

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: Ufi Gel Hard

Manufacturer: VOCO GmbH

SDS Expiry: 12 April 2030

Supplier Details: Henry Schein New Zealand
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0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 3.1C, 6.4A, 6.5B,

HSNO Group Standard: Dental Products Flammable Group Standard 2020 HSR002556

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – June 2026

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/04/2025

Reviewed on 12/04/2025

1 Identification

· **Product identifier**

· **Trade name:** Ufi Gel hard C base

· **Information:**

This product is a medical device within the meaning of the US Federal Food, Drug and Cosmetic Act, the Canadian Medical Devices Regulations (CMDR) SOR/98-282 and the Canadian Food and Drugs Act R.S.S., 1985, c. F-27, which is used invasively or in contact with the body. It is therefore exempt from the classification and labeling requirements of the US Hazard Communication Standard (HCS), WHMIS, the Canadian Hazardous Products Act (HPA) and the Canadian Hazardous Products Regulations Act (HPR).

A safety data sheet is not required by law for this product. This information is provided on a voluntary basis.

· **Application of the substance / the mixture** Luting of prosthetic teeth

· **Uses advised against** No further relevant information available.

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier**

VOCO GmbH

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· **Information department:**

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2 Hazard(s) identification

Health effects are based on the unmixed/uncured material.

Under FDA regulations this product is classified as a medical device.

Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

· **Classification of the substance or mixture**

This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d).

The classification criteria of Regulation (EC) No 1272/2008 are not directly applicable to this product, but are considered by us as an orienting basis for assessment. The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes. The following hazards based on the classification criteria of Regulation (EC) No 1272/2008 for humans and the environment cannot be excluded:



GHS07

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

Eye Irritation 2B H320 Causes eye irritation.

· **Additional information:** Health effects are based on the unmixed/uncured material.

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Trade name: Ufi Gel hard C base

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- **Label elements**
- **Hazard pictograms**



GHS07

- **Hazard statements**
 - Causes eye irritation.
 - May cause an allergic skin reaction.
- **Precautionary statements**
 - Wear protective gloves.
 - If on skin: Wash with plenty of water.
 - If skin irritation or rash occurs: Get medical advice/attention.
 - Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
 - Use only for intended scope of application.
 - None
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 72869-86-4	Urethane dimethacrylate Sensitization - Skin 1B, H317	5-10%
	Catalyst Eye Damage 1, H318 Acute Toxicity - Oral 4, H302; Sensitization - Skin 1, H317	≤1%

- **Additional information:**
 - Further information on ingredients can be found in the instructions for use.
 - In case of known hypersensitivity to the ingredients mentioned in the instructions for use, do not use the product.

4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Seek medical treatment in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**
 - Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
 - **Most important symptoms and effects, both acute and delayed** No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
 - No further relevant information available.

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Safety Data Sheet

acc. to OSHA HCS

Printing date 12/04/2025

Reviewed on 12/04/2025

Trade name: Ufi Gel hard C base

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5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.
- **Protective Action Criteria for Chemicals**

- **PAC-1:**

CAS: 72869-86-4	Urethane dimethacrylate	120 mg/m ³
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- **PAC-2:**

CAS: 72869-86-4	Urethane dimethacrylate	1,300 mg/m ³
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- **PAC-3:**

CAS: 72869-86-4	Urethane dimethacrylate	7,900 mg/m ³
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7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Observe the instructions for use! This contains the relevant application and safety information for the use of this product.
No special precautions are necessary if used correctly.
For dental use only.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** See storage instructions on package
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:**
The lists that were valid during the creation were used as basis.
Due to the proportions contained in relation to the amount of product during application and the way it is the product, monitoring of specific, workplace-related limit values is not applicable.

