

Safety Data Sheet

according to UK REACH Regulation

VITA ADIVA CERA ETCH

Revision date: 20.01.2023

Product code: 307

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

VITA ADIVA CERA ETCH

UFI: 6NH1-20UD-X00W-YF2U

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Use as laboratory reagent

1.3. Details of the supplier of the safety data sheet

Company name: VITA Zahnfabrik H.Rauter GmbH & Co.KG

Street: Spitalgasse 3

Place: D-79713 Bad Säckingen

Post-office box: 1338

D-79704 Bad Säckingen

Telephone: +49(0)7761-562-0

Telefax: +49(0)7761-562-299

e-mail: info@vita-zahnfabrik.com

Contact person: regulatory affairs

e-mail: info@vita-zahnfabrik.com

Internet: www.vita-zahnfabrik.com

Responsible Department: Regulatory Affairs

1.4. Emergency telephone number:

+49-(0)761-19240

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Met. Corr. 1; H290

Acute Tox. 2; H310

Acute Tox. 3; H301

Acute Tox. 4; H332

Skin Corr. 1A; H314

Eye Dam. 1; H318

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

hydrofluorid acid

Sulphuric acid

Signal word: Danger

Pictograms:



Hazard statements

H301 Toxic if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

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H332 Harmful if inhaled.

Precautionary statements

P405 Store locked up.
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
7664-93-9	Sulphuric acid			5 - < 10 %
	231-639-5	016-020-00-8		
	Skin Corr. 1A; H314			
7664-39-3	hydrofluorid acid			1 - < 5 %
	231-634-8	009-002-00-6	01-2119458860-33	
	Acute Tox. 1, Acute Tox. 2, Acute Tox. 2, Skin Corr. 1A; H310 H330 H300 H314			
64-17-5	ethyl alcohol			1 - < 5 %
	200-578-6	603-002-00-5	01-2119457610-43	
	Flam. Liq. 2, Eye Irrit. 2; H225 H319			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
7664-93-9	231-639-5	Sulphuric acid	5 - < 10 %
	Skin Corr. 1A; H314: >= 15 - 100 Skin Irrit. 2; H315: >= 5 - < 15 Eye Irrit. 2; H319: >= 5 - < 15		
7664-39-3	231-634-8	hydrofluorid acid	1 - < 5 %
	inhalation: ATE = 0.5 mg/l (vapours); inhalation: ATE = 0.05 mg/l (dusts or mists); dermal: ATE = 5 mg/kg; oral: ATE = 5 mg/kg		
64-17-5	200-578-6	ethyl alcohol	1 - < 5 %
	dermal: LD50 = 7060 mg/kg		

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.

After inhalation

Provide fresh air. Medical treatment necessary. IF INHALED: Call a POISON CENTER/doctor// if you feel unwell.

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After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Call a physician immediately. IF ON SKIN (or hair): Ca-Gluconate solution. Immediately call a POISON CENTER/doctor/.

After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Immediately call a POISON CENTER/doctor/.

After ingestion

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Adverse human health effects and symptoms: Gastric perforation. Call a physician immediately. If swallowed, immediately drink: Ca-Gluconate solution

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

Use as laboratory reagent

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
64-17-5	Ethanol	1000	1920		TWA (8 h)	WEL
7664-39-3	Hydrogen fluoride (as F)	1.8	1.5		TWA (8 h)	WEL
		3	2.5		STEL (15 min)	WEL
7664-93-9	Sulphuric acid (mist)	-	0.05		TWA (8 h)	WEL

8.2. Exposure controls



Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection.

Hand protection

Recommended glove articles KCL Dermatrill P Wearing time with occasional contact (splashes): 480 min When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Wear suitable protective clothing.

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Respiratory protection

If handled uncovered, arrangements with local exhaust ventilation have to be used.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Colour: light red
Odour: characteristic

Changes in the physical state

Melting point/freezing point: not determined
Boiling point or initial boiling point and boiling range: 100 °C

Flammability

Solid/liquid: not applicable
Gas: not applicable

Lower explosion limits: not determined
Upper explosion limits: not determined

Self-ignition temperature

Solid: not applicable
Gas: not applicable

Decomposition temperature: not determined
pH-Value: 2,0

Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined

Vapour pressure: ≤1100 hPa
(at 50 °C)

Density: 1,06000 g/cm³

Relative vapour density: not determined

9.2. Other information

Information with regard to physical hazard classes

Oxidizing properties
Not oxidising.

