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

Date of issue: 01.02.2017
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1. Identification of the substance/mixture and of the company/undertaking

Product Identifier
Trade name: VITA ADIVA ZR-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
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.
P233 Keep container tightly closed.
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
3. Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Chemical characterization:</th>
<th>Beschreibung:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation based on acetone</td>
<td></td>
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</tbody>
</table>

**Hazardous components:**
CAS 67-64-1 (EINECS: 200-662-2) Acetone GHS02, GHS07, H225, H319, H336

4. First-aid measures

<table>
<thead>
<tr>
<th>General information: Seek medical advice, if symptoms occur, which can be caused by the product</th>
</tr>
</thead>
<tbody>
<tr>
<td>after skin contact: Wash with plenty of water and soap</td>
</tr>
<tr>
<td>after inhalation: Fresh air. Consult a physician if feeling unwell.</td>
</tr>
<tr>
<td>after eye contact: Rinse opened eye for several minutes under running water and consult an ophthalmologist</td>
</tr>
</tbody>
</table>

5. Fire fighting measures

<table>
<thead>
<tr>
<th>Extinguishing media: CO2, powder, water spray. Use extinguishing method and media suitable to surrounding fire</th>
</tr>
</thead>
</table>

**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:**
Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms

**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. Ensure supply of fresh air.

**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:** Keep away from heat and fire. Take measure to prevent electrostatic charge

**Storage:** Store at a dry place. Store tightly closed. 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
8. Exposure controls/personal protection
Components with limits of values to be supervised at the workplace:

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>name</th>
<th>art</th>
<th>value</th>
<th>unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>67-64-1</td>
<td>Acetone</td>
<td>TRGS 900</td>
<td>500</td>
<td>ml/m³ (ppm)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>or 1200</td>
<td>mg/m³</td>
</tr>
</tbody>
</table>

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
Form: liquid
Color: colorless
Odor: characteristic

Safety relevant basic data
Melting point/melting range: n.d.
Boiling point/boiling range: 55 °C
Flash point: -20 °C DIN 51794
Ignition temperature: no information available
Danger of explosion:
Density: ca. 0.8 g/cm³
Vapor pressure: n.d.
Solubility in/miscibility with:
Water: soluble
Content of solvents:
Organic solvents: Acetone

10. Stability and reactivity
Thermal decomposition / conditions to be avoided
Possibility of hazardous reactions: no information available
Conditions to avoid: Heat, sunlight, peroxides, alcali hydroxides, halogens, halogenated hydrocarbons, strong oxidizers, free radical initiators.
Hazardous decomposition products: No information available.
11. Toxicological information

Acute toxicity: (acetone)
LD$_{50}$ (oral, rat) 5800 mg/kg

Primary irritation:
- skin: irritant. Degreasing effect on the skin, possibly followed by secondary inflammation.
- eye: irritant

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 1090 ACETON, 3, II

Sea transport IMDG:
UN 1090 ACETONE, 3 II
EmS: F-E S-D

Air transport ICAO-TI and IATA-DGR:
UN 1090 ACETONE, 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.