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Trade name: Ufi Gel hard C base

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- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
In the context of the use of this product, the hygiene standards customary and general in dental practice, such as hand, mouth and eye protection, must be applied.
- **Protection of hands:** Single-use gloves.
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Pasty
Color:	Light red
Odor:	Characteristic
- **pH-value:** Not determined.
- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Ignition temperature:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Density:** Not determined.
- **Solubility in / Miscibility with Water:** Not miscible or difficult to mix.
- **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.
- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

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(Contd. on page 5)

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Trade name: Ufi Gel hard C base

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11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed
- **NTP (National Toxicology Program)**
None of the ingredients is listed.
- **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **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.
- **Ecotoxicological effects:**
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Void

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Trade name: Ufi Gel hard C base

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· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es) · DOT, ADR, ADN, IMDG, IATA · Class	Void
· Packing group · DOT, ADR, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
Regulation (EU) 2017/745
Medical Devices Regulation
Directive 93/42/EEC concerning medical devices
US Federal Food, Drug and Cosmetic Act
Canadian Medical Devices Regulations
- **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

One or more substances contained in this material are not listed on the TSCA Inventory.
Contact manufacturer or supplier for more information.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients are listed

· **TLV (Threshold Limit Value)**

Contact manufacturer for more information.

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· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients are listed

16 Other information

The product to which this data sheet is assigned is a medical device within the meaning of the US Federal Food, Drug and Cosmetic Act (FFDCA), the Canadian Medical Devices Regulations (CMDR) SOR/98-282 and the Canadian Food and Drugs Act R.S.S., 1985, c. F-27 and to the EU Medical Devices Regulation EU 2017/745, that is used invasively or in contact with the body. Invasive medical devices or medical devices in direct physical contact are exempt from the requirements for classification and labelling according to Hazard Communication Standard (HCS), WHMIS, Canadian Hazardous Products Act (HPA) and Canadian Hazardous Products Regulations Act (HPR) and also to Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d). The Medical Devices Regulation does not require a safety data sheet for invasive medical devices or medical devices in direct body contact, as the safe use of the product is indicated in the instructions for use and/or the labelling. Nevertheless, we provide a data sheet in order to provide as transparent a source as possible for the assessment of hazards to humans and the environment.

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.

Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

· **Department issuing SDS:** Knowledge Communication Department

· **Contact:**

Global headquarter:

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For further contact information, please visit www.voco.dental

· **Date of preparation / last revision** 12/04/2025 / 1

· **Abbreviations and acronyms:**

Acute Toxicity - Oral 4: Acute toxicity – Category 4

Eye Damage 1: Serious eye damage/eye irritation – Category 1

Eye Irritation 2B: Serious eye damage/eye irritation – Category 2B

Sensitization - Skin 1: Skin sensitisation – Category 1

Sensitization - Skin 1B: Skin sensitisation – Category 1B

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2025

Reviewed on 12/05/2025

1 Identification

· **Product identifier**

· **Trade name:** Ufi Gel hard C catalyst

· **Information:**

This product is a medical device within the meaning of the US Federal Food, Drug and Cosmetic Act, the Canadian Medical Devices Regulations (CMDR) SOR/98-282 and the Canadian Food and Drugs Act R.S.S., 1985, c. F-27, which is used invasively or in contact with the body. It is therefore exempt from the classification and labeling requirements of the US Hazard Communication Standard (HCS), WHMIS, the Canadian Hazardous Products Act (HPA) and the Canadian Hazardous Products Regulations Act (HPR).

A safety data sheet is not required by law for this product. This information is provided on a voluntary basis.

· **Application of the substance / the mixture** Luting of prosthetic teeth

· **Uses advised against** No further relevant information available.

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier**

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· **Emergency telephone number:**

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2 Hazard(s) identification

· **Classification of the substance or mixture**

This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d).

The classification criteria of Regulation (EC) No 1272/2008 are not directly applicable to this product, but are considered by us as an orienting basis for assessment. The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes. The following hazards based on the classification criteria of Regulation (EC) No 1272/2008 for humans and the environment cannot be excluded:



GHS07

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

Eye Irritation 2B H320 Causes eye irritation.

