

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 24.09.2015

Version number 8

Revision: 24.09.2015

Not classified as 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:** *Admira Fusion/x-tra*
- **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 filling material*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Australian 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 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**
May cause an allergic skin reaction.
- **Precautionary statements**
Wear protective gloves / protective clothing.
If skin irritation occurs: 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/information on ingredients

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

- **Dangerous components:**

<i>organically modified silicic acid</i>	<i>Skin Irrit. 2, H315</i>	<i>10-25%</i>
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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.*
- **After swallowing:** *If symptoms persist consult doctor.*
- **4.2 Most important symptoms and effects, both acute and delayed** *No further relevant information available.*

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- **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:** Pick up mechanically.
- **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:** See storage instructions on package
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **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.
- **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

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application.

· **Eye protection:** Safety glasses

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	<i>Pasty</i>
· Colour:	<i>According to product specification</i>
· Odour:	<i>Characteristic</i>
· Odour threshold:	<i>Not determined.</i>

· pH-value:	<i>Not determined.</i>
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· Change in condition

· Melting point/Melting range:	<i>Undetermined.</i>
· Boiling point/Boiling range:	<i>Undetermined.</i>

· Flash point:	<i>Not applicable.</i>
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· Flammability (solid, gaseous):	<i>Not applicable.</i>
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· Decomposition temperature:	<i>Not determined.</i>
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· Self-igniting:	<i>Product is not selfigniting.</i>
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· Danger of explosion:	<i>Product does not present an explosion hazard.</i>
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· Density:	<i>Not determined.</i>
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· Relative density	<i>Not determined.</i>
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· Vapour density	<i>Not determined.</i>
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· Evaporation rate	<i>Not determined.</i>
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· Solubility in / Miscibility with water:	<i>Not miscible or difficult to mix.</i>
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· Partition coefficient (n-octanol/water):	<i>Not determined.</i>
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· Viscosity:

· Dynamic:	<i>Not determined.</i>
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· Kinematic:	<i>Not determined.</i>
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· 9.2 Other information	<i>No further relevant information available.</i>
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SECTION 10: Stability and reactivity

· 10.1 Reactivity	<i>No further relevant information available.</i>
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· 10.2 Chemical stability

· Thermal decomposition / conditions to be avoided:	<i>No decomposition if used according to specifications.</i>
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· 10.3 Possibility of hazardous reactions	<i>No dangerous reactions known.</i>
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· 10.4 Conditions to avoid	<i>No further relevant information available.</i>
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· 10.5 Incompatible materials:	<i>No further relevant information available.</i>
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· 10.6 Hazardous decomposition products:	<i>No dangerous decomposition products known.</i>
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SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
- **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.
- **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:**
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

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| · 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 | - |

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· ADG, IMDG, IATA	<i>Void</i>
· 14.5 Environmental hazards:	
· Marine pollutant:	<i>No</i>
· 14.6 Special precautions for user	<i>Not applicable.</i>
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	<i>Not applicable.</i>
· UN "Model Regulation":	<i>-</i>

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 MSDS:** *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

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

· *** Data compared to the previous version altered.**