

SAFETY DATA SHEETS

This SDS packet was issued with item:

070498394

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070454629 070454637 070454645 070454652 070454660 070454678 070454686 070454694 070454702 070454710
070454728 070454736 070454744 070454751 070454769 070454777 070454785 070454793 070454801 070454819
070454827 070454835 070454850 070454868 070454876 070454884 070454892 070454900 070454918 070454926
070454934 070454942 070454959 070454967 070454975 070454983 070454991 070455006 070455014 070455022
070455113 070455121 070498378 070498402 070498408 070498410 070498428 070498436 070498444 070498451
070498469 070498477 070498485 070498493 070498501 071474006 071474030

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 24.09.2015

Version number 8

Revision: 23.09.2015

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:**
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven
- **Further information obtainable from:** Scientific department tel. +49 (0)4721-719-0
- **1.4 Emergency telephone number:** Poison Control Center Mainz +49 (0)6131-19240

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:**

organically modified silicic acid	Skin Irrit. 2, H315	10-25%
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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.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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Safety data sheet

according to 1907/2006/EC, Article 31

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Revision: 23.09.2015

Trade name: *Admira Fusion/x-tra*

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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 application.

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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 24.09.2015

Version number 8

Revision: 23.09.2015

Trade name: *Admira Fusion/x-tra*· Eye protection: *Safety glasses*

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Pasty
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.

· pH-value: Not determined.

· Change in condition

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

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not applicable.

· Decomposition temperature: Not determined.

· Self-igniting: Product is not selfigniting.

· Danger of explosion: 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.

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

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

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Trade name: *Admira Fusion/x-tra*

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- **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:**
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

• 14.1 UN-Number	
• ADR, ADN, IMDG, IATA	Void
• 14.2 UN proper shipping name	-
• ADR, ADN, IMDG, IATA	Void
• 14.3 Transport hazard class(es)	-
• ADR, ADN, IMDG, IATA	
• Class	Void
• 14.4 Packing group	-
• ADR, IMDG, IATA	Void
• 14.5 Environmental hazards:	
• Marine pollutant:	No
• 14.6 Special precautions for user	Not applicable.

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Trade name: *Admira Fusion/x-tra*

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- | | |
|---|-----------------|
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

SECTION 15: Regulatory information

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

GB

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2015

Reviewed on 09/24/2015

1 Identification

- **Product identifier**
- **Trade name:** *Admira Fusion/x-tra*
- **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*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven
- **Information department:** Scientific department tel. +49 (0)4721-719-0
- **Emergency telephone number:** Scientific department tel. +49 (0)4721-719-0

2 Hazard(s) identification

- **Classification of the substance or mixture**



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

- **Label elements**
- **Hazard pictograms** GHS07
- **Signal word** *Warning*
- **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.
- **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:**

organically modified silicic acid	10-25%
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4 First-aid measures

- **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.*
- **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 09/24/2015

Reviewed on 09/24/2015

Trade name: *Admira Fusion/x-tra*

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5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** 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:** See storage instructions on package
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **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 item 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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

- **Material of gloves**

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Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2015

Reviewed on 09/24/2015

Trade name: *Admira Fusion/x-tra*

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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:**

According to product specification

· **Odor:**

Characteristic

· **Odour threshold:**

Not determined.

· **pH-value:**

Not determined.

· **Change in condition**

· **Melting point/Melting range:**

Undetermined.

· **Boiling point/Boiling range:**

Undetermined.

· **Flash point:**

Not applicable.

· **Flammability (solid, gaseous):**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **Auto igniting:**

Product is not selfigniting.

· **Danger of explosion:**

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.

· **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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Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2015

Reviewed on 09/24/2015

Trade name: *Admira Fusion/x-tra*

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11 Toxicological information

Information on toxicological effects

Acute toxicity:

Primary irritant effect:

on the skin:

Testing according to ISO 10993-1:10993-10 showed no skin irritation for this product when fully cured

on the eye: No irritating effect.

Sensitization: Sensitization possible through skin contact.

Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

Carcinogenic categories

IARC (International Agency for Research on Cancer)

	fumed silica	3
128-37-0	2,6-di-tert-butyl-p-cresol	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.

Additional ecological information:

General notes:

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.

Other adverse effects: No further relevant information available.

13 Disposal considerations

Waste treatment methods

Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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

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Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2015

Reviewed on 09/24/2015

Trade name: *Admira Fusion/x-tra*

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· 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":	-

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- 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):

fumed silica

- 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 established by ACGIH)

128-37-0 | 2,6-di-tert-butyl-p-cresol

A4

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

None of the ingredients are listed.

- GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- Hazard pictograms GHS07

- Signal word Warning

- Hazard statements

May cause an allergic skin reaction.

- Precautionary statements

Wear protective gloves / protective clothing.

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Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2015

Reviewed on 09/24/2015

Trade name: *Admira Fusion/x-tra*

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If skin irritation occurs: Get medical advice attention.

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

16 Other information

- **Department issuing SDS:** Scientific department

- **Contact:** Tel.: +49 (0)4721-719-0

- **Date of preparation / last revision** 09/24/2015 - 7

- **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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 Sens. 1: Sensitisation - Skin, Hazard Category 1

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

US