· **Additional information:**

This product is a medical device within the meaning of the US Federal Food, Drug and Cosmetic Act, the Canadian Medical Devices Regulations (CMDR) SOR/98-282 and the Canadian Food and Drugs Act R.S.S., 1985, c. F-27, which is used invasively or in contact with the body. It is therefore exempt from the classification and labeling requirements of the US Hazard Communication Standard (HCS), WHMIS, the Canadian Hazardous Products Act (HPA) and the Canadian Hazardous Products Regulations Act (HPR).

Health effects are based on the unmixed/uncured material.

Under FDA regulations this product is classified as a medical device.

Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

(Contd. on page 2)

Safety Data Sheet

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Printing date 12/05/2025

Reviewed on 12/05/2025

Trade name: Ufi Gel hard C catalyst

(Contd. of page 1)

- **Label elements**
- **Hazard pictograms**



GHS07

- **Hazard statements**
 - Causes eye irritation.
 - May cause an allergic skin reaction.
- **Precautionary statements**
 - Avoid breathing dust/fume/gas/mist/vapors/spray
 - Avoid release to the environment.
 - Wear protective gloves.
 - If on skin: Wash with plenty of water.
 - If skin irritation or rash occurs: Get medical advice/attention.
 - Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards** Use only for intended scope of application.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 72869-86-4	Urethane dimethacrylate ⚠ Sensitization - Skin 1B, H317	5-10%
	benzoyl peroxyde ⚠ Organic Peroxides - Type C, H242 ⚠ Eye Irritation 2A, H319; Sensitization - Skin 1, H317	≤2.5%

- **Additional information:**
 - Further information on ingredients can be found in the instructions for use.
 - In case of known hypersensitivity to the ingredients mentioned in the instructions for use, do not use the product.

4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**
 - Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
 - Rinse out mouth and then drink plenty of water.
 - If symptoms persist consult doctor.
- **Information for doctor:**
 - **Most important symptoms and effects, both acute and delayed** No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

US

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2025

Reviewed on 12/05/2025

Trade name: Ufi Gel hard C catalyst

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5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.
- **Protective Action Criteria for Chemicals**

- **PAC-1:**

CAS: 72869-86-4	Urethane dimethacrylate	120 mg/m ³
	benzoyl peroxyde	15 mg/m ³

- **PAC-2:**

CAS: 72869-86-4	Urethane dimethacrylate	1,300 mg/m ³
	benzoyl peroxyde	1,200 mg/m ³

- **PAC-3:**

CAS: 72869-86-4	Urethane dimethacrylate	7,900 mg/m ³
	benzoyl peroxyde	7,000 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Observe the instructions for use! This contains the relevant application and safety information for the use of this product.
No special precautions are necessary if used correctly.
For dental use only.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** See storage instructions on package
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2025

Reviewed on 12/05/2025

Trade name: Ufi Gel hard C catalyst

(Contd. of page 3)

· **Additional information:**

Due to the proportions contained in relation to the amount of product during application and the way it is the product, monitoring of specific, workplace-related limit values is not applicable.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

In the context of the use of this product, the hygiene standards customary and general in dental practice, such as hand, mouth and eye protection, must be applied.

· **Protection of hands:** Single-use gloves.

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Eye protection:** Safety glasses

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Pasty

Color: White

· **Odor:** Characteristic

· **pH-value:** Not determined.

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable.

· **Ignition temperature:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Density:** Not determined.

· **Solubility in / Miscibility with**

Water: Not miscible or difficult to mix.

· **Viscosity:**

Dynamic: Not determined.

Kinematic: Not determined.

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability**

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** No dangerous decomposition products known.