Other safety characteristics

Solid content: 1,5 %
Evaporation rate: not determined

Further Information

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

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10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

Fatal in contact with skin.

Toxic if swallowed.

Harmful if inhaled.

ATEmix calculated

ATE (oral) 100,4 mg/kg; ATE (dermal) 100,4 mg/kg; ATE (inhalation vapour) 10,04 mg/l; ATE (inhalation dust/mist) 1,004 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
7664-39-3	hydrofluorid acid				
	oral	ATE 5 mg/kg			
	dermal	ATE 5 mg/kg			
	inhalation vapour	ATE 0.5 mg/l			
	inhalation dust/mist	ATE 0.05 mg/l			
64-17-5	ethyl alcohol				
	dermal	LD50 7060 mg/kg			

Irritation and corrosivity

Causes severe skin burns and eye damage.

Causes serious eye damage.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP]. Special hazards arising from the substance or mixture!

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

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12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:

UN 2922

14.2. UN proper shipping name:

CORROSIVE LIQUID, TOXIC, N.O.S. (Sulphuric acid; hydrofluorid acid)

14.3. Transport hazard class(es):

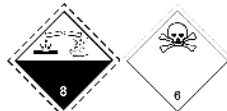
8

14.4. Packing group:

II

Hazard label:

8+6.1



Classification code:

CT1

Special Provisions:

274

Limited quantity:

1 L

Excepted quantity:

E2

Transport category:

2

Hazard No:

86

Tunnel restriction code:

E

Inland waterways transport (ADN)

14.1. UN number or ID number:

UN 2922

14.2. UN proper shipping name:

CORROSIVE LIQUID, TOXIC, N.O.S. (Sulphuric acid; hydrofluorid acid)

14.3. Transport hazard class(es):

8

14.4. Packing group:

II

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Hazard label:

8+6.1



Classification code:

CT1

Special Provisions:

274 802

Limited quantity:

1 L

Excepted quantity:

E2

Marine transport (IMDG)

14.1. UN number or ID number:

UN 2922

14.2. UN proper shipping name:

CORROSIVE LIQUID, TOXIC, N.O.S. (Sulphuric acid; hydrofluorid acid)

14.3. Transport hazard class(es):

8

14.4. Packing group:

II

Hazard label:

8+6.1



Special Provisions:

274

Limited quantity:

1 L

Excepted quantity:

E2

EmS:

F-A, S-B

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:

UN 2922

14.2. UN proper shipping name:

CORROSIVE LIQUID, TOXIC, N.O.S. (Sulphuric acid; hydrofluorid acid)

14.3. Transport hazard class(es):

8

14.4. Packing group:

II

Hazard label:

8+6.1



Special Provisions:

A3 A803

Limited quantity Passenger:

0.5 L

Passenger LQ:

Y840

Excepted quantity:

E2

IATA-packing instructions - Passenger:

851

IATA-max. quantity - Passenger:

1 L

IATA-packing instructions - Cargo:

855

IATA-max. quantity - Cargo:

30 L

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS:

No

14.6. Special precautions for user

Warning: Toxic. strongly corrosive.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

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Restrictions on use (REACH, annex XVII):

Entry 3, Entry 40, Entry 75

National regulatory information

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water hazard class (D):

2 - obviously hazardous to water

Skin resorption/Sensitization:

Permeates easily through outer skin and causes poisoning.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,8,14.

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Classification for mixtures and used evaluation method according to GB CLP Regulation

Classification	Classification procedure
Met. Corr. 1; H290	
Acute Tox. 2; H310	Calculation method
Acute Tox. 3; H301	Calculation method
Acute Tox. 4; H332	Calculation method
Skin Corr. 1A; H314	Calculation method
Eye Dam. 1; H318	Calculation method

Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H290	May be corrosive to metals.
H300	Fatal if swallowed.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H332	Harmful if inhaled.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product

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named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

