

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: Bifix Temp

Manufacturer: VOCO

SDS Expiry: 2 May 2027

Supplier Details: Henry Schein New Zealand
243-249 Bush Road, Rosedale, Auckland, 0632
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre –
0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 6

HSNO Group Standard: Dental Products Subsidiary Hazard Group Standard 2020
HSR002558

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

Date Prepared: This coversheet was prepared – May 2023

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 according to WHS Regulations

Printing date 02.05.2022

Version number 6

Revision: 02.05.2022

Hazardous according to criteria of Australian Safety and Compensation Council.

SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name: Bifix Temp base**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Dental luting cement
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Australien contact and address:
VOCO Australia Pty Ltd.
Suite 406-408, 251 Oxford Street,
Bondi Junction, NSW 2022
- **Further information obtainable from:** Australia 02 9369 1770
- **1.4 Emergency telephone number:** Australia: 131126

SECTION 2: Hazard(s) Identification

- **2.2 Label elements**
- **Classification according to Regulation (EC) No 1272/2008**
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Labelling according to Regulation (EC) No 1272/2008**
As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- **Hazard pictograms** GHS07
- **Hazard statements**
Causes serious eye irritation.
May cause an allergic skin reaction.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wear protective gloves / eye protection / face protection.
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.
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards** Use only for intended scope of application
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition and Information on Ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

| | | | |
|-----------------|-----------------------------------|--|--------|
| CAS: 72869-86-4 | Urethanedimethacrylate | Skin Sens. 1B, H317 | 5-10% |
| CAS: 109-16-0 | Triethylene glycol dimethacrylate | Skin Sens. 1, H317 | 5-10% |
| | Catalyst | Eye Dam. 1, H318 Acute Tox. 4, H302 | 1-2.5% |

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Trade name: Bifix Temp base

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SECTION 4: First Aid Measures

- **4.1 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.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Fire Fighting Measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental Release Measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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.

SECTION 7: Handling and Storage

- **7.1 Precautions for safe handling**
For dental use only.
Follow the instructions for use.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls and personal protection

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients 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 valid during the making were used as basis.

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Trade name: Bifix Temp base

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- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**



Protective 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

SECTION 9: Physical and Chemical Properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

| | |
|------------------|-----------------|
| Form: | Pasty |
| Colour: | Cream coloured |
| Odour: | Characteristic |
| Odour threshold: | Not determined. |

· pH-value: Not determined.

· Change in condition

| | |
|--|---------------|
| Melting point/freezing point: | Undetermined. |
| Initial boiling point and boiling range: | Undetermined. |

· Flash point: 101 °C

· Flammability (solid, gas): Not applicable.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Density: Not determined.

· Relative density: Not determined.

· Vapour density: Not determined.

· Evaporation rate: Not determined.

· Solubility in / Miscibility with water:

Not miscible or difficult to mix.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined.

Kinematic: Not determined.

· 9.2 Other information

No further relevant information available.

SECTION 10: Stability and Reactivity

· 10.1 Reactivity No further relevant information available.

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Trade name: Bifix Temp base

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

SECTION 11: Toxicological Information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation**
Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** 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.

SECTION 12: Ecological Information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

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

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Trade name: *Bifix Temp base*

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SECTION 14: Transport information

| | |
|---|-----------------|
| · 14.1 UN-Number · ADG, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name · ADG, ADN, IMDG, IATA | - Void |
| · 14.3 Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class | - Void |
| · 14.4 Packing group · ADG, IMDG, IATA | - Void |
| · 14.5 Environmental hazards: · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

| |
|---|
| · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture |
| · Australian Inventory of Industrial Chemicals All ingredients are listed. |
| · Australia: Priority Existing Chemicals None of the ingredients is listed. |
| · Directive 2012/18/EU · Named dangerous substances - ANNEX I None of the ingredients is listed. |

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Scientific department
- **Contact:** Tel.: +49 (0)4721-719-0
- **Abbreviations and acronyms:**
 Acute Tox. 4: Acute toxicity – Category 4
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 Skin Sens. 1: Skin sensitisation – Category 1
 Skin Sens. 1B: Skin sensitisation – Category 1B

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Safety Data Sheet

according to WHS Regulations

Printing date 02.05.2022

Version number 8

Revision: 02.05.2022

Hazardous according to criteria of Australian Safety and Compensation Council.

SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name:** *Bifix Temp catalyst*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** *Dental luting cement*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*Australien contact and address:
VOCO Australia Pty Ltd.
Suite 406-408, 251 Oxford Street,
Bondi Junction, NSW 2022*
- **Further information obtainable from:** *Australia 02 9369 1770*
- **1.4 Emergency telephone number:** *Australia: 131126*

SECTION 2: Hazard(s) Identification

- **2.2 Label elements**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Labelling according to Regulation (EC) No 1272/2008**
As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- **Hazard pictograms** *GHS07*
- **Hazard statements**
May cause an allergic skin reaction.
- **Precautionary statements**
*Avoid breathing dust/fume/gas/mist/vapours/spray.
Wear protective gloves.
Take off contaminated clothing and wash it before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
Specific treatment (see on this label).
Dispose of contents/container in accordance with local/regional/national/international regulations.*
- **2.3 Other hazards** *Use only for intended scope of application*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

SECTION 3: Composition and Information on Ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

· **Dangerous components:**

| | | | |
|-----------------|-----------------------------------|---|-------|
| CAS: 109-16-0 | Triethylene glycol dimethacrylate | Skin Sens. 1, H317 | 5-10% |
| CAS: 72869-86-4 | Urethanedimethacrylate | Skin Sens. 1B, H317 | 5-10% |
| | benzoyl peroxyde | Org. Perox. B, H241 Eye Irrit. 2, H319; Skin Sens. 1, H317 | ≤2.5% |

SECTION 4: First Aid Measures

- **4.1 Description of first aid measures**
- **General information:** *No special measures required.*

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Trade name: *Bifix Temp catalyst*

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- **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.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Fire Fighting Measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental Release Measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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.

SECTION 7: Handling and Storage

- **7.1 Precautions for safe handling**
For dental use only.
Follow the instructions for use.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls and personal protection

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients 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 valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.

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Trade name: Bifix Temp catalyst

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· **Protection of hands:**

Protective 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:** Not required.

SECTION 9: Physical and Chemical Properties

· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:**

| | |
|-------------------------|-----------------|
| Form: | Pasty |
| Colour: | Transparent |
| Odour: | Characteristic |
| Odour threshold: | Not determined. |

· **pH-value:** Not determined.· **Change in condition**

| | |
|---|---------------|
| Melting point/freezing point: | Undetermined. |
| Initial boiling point and boiling range: | Undetermined. |

· **Flash point:** 101 °C· **Flammability (solid, gas):** Not applicable.· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.· **Density:** Not determined.· **Relative density** Not determined.· **Vapour density** Not determined.· **Evaporation rate** Not determined.· **Solubility in / Miscibility with water:** Not miscible or difficult to mix.· **Partition coefficient: n-octanol/water:** Not determined.· **Viscosity:**· **Dynamic:** Not determined.· **Kinematic:** Not determined.· **9.2 Other information** No further relevant information available.

SECTION 10: Stability and Reactivity

· **10.1 Reactivity** No further relevant information available.· **10.2 Chemical stability**· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.· **10.3 Possibility of hazardous reactions** No dangerous reactions known.· **10.4 Conditions to avoid** No further relevant information available.· **10.5 Incompatible materials:** No further relevant information available.

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Trade name: *Bifix Temp catalyst*

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- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological Information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation**
Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** 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.

SECTION 12: Ecological Information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

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

SECTION 14: Transport information

- | | |
|---|--|
| <ul style="list-style-type: none"> · 14.1 UN-Number | <p>Attention: special provisions A197 IATA, 375 ADR and/or IMDG-Code paragraph 2.10.2.7 may be applied during transport.</p> |
| <ul style="list-style-type: none"> · ADG, ADN, IMDG, IATA | <p>Void</p> |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name | <p>-</p> |

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Trade name: *Bifix Temp catalyst*

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| | |
|---|-----------------|
| · ADG, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | - |
| · ADG, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | - |
| · ADG, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

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

· Australian Inventory of Industrial Chemicals

All ingredients are listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Department issuing SDS: Scientific department

· Contact: Tel.: +49 (0)4721-719-0

· Abbreviations and acronyms:

Org. Perox. B: Organic peroxides – Type B

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

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