US

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/05/2025

Reviewed on 12/05/2025

Trade name: Ufi Gel hard C catalyst

(Contd. of page 4)

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

	benzoyl peroxyde	3
CAS: 128-37-0	Butylated hydroxytoluene	3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **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.
- **Ecotoxicological effects:**
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow product to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Void
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Void

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Trade name: *Ufi Gel hard C catalyst*

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|-----------------------------------------------------------------------------------|-----------------|
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
 Regulation (EU) 2017/745
 Medical Devices Regulation
 Directive 93/42/EEC concerning medical devices
 US Federal Food, Drug and Cosmetic Act
 Canadian Medical Devices Regulations
- **Sara**

· Section 355 (extremely hazardous substances):

None of the ingredients are listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients are listed.

· TSCA (Toxic Substances Control Act):

One or more substances contained in this material are not listed on the TSCA Inventory. Contact manufacturer or supplier for more information.

· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients are listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients are listed

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients are listed

· Chemicals known to cause developmental toxicity:

None of the ingredients are listed

· Cancerogenity categories

· EPA (Environmental Protection Agency)

None of the ingredients are listed

· TLV (Threshold Limit Value)

benzoyl peroxyde

A4

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Trade name: Ufi Gel hard C catalyst

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· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients are listed

16 Other information

The product to which this data sheet is assigned is a medical device within the meaning of the US Federal Food, Drug and Cosmetic Act (FFDCA), the Canadian Medical Devices Regulations (CMDR) SOR/98-282 and the Canadian Food and Drugs Act R.S.S., 1985, c. F-27 and to the EU Medical Devices Regulation EU 2017/745, that is used invasively or in contact with the body. Invasive medical devices or medical devices in direct physical contact are exempt from the requirements for classification and labelling according to Hazard Communication Standard (HCS), WHMIS, Canadian Hazardous Products Act (HPA) and Canadian Hazardous Products Regulations Act (HPR) and also to Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d). The Medical Devices Regulation does not require a safety data sheet for invasive medical devices or medical devices in direct body contact, as the safe use of the product is indicated in the instructions for use and/or the labelling. Nevertheless, we provide a data sheet in order to provide as transparent a source as possible for the assessment of hazards to humans and the environment.

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.

Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

· **Department issuing SDS:** Knowledge Communication Department

· **Contact:**

Global headquarter:

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D-27472 Cuxhaven

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· **Date of preparation / last revision** 12/05/2025 / 3

· **Abbreviations and acronyms:**

Organic Peroxides - Type C: Organic peroxides – Type C/D

Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

Eye Irritation 2B: Serious eye damage/eye irritation – Category 2B

Sensitization - Skin 1: Skin sensitisation – Category 1

Sensitization - Skin 1B: Skin sensitisation – Category 1B

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Printing date 12/04/2025

Reviewed on 12/04/2025

1 Identification

· **Product identifier**

· **Trade name:** Ufi Gel hard C Adhäsiv

· **Information:**

This product is a medical device within the meaning of the US Federal Food, Drug and Cosmetic Act, the Canadian Medical Devices Regulations (CMDR) SOR/98-282 and the Canadian Food and Drugs Act R.S.S., 1985, c. F-27, which is used invasively or in contact with the body. It is therefore exempt from the classification and labeling requirements of the US Hazard Communication Standard (HCS), WHMIS, the Canadian Hazardous Products Act (HPA) and the Canadian Hazardous Products Regulations Act (HPR).

A safety data sheet is not required by law for this product. This information is provided on a voluntary basis.

· **Application of the substance / the mixture** Dental bonding agent

· **Uses advised against** No further relevant information available.

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier**

VOCO GmbH

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· **Emergency telephone number:**

Knowledge Communication Department

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Mo - Fr / 08:00h - 16:00h / CET

2 Hazard(s) identification

· **Classification of the substance or mixture**

This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d).

The classification criteria of Regulation (EC) No 1272/2008 are not directly applicable to this product, but are considered by us as an orienting basis for assessment. The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes. The following hazards based on the classification criteria of Regulation (EC) No 1272/2008 for humans and the environment cannot be excluded:



GHS02 Flame

Flammable Liquids 3

H226 Flammable liquid and vapor.