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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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3. <u>Composition/Information on Ingredients</u> Chemical characterization: Description: Solution of methacrylsilanes in ethanol Hazardous components: 64-17-5 (CAS-No.) Ethanol GHS02, H225
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: fresh air after eye contact: Rinse opened eye for several minutes under running water and consult a doctor after swallowing: Consult a physician.
5. <u>Fire fighting measures</u> Extinguishing media: CO ₂ , powder, water spray, foam. 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. <u>Accidental release measures</u> 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. 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: 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
64-17-5	Ethanol	TRGS 900	500	ml/m ³ (ppm)
			or 960	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			
	<table><tr><th>Value</th><th>Unit</th><th>Method</th></tr></table>	Value	Unit	Method
Value	Unit	Method		

Safety relevant basic data

Melting point/melting range: -114 °C

Boiling point/boiling range: 78 °C.

Flash point: 12 °C

Ignition temperature: 425 °C.

Danger of explosion: Lower limit of explosion 3.5 % Kühn-
 Upper limit of explosion 15 % Birett

Density: ca. 0.8 g/cm³

Vapor pressure: n.d.

pH: neutral

Solubility in/miscibility with:

Water: soluble

Content of solvents:

Organic solvents: 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)

LD₅₀ (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.

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according to 1907/2006/EC, Article 31

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

Product Identifier

Trade name: VITA ADIVA F-CEM

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

Skin Sens. 1; H317 May cause allergic skin reaction

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

H317 May cause allergic skin reaction

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302+P352 IF ON SKIN: Wash with plenty of soap and water

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: Description: Mixture of resin based on Bis-GMA, catalyst, stabilizer, pigments Hazardous components: Methacrylates GHS07, H315, H319, H317, 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: fresh air after eye contact: rinse with plenty of water and consult a doctor after swallowing: If symptoms persist consult a doctor
5. <u>Fire fighting measures</u> Extinguishing media: CO ₂ , 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. <u>Accidental release measures</u> Personal precautions: not required Environmental precautions: Do not allow to enter drains/surface water/ ground-water. Methods for cleaning up: Pick up mechanically. 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. Information for safe handling: Observe normal care for working with chemicals. Information about fire and explosion protection: No special measures required 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:

The product contains no relevant quantities of components with limits of 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:

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:	flowable paste		
Color:	tooth colored		
Odor:	odorless		
	<u>Value</u>	<u>Unit</u>	<u>Method</u>

Safety relevant basic data

Melting point/melting range: n.a.

Boiling point/boiling range: n.a.

Flash point: n.d.

Ignition temperature: n.d.

Danger of explosion: none

Density: 1.72 (20°C) g/cm³

Vapor pressure: n.a.

pH: neutral

Solubility in/miscibility with: Partially soluble in toluene, silicone oil

Water: insoluble

Content of solvents: none

Organic solvents: none

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. <u>Toxicological information</u> Acute toxicity: no data available Primary irritation: skin: irritant eye: irritant Sensitization: sensitization by skin contact possible Additional toxicological information: Allergic reactions to the product 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. <u>Ecological information</u> General information: Avoid transfer into environment Classification of water endangerment: WGK=1 (slightly polluting substance).
13. <u>Disposal considerations</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 and GGVS/GGVE (Germany): no subject to transport regulations Sea transport IMDG: no subject to transport regulations Air transport ICAO-TI and 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: 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.

Safety Data Sheet

according to UK REACH Regulation

VITA ADIVA OXY-PREVENT

Revision date: 15.08.2023

Product code: 308

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

VITA ADIVA OXY-PREVENT

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Auxiliary for manufacture of dental products

1.3. Details of the supplier of the safety data sheet

Company name: VITA Zahnfabrik H.Rauter GmbH & Co.KG

Street: Spitalgasse 3

Place: D-79713 Bad Säckingen

Post-office box: 1338

D-79704 Bad Säckingen

Telephone: +49(0)7761-562-0

Telefax: +49(0)7761-562-299

E-mail: info@vita-zahnfabrik.com

Contact person: regulatory affairs

E-mail: info@vita-zahnfabrik.com

Internet: www.vita-zahnfabrik.com

Responsible Department: Regulatory Affairs

Further Information

medical device

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

2.2. Label elements

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Substance, organic

Hazardous components

none (according to UK REACH Regulation)

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

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After ingestion

Rinse mouth immediately and drink plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable. Vapours can form explosive mixtures with air.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Use water spray jet to protect personnel and to cool endangered containers. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

