

# Safety Data Sheet

## according to 1907/2006/EC, Article 31

Date of issue: 01.02.2017  
Printing date: 27.02.2017

Version: 1

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

#### **Product Identifier**

**Trade name: VITA ADIVA C-PRIME**

**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:**

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

#### **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

#### **Precautionary statements**

P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

#### **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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<b>3. <u>Composition/Information on Ingredients</u></b>
<p><b>Chemical characterization:</b>  <b>Description:</b>          Solution of methacrylsilanes in ethanol  <b>Hazardous components:</b>          64-17-5 (CAS-No.)                  Ethanol                  GHS02, H225</p>
<b>4. <u>First-aid measures</u></b>
<p><b>General information:</b> Seek medical advice, if symptoms occur, which can be caused by the product  <b>after skin contact:</b> wash with plenty of water and soap  <b>after inhalation:</b> fresh air  <b>after eye contact:</b> Rinse opened eye for several minutes under running water and consult a doctor  <b>after swallowing:</b> Consult a physician.</p>
<b>5. <u>Fire fighting measures</u></b>
<p><b>Extinguishing media:</b>          CO<sub>2</sub>, powder, water spray, foam.          Use extinguishing method and media suitable to surrounding fire.  <b>Special hazards arising from the substance or mixture</b> No further relevant information available  <b>Protective equipment</b> Wear self-contained respiratory protective equipment</p>
<b>6. <u>Accidental release measures</u></b>
<p><b>Personal precautions, protective equipment and emergency procedures:</b>          Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms  <b>Environmental precautions:</b>          Do not allow to enter drains/surface water/ ground-water.  <b>Methods for cleaning up:</b>          Absorb with liquid binding material. Clean up affected area.  <b>Reference to other sections:</b>          See Section 7 for information on safe handling          See Section 8 for information on personal protection equipment          See Section 13 for disposal information</p>
<b>7. <u>Handling and storage</u></b>
<p><b>Handling:</b>          This product should only be supplied or handled to dentists or dental technicians or upon their instructions.  <b>Precautions for safe handling:</b> Observe normal care for working with chemicals  <b>Information about fire and explosion protection:</b> Keep away from heat and fire. Take measure to prevent electrostatic charge  <b>Storage:</b> Store at a dry place. Store tightly closed. Storage temperature &lt;25°C.  <b>Requirements at storerooms and containers:</b> Store only in the original containers  <b>Further information on storage conditions:</b>          Store away from food stuffs.  <b>Specific end uses:</b> 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
64-17-5	Ethanol	TRGS 900	500	ml/m <sup>3</sup> (ppm)
			or 960	mg/m <sup>3</sup>

**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**

<b>Form:</b>	liquid			
<b>Color:</b>	colorless			
<b>Odor:</b>	characteristic			
	<table border="1"> <thead> <tr> <th>Value</th> <th>Unit</th> <th>Method</th> </tr> </thead> </table>	Value	Unit	Method
Value	Unit	Method		

**Safety relevant basic data**

<b>Melting point/melting range:</b>	-114	°C
<b>Boiling point/boiling range:</b>	78	°C.
<b>Flash point:</b>	12	°C
<b>Ignition temperature:</b>	425	°C.
<b>Danger of explosion:</b>	Lower limit of explosion	3.5 % Kühn-
	Upper limit of explosion	15 % Birett
<b>Density:</b>	ca. 0.8	g/cm <sup>3</sup>
<b>Vapor pressure:</b>	n.d.	
<b>pH:</b>	neutral	
<b>Solubility in/miscibility with:</b>		
<b>Water:</b>	soluble	
<b>Content of solvents:</b>		
<b>Organic solvents:</b>	ethanol	

### 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, hydrides, strong oxidizing agents, radical initiators.

**Hazardous decomposition products:** no information available.

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### **11. Toxicological information**

**Acute toxicity: (ethanol)**

LD<sub>50</sub> (oral, rat) 6200 mg/kg

**Primary irritation:**

**skin:** degreasing effect

**eye:** irritation

**Sensitization:** no information available

**Additional toxicological information:**

Allergic reactions 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:** Avoid transfer into environment

**Classification of water endangerment:** WGK=1 (slightly polluting substance).

### **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):**

UN 1170 ETHANOL, 3, II

**Sea transport IMDG:**

UN 1170 ETHANOL, 3, II

EmS F-E S-D

**Air transport ICAO-TI and IATA-DGR:**

UN 1170 ETHANOL, 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. 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:**

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.