Data Sheet

according to 1907/2006/EC, Article 31

Revision Date: 11.04.2019

Version: 1

Date of Print: 11.04.2019

1. Product identification/preparation/company undertaking

Product details

Trade name: Harvard SuperSnap® Mono Regular Snap
 Harvard SuperSnap® Mono Quick Snap

Use or preparation: Impression material

Manufacturer/supplier:

Harvard Dental International GmbH,
 Margaretenstraße 2-4,
 15366 Hoppegarten, Germany
 info@harvard-dental-international.de

Emergency information:

+ 49 (0) 30 99 28 978-0 (Quality Management)

2. Hazards identification

Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008: void

Information concerning particular hazards for human and environment:

The product does not have 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: void

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

3. Composition/Information of Ingredients

Chemical characterization:

Description:

mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica

Hazardous components: none

4. First-aid measures:

General information: no special measures required

after skin contact: wash with plenty of water and soap

after eye contact: rinse with plenty of water and consult a doctor

after swallowing: If symptoms persist consult a doctor

5. Fire fighting measures

Extinguishing media: CO₂, water

Protective equipment: no special measures required

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6. Accidental release measures**Personal precautions:** not required**Environmental precautions:** no special measures required**Methods for cleaning up:** pick up mechanically**Additional information:** none**7. Handling and storage****Handling:****Information for safe handling:** For dental use only. No special measures required.**Recommendation for fire and explosion protection:** No special measures required**Storage:****Requirements at storerooms and containers:** No special measures required**Requirements for storage with other products:** not required**Further information on storage conditions:** none**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 measures of protection and hygiene:** normal hygienic measures**Respiratory protection:** not required**Protection of hands:** not required**Eye protection:** not absolute required**9. Physical and chemical properties****Appearance:****Form:** paste**Color:** blue**Odor:** odorless

Value	Unit	Method
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Information on change in the physical state**Melting point/melting range:** n.a. °C**Boiling point/boiling range:** n.a. °C**Flash point:** n.a. °C**Autoignition temperature:** n.a.**Danger of explosion:** none**Density:** 1,42 (20°C) g/cm³**Vapor pressure:** n.a. mbar**Viscosity:** paste**pH:** neutral**Solubility in/miscibility with:** Partially soluble in toluene, petrol ether**Water:** insoluble**Content of solvents:** none**Organic solvents:** -----**Water:** -----**Content of solids:** n.a.

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10. <u>Stability and reactivity</u> Conditions to avoid: No decomposition if used according to specification Hazardous decomposition products: none under normal conditions of storage and use
11. <u>Toxicological information</u> Acute toxicity: Primary irritation: skin: no irritating effect eye: no irritating effect Additional toxicological information: 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. <u>Ecological information</u> General information: Avoid transfer into environment Classification of water endangerment: WGK 1 (German regulation) slightly hazardous for water
13. <u>Disposal consideration</u> Product: Recommendation: Small quantities can be disposed of with household waste. 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: no subject to transport regulations Maritime transport: IMDG-Code: no subject to transport regulations Air transport ICAO-TI/IATA-DGR: no subject to 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:

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.