No special measures are necessary.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

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Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

Auxiliary for manufacture of dental products

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
56-81-5	Glycerol, mist	-	10		TWA (8 h)	WEL

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. NBR (Nitrile rubber)

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Open windows to ensure natural ventilation.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	
Odour:	characteristic
Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	192 °C
Flammability:	not applicable
Flash point:	180 °C
Decomposition temperature:	not determined
pH-Value:	not determined
Solubility in other solvents	
not determined	
Partition coefficient n-octanol/water:	not determined
Vapour pressure:	not determined
Density:	not determined
Relative vapour density:	not determined

9.2. Other information

Information with regard to physical hazard classes

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Explosive properties

The product is not: Explosive.

Self-ignition temperature

Solid:

not applicable

Gas:

not applicable

Oxidizing properties

Not oxidising.

Other safety characteristics

Evaporation rate:

not determined

Solid content:

not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

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SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

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according to UK REACH Regulation

VITA ADIVA OXY-PREVENT

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14.4. Packing group:

No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 75

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1.

Safety Data Sheet

according to UK REACH Regulation

VITA ADIVA OXY-PREVENT

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Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

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 TE-CEM

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 Irritation, Category 2; H315 Causes skin irritation

Eye Irritation, Category 2; H319 Causes serious eye irritation

STOT SE, Category 3, H335 May cause respiratory irritation

Acute aquatic toxicity, Category 1, H400 Very toxic to aquatic life

Chronic aquatic toxicity, Category 1, H410 Very toxic to aquatic life with long lasting effects

Information concerning particular hazards for human and environment:

The product has 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:

Hazard pictograms



Signal word

Warning

Hazard statements

H315 Causes skin irritation

H319 Causes serious eye irritation

H335 May cause respiratory irritation

H400 Very toxic to aquatic life

Precautionary statements

P262 Do not get in eyes, on skin or on clothing.

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: Mixture

Description of the mixture: Mixture of organic acids, zinc oxide and methacrylates

Hazardous components:

Methacrylates [Index-No. 607-134-00-4] GHS07, H315, H319, H335

Zinc oxide [CAS-No. 1314-13-2] GHS09, H410, H411

4. First-aid measures

General information: no special measures required

after skin contact: wash with plenty of water and soap

after eye contact: Rinse opened eye for several minutes under running water and consult a doctor

after swallowing: Seek medical advice immediately

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

Environmental precautions:

Do not allow to enter drains/surface water/ ground-water.

Methods for cleaning up:

Take up mechanically. Clean up affected area. Forward for disposal.

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: 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, storage temperature < 25°C. Store away from food stuffs.

Specific end uses: No further relevant information available

Safety Data Sheet

according to 1907/2006/EC, Article 31

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 Printing date: 27.02.2017

Version: 1

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 and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs and beverages.

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:	paste		
Color:	Tooth colored		
Odor:	odorless		
	<u>Value</u>	<u>Unit</u>	<u>Method</u>

Safety relevant basic data

Melting point/melting range: n.a.

Boiling point/boiling range: n.a.

Flash point: n.a.

Ignition temperature: Product is not selfigniting

Danger of explosion: None

Density: 1,56 (20 °C) g/cm³

Vapor pressure: Not applicable (non volatile)

Solubility in/miscibility with: slightly in toluene, organic solvents

Water: insoluble

Content of solvents: none

Organic solvents: none

10. Stability and reactivity

Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications.

Possibility of hazardous reactions: No dangerous reaction known

Conditions to avoid: avoid heat, direct sunlight

Incompatible materials: Peroxides, metal powders, strong oxidizers, free radical initiators

Hazardous decomposition products: No dangerous decomposition products known.

11. Toxicological information

Allergic reactions to methacrylates by chronic exposure to the product are possible

Acute toxicity:

Primary irritation:

skin: slightly irritating

eye: irritating effect

Sensitization: no sensitizing effect known

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according to 1907/2006/EC, Article 31

Date of issue: 01.02.2017
 Printing date: 27.02.2017

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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. Ecological information

Toxicity:

Aquatic toxicity: May cause long term adverse effect in the aquatic environment

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 product 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: Handle contaminated packaging in the same way as the substance itself.

Recommendation: Disposal must be made according to official regulations

14. Transport information

Land transport ADR/RID and GGVS/GGVE (Germany)

no subject to transport regulations.

Sea transport IMDG

no subject to transport regulations.

Air transport ICAO-TI and IATA-DGR

no subject to transport regulations.

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.

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 T-BOND I

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

Danger

Hazard statements

H315 Causes skin irritation

H319 Causes serious eye irritation

H335 May cause respiratory irritation

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302+P352 IF ON SKIN: Wash with plenty of soap and water

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

Safety Data Sheet

according to 1907/2006/EC, Article 31

Date of issue: 01.02.2017
 Printing date: 27.02.2017

Version: 1

3. Composition/Information on Ingredients

Chemical characterization:

Description:

Modified acrylic acid, poly acrylic acid, methacrylates, catalysts, stabilizers in ethanol

Hazardous components:

607-134-00-4 (Index No.)	Methacrylates	GHS07, H315, H319, H335
64-17-5 (CAS-No.)	Ethanol	GHS02, H225

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

after eye contact: Rinse opened eye for several minutes under running water and consult a doctor

after swallowing: Consult 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.

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

Safety Data Sheet

according to 1907/2006/EC, Article 31

Date of issue: 01.02.2017
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Version: 1

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 ³ (ppm)
			or 960	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.a.

Boiling point/boiling range: n.a.

Flash point: n.a.

Ignition temperature: no information available

Danger of explosion:

Density: ca. 1.0 g/cm³

Vapor pressure: n.d.

pH: ca. 3

Solubility in/miscibility with:

Water: soluble

Content of solvents:

Organic solvents: 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.

Safety Data Sheet

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11. Toxicological information

Acute toxicity: (ethanol)

LD₅₀ (oral, rat) 6200 mg/kg

Primary irritation:

skin: irritant

eye: irritant

Sensitization: no information available

Additional toxicological information:

Allergic reactions to methacrylates 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):

No subject to transport regulations

Sea transport IMDG:

No subject to transport regulations

Air transport ICAO-TI and IATA-DGR:

No subject to transport regulations

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.

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 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

Safety Data Sheet

according to 1907/2006/EC, Article 31

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3. <u>Composition/Information on Ingredients</u> Chemical characterization: Beschreibung: Preparation based on acetone Hazardous components: CAS 67-64-1(EINECS: 200-662-2) Acetone GHS02, GHS07, H225, H319, H336
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: Fresh air. Consult a physician if feeling unwell. after eye contact: Rinse opened eye for several minutes under running water and consult an ophtalmologist after swallowing: Caution: Aspiration hazard. Keep respiratory tract clear. Call a physician.
5. <u>Fire fighting measures</u> Extinguishing media: CO ₂ , 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. <u>Accidental release measures</u> 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. <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: 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

Safety Data Sheet

according to 1907/2006/EC, Article 31

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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</u> <u>Unit</u> <u>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.

Safety Data Sheet

according to 1907/2006/EC, Article 31

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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.

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 T-BOND II

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

3. Composition/Information on Ingredients

Chemical characterization:

Description:

Solution of methacrylates, catalysts and stabilizers in ethanol

Hazardous components:

64-17-5 (CAS-No.)	Ethanol	GHS02, H225
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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
after eye contact: Rinse opened eye for several minutes under running water and consult a doctor
after swallowing: Consult 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.
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

Safety Data Sheet

according to 1907/2006/EC, Article 31

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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 ³ (ppm)
			or 960	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</u> <u>Unit</u> <u>Method</u>

Safety relevant basic data

Melting point/melting range: -114 °C

Boiling point/boiling range: 78 °C.

Flash point: 12 °C

Ignition temperature: 425 °C.

Danger of explosion: Lower limit of explosion 3.5 % Kühn-
 Upper limit of explosion 15 % Birett

Density: 0.8 g/cm³

Vapor pressure: n.d.

pH: neutral

Solubility in/miscibility with:

Water: soluble

Content of solvents:

Organic solvents: 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.

Safety Data Sheet

according to 1907/2006/EC, Article 31

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11. Toxicological information

Acute toxicity: (ethanol)

LD₅₀ (oral, rat) 6200 mg/kg

Primary irritation:

skin: degreasing effect

eye: slight 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.