SAFETY DATA SHEETS

This SDS packet was issued with item:

071815182

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

070494369 071705722 071705730 071705748 071705755 071705763 071705771 071705789 071705797 071705805 071706001 071706035 071706043 071806702

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071807403 071807494 071815190

Printing date 28.03.2013

Version number 2

Revision: 14.03.2013

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

· 1.1 Product identifier

· Trade name: Aquasil Ultra

Monophase, XLV, LV, Heavy

· 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· Application of the substance / the preparation Dental impression material

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

DENTSPLY DeTrey GmbH

De-Trey-Str. 1

D-78467 Konstanz

GERMANY

Tel.: +49-(0)7531-583-0 Fax: +49-(0)7531-583-104

email: KonstanzDEU.info-sdb@dentsply.com

· Further information obtainable from:

- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- · 1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

2 Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC not applicable
- · Information concerning particular hazards for human and environment:

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- · 2.2 Label elements
- · Labelling according to EU guidelines:

Observe the general safety regulations when handling chemicals

The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · 3.2 Chemical characterization: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.
- · Dangerous components: Void
- · Additional information For the wording of the listed risk phrases refer to section 16.

3B —

(Contd. on page 2)

Printing date 28.03.2013

Version number 2

Revision: 14.03.2013

Trade name: Aquasil Ultra

Monophase, XLV, LV, Heavy

(Contd. of page 1)

4 First aid measures

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

5 Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents

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

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: Self-contained respiratory protective device.

6 Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 6.2 Environmental precautions: No special measures required.
- · 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 No dangerous substances are released.

7 Handling and storage

- · 7.1 Precautions for safe handling Observe normal care for working with chemicals.
- · Handling Product is intended 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: Protect from heat and direct sunlight.
- · 7.3 Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

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

(Contd. on page 3)

Printing date 28.03.2013

Version number 2

Revision: 14.03.2013

Trade name: Aquasil Ultra

Monophase, XLV, LV, Heavy

(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.

- · Respiratory protection: Not required.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· 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.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- · Eye protection: Safety glasses
- · Body protection: Protective work clothing.

· 9.1 Information on basic p · General Information	physical and chemical properties	
Арреarance:		
Form:	Pasty	
Colour: Odour:	According to product specification Characteristic	
pH-value:	Not applicable.	
Change in condition Melting point/Melting ra Boiling point/Boiling ra		
Flash point:	Not applicable	
Self-igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Vapour pressure:	Not applicable.	
Density at 20 °C:	1.2 g/cm³	
Solubility in / Miscibility w Water:	vith Insoluble	
Viscosity: dynamic:	Not determined	

(Contd. on page 4)

Printing date 28.03.2013

Version number 2

Revision: 14.03.2013

Trade name: Aquasil Ultra

Monophase, XLV, LV, Heavy

		(Contd. of page 2
kinematic:	Not determined.	
· Solvent content: Organic solvents:	0.0 %	
Solids content: - 9.2 Other information	40 % No further relevant information available.	

10 Stability and reactivity

- · 10.1 Reactivity
- · 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

11 Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity:
- · Primary irritant effect:
- · on the skin: may cause skin irritation
- · on the eye: Irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

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

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.
- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation Smaller quantities can be disposed of with household waste.

(Contd. on page 5)

Printing date 28.03