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%

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.

(Contd. on page 2)

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

(Contd. of page 1)

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.

(Contd. on page 3)

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

(Contd. of page 2)

· ***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:	*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

(Contd. on page 4)

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

(Contd. of page 3)

· **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 (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.

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.

(Contd. on page 5)

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

(Contd. of page 4)

· ***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.***