GHS07

Eye Irritation 2A

H319 Causes serious eye irritation.

Sensitization - Skin 1

H317 May cause an allergic skin reaction.

Specific Target Organ Toxicity - Single Exposure 3 H336 May cause drowsiness or dizziness.

· **Additional information:**

Health effects are based on the unmixed/uncured material.

Under FDA regulations this product is classified as a medical device.

Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

This product is a medical device within the meaning of the US Federal Food, Drug and Cosmetic Act, the Canadian Medical Devices Regulations (CMDR) SOR/98-282 and the Canadian Food and Drugs Act R.S.S., 1985, c. F-27, which is used invasively or in contact with the body. It is therefore exempt from the

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classification and labeling requirements of the US Hazard Communication Standard (HCS), WHMIS, the Canadian Hazardous Products Act (HPA) and the Canadian Hazardous Products Regulations Act (HPR).

- **Label elements**
- **Hazard pictograms**



GHS02 GHS07

- **Hazard statements**

Flammable liquid and vapor.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause drowsiness or dizziness.

- **Precautionary statements**

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

Avoid breathing dust/fume/gas/mist/vapors/spray

Wash thoroughly after handling.

Wear protective gloves / eye protection.

If on skin: Wash with plenty of water.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Store in a well-ventilated place. Keep container tightly closed.

Store in a well-ventilated place. Keep cool.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Other hazards** Use only for intended scope of application.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.




- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

	Aceton  Flammable Liquids 2, H225  Eye Irritation 2A, H319; Specific Target Organ Toxicity - Single Exposure 3, H336	50-100%
CAS: 868-77-9	2-hydroxyethyl methacrylate  Skin Irritation 2, H315; Eye Irritation 2A, H319; Sensitization - Skin 1, H317	2.5-5%

- **Additional information:**

Further information on ingredients can be found in the instructions for use.

In case of known hypersensitivity to the ingredients mentioned in the instructions for use, do not use the product.

4 First-aid measures

- **Description of first aid measures**

- **General information:** No special measures required.

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.

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- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.
- **Protective Action Criteria for Chemicals**

· PAC-1:		
	Aceton	200 ppm
CAS: 868-77-9	2-hydroxyethyl methacrylate	1.9 mg/m ³
· PAC-2:		
	Aceton	3200* ppm
CAS: 868-77-9	2-hydroxyethyl methacrylate	21 mg/m ³
· PAC-3:		
	Aceton	5700* ppm
CAS: 868-77-9	2-hydroxyethyl methacrylate	1,000 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Observe the instructions for use! This contains the relevant application and safety information for the use of this product.
No special precautions are necessary if used correctly.
For dental use only.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.

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- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** See storage instructions on package
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:**
Due to the proportions contained in relation to the amount of product during application and the way it is the product, monitoring of specific, workplace-related limit values is not applicable.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
In the context of the use of this product, the hygiene standards customary and general in dental practice, such as hand, mouth and eye protection, must be applied.
- **Breathing equipment:** Not required.
- **Protection of hands:** Single-use gloves.
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Fluid
Color:	Colorless
Odor:	Characteristic
- **pH-value:** Not determined.
- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Ignition temperature:** Product is not selfigniting.
- **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
- **Density:** Not determined.
- **Solubility in / Miscibility with**

Water:	Not miscible or difficult to mix.
---------------	-----------------------------------
- **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

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· **Other information** *No further relevant information available.*

10 Stability and reactivity

- **Reactivity** *No further relevant information available.*
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Possibility of hazardous reactions** *No dangerous reactions known.*
- **Conditions to avoid** *No further relevant information available.*
- **Incompatible materials:** *No further relevant information available.*
- **Hazardous decomposition products:** *No dangerous decomposition products known.*

