

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 M-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

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3. Composition/Information on Ingredients

Chemical characterization:

Beschreibung:

Preparation based on acetone

Hazardous components:

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

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. Consult a physician if feeling unwell.

after eye contact: Rinse opened eye for several minutes under running water and consult an ophthalmologist

after swallowing: Caution: Aspiration hazard. Keep respiratory tract clear. Call a physician.

5. Fire fighting measures

Extinguishing media:

CO₂, powder, water spray.

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:

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

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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
67-64-1	Acetone	TRGS 900	500	ml/m ³ (ppm)
			or 1200	mg/m ³

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
	<u>Value Unit Method</u>

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.

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11. Toxicological information

Acute toxicity: (acetone)

LD₅₀ (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.