Printing date 14.12.2016 Version number 10 Revision: 14.12.2016

Hazardous according to criteria of Australian Safety and Compensation Council

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

- · 1.1 Product identifier
- · Trade name: Solobond Plus primer
- · 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 bonding material
- · 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: Hazards identification

- · 2.1 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 an allergic skin reaction.

- · 2.2 Label elements
- · 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 skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· Precautionary statements

Wear protective gloves / eye protection.

Wear protective clothing.

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

If eye irritation persists: Get medical advice/attention.

- · 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/information on ingredients

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

Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	
·	0-25%
CT () 1	
7, 7, 7 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1,	0-25%
Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336	

(Contd. on page 2)

Printing date 14.12.2016 Version number 10 Revision: 14.12.2016

Trade name: Solobond Plus primer

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · 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.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- $\cdot \textit{4.3 Indication of any immediate medical attention and special treatment needed} \\$

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- 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.
- · 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

Keep container tightly sealed.

· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· Additional information about design of technical facilities: No further data; see item 7.

(Contd. on page 3)

Printing date 14.12.2016 Version number 10 Revision: 14.12.2016

Trade name: Solobond Plus primer

(Contd. of page 2)

· 8.1 Control parameters

· 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.

Avoid contact with the eyes and skin.

- · 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

2.5

- · General Information
- · Appearance:

Form: Fluid
Colour: Colourless
Odour: Characteristic

· pH-value at 20 °C:

· Change in condition

Melting point/Melting range: Undetermined. Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Self-igniting: Product is not selfigniting.

• Danger of explosion: Product does not present an explosion hazard.

• Density at 20 °C: 1.01 g/cm^3

· Solubility in / Miscibility with

water: Fully miscible.

· 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.

(Contd. on page 4)

Printing date 14.12.2016 Version number 10 Revision: 14.12.2016

Trade name: Solobond Plus primer

(Contd. of page 3)

- · 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

Causes skin irritation.

· Serious eye damage/irritation

Causes serious eye irritation.

· Respiratory or skin sensitisation

May cause an allergic skin reaction.

- · CMR effects (carcinogenity, 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.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

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Printing date 14.12.2016 Version number 10 Revision: 14.12.2016

Trade name: Solobond Plus primer

(Contd. of page 4)

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 Ann Marpol and the IBC Code	ex II of 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 Chemical Substances

All ingredients are 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:

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 Harmonised 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 (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2 Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* * Data compared to the previous version altered.

ΑU

Printing date 14.12.2016 Version number 18 Revision: 14.12.2016

Hazardous according to criteria of Australian Safety and Compensation Council

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

- · 1.1 Product identifier
- · Trade name: Solobond Plus adhesive
- · 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 bonding material
- · 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: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H336 May cause drowsiness or dizziness.

- · 2.2 Label elements
- · 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 GHS02, GHS07
- · Hazard statements

Highly flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause drowsiness or dizziness.

· Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. *Use explosion-proof electrical/ventilating/lighting/equipment.*

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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

Store locked up.

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

- · 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/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- $\cdot \textbf{\textit{Description:}} \ \textit{Mixture of substances listed below with nonhazardous additions.}$

(Contd. on page 2)

Printing date 14.12.2016 Version number 18 Revision: 14.12.2016

Trade name: Solobond Plus adhesive

		Contd. of page 1
· Dangerous	s components:	
67-64-1	acetone	50-100%
	Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336	
1565-94-2	BIS GMA	10-25%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
109-16-0	Triethylene glycol dimethacrylate	10-25%
	Skin Sens. 1, H317	
868-77-9	2-hydroxyethyl methacrylate	5-10%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	1

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · 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.
- 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: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: CO2, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · 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 Ensure adequate ventilation
- 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).

Do not flush with water or aqueous cleansing agents

· 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.
- · Information about fire and explosion protection: Keep ignition sources away Do not smoke.
- · 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.

(Contd. on page 3)

Printing date 14.12.2016 Version number 18 Revision: 14.12.2016

Trade name: Solobond Plus adhesive

(Contd. of page 2)

· Further information about storage conditions:

Keep container tightly sealed.

See storage instructions on package

 \cdot 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · 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.

Avoid contact with the eyes and skin.

- · 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: Fluid
Colour: Yellowish
Odour: Characteristic

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined. Boiling point/Boiling range: Undetermined.

· Flash point: -12 °C

· Self-igniting: Product is not selfigniting.

· Danger of explosion: Product is not explosive. However, formation of explosive air/vapour

mixtures are possible.

· Density: Not determined.

· Solubility in / Miscibility with

water: Not miscible or difficult to mix.

(Contd. on page 4)

Trade name: Solobond Plus adhesive

(Contd. of page 3)

· 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.
- · 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.
- · LD/LC50 values relevant for classification:

67-64-1 acetone

 Oral
 LD50
 5800 mg/kg (rat)

 Dermal
 LD50
 20000 mg/kg (rabbit)

- · Primary irritant effect:
- · Skin corrosion/irritation

Causes skin irritation.

· Serious eye damage/irritation

Causes serious eye irritation.

· Respiratory or skin sensitisation

May cause an allergic skin reaction.

- · CMR effects (carcinogenity, 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

May cause drowsiness or dizziness.

- · 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.

(Contd. on page 5)

Printing date 14.12.2016 Version number 18 Revision: 14.12.2016

Trade name: Solobond Plus adhesive

(Contd. of page 4)

- · 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	tion	
14.1 UN-Number ADG, IMDG, IATA	UN1090	
14.2 UN proper shipping name		
ADG	1090 ACETONE	
IMDG, IATA	ACETONE	
14.3 Transport hazard class(es)		
ADG, IMDG, IATA		
Class	3 Flammable liquids.	
Label	3	
14.4 Packing group		
ADG, IMDG, IATA	II	
14.5 Environmental hazards:		
Marine pollutant:	No	
14.6 Special precautions for user	Warning: Flammable liquids.	
Danger code (Kemler):	33	
EMS Number:	F- E , S - D	
Stowage Category	E	
14.7 Transport in bulk according to Ann		
Marpol and the IBC Code	Not applicable.	
Transport/Additional information:		
ADG		
Limited quantities (LQ)	IL	
Transport category	2	
Tunnel restriction code	D/E	

SECTION 15: Regulatory information

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

· Australian Inventory of Chemical Substances

All ingredients are listed.

(Contd. on page 6)

Printing date 14.12.2016 Version number 18 Revision: 14.12.2016

Trade name: Solobond Plus adhesive

(Contd. of page 5)

· Directive 2012/18/EU

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

· Seveso category P5c FLAMMABLE LIQUIDS

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:

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 Harmonised 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 (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* * Data compared to the previous version altered.

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