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** *Irritant to skin and mucous membranes.*
- **on the eye:** *Irritating effect.*
- **Sensitization:** *Sensitization possible through skin contact.*
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **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.*
- **Ecotoxicological effects:**
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

-US
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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> · UN-Number · DOT, ADR, IMDG, IATA | <p style="margin-left: 20px;">UN1090</p> |
| <ul style="list-style-type: none"> · UN proper shipping name · DOT · ADR · IMDG, IATA | <p style="margin-left: 20px;">Acetone mixture
1090 ACETONE mixture
ACETONE mixture</p> |
| <ul style="list-style-type: none"> · Transport hazard class(es) · DOT | <div style="text-align: center;">  </div> <p style="margin-left: 20px;">3 Flammable liquids</p> |
| <ul style="list-style-type: none"> · Class · Label | <p style="margin-left: 20px;">3
3</p> |
| <ul style="list-style-type: none"> · ADR, IMDG, IATA | |
| <ul style="list-style-type: none"> · Class · Label | <div style="text-align: center;">  </div> <p style="margin-left: 20px;">3 Flammable liquids</p> |
| <ul style="list-style-type: none"> · Label | <p style="margin-left: 20px;">3</p> |
| <ul style="list-style-type: none"> · Packing group · DOT, ADR, IMDG, IATA | <p style="margin-left: 20px;">II</p> |
| <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: | <p style="margin-left: 20px;">No</p> |
| <ul style="list-style-type: none"> · Special precautions for user · Hazard identification number (Kemler code): · EMS Number: | <p style="margin-left: 20px;">Warning: Flammable liquids
33
F-E,S-D</p> |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | <p style="margin-left: 20px;">Not applicable.</p> |
| <ul style="list-style-type: none"> · UN "Model Regulation": | <p style="margin-left: 20px;">UN 1090 ACETONE MIXTURE, 3, II</p> |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
Regulation (EU) 2017/745
Medical Devices Regulation
Directive 93/42/EEC concerning medical devices
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Trade name: Ufi Gel hard C Adhäsiv

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This product is regulated by Regulation (EU) No 2019/1148 - Regulation on the marketing and use of explosives precursors: All suspicious transactions and the loss and theft of significant quantities must be reported to the relevant national contact point. See https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/crisis-and-terrorism/explosives/explosives-precursors/docs/list_of_competent_authorities_and_national_contact_points_en.pdf.

· Sara

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

One or more substances contained in this material are not listed on the TSCA Inventory.
Contact manufacturer or supplier for more information.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

Aceton

I

· **TLV (Threshold Limit Value)**

Aceton

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients are listed

16 Other information

The product to which this data sheet is assigned is a medical device within the meaning of the US Federal Food, Drug and Cosmetic Act (FFDCA), the Canadian Medical Devices Regulations (CMDR) SOR/98-282 and the Canadian Food and Drugs Act R.S.S., 1985, c. F-27 and to the EU Medical Devices Regulation EU 2017/745, that is used invasively or in contact with the body. Invasive medical devices or medical devices in direct physical contact are exempt from the requirements for classification and labelling according to Hazard Communication Standard (HCS), WHMIS, Canadian Hazardous Products Act (HPA) and Canadian Hazardous Products Regulations Act (HPR) and also to Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d). The Medical Devices Regulation does not require a safety data sheet for invasive medical devices or medical devices in direct body contact, as the safe use of the product is indicated in the instructions for use and/or the labelling. Nevertheless, we provide a data sheet in order to provide as transparent a source as possible for the assessment of hazards to humans and the environment.

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For further contact information, please visit www.voco.dental**· Date of preparation / last revision** 12/04/2025 / -**· Abbreviations and acronyms:**

Flammable Liquids 2: Flammable liquids – Category 2

Flammable Liquids 3: Flammable liquids – Category 3

Skin Irritation 2: Skin corrosion/irritation – Category 2

Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

Sensitization - Skin 1: Skin sensitisation – Category 1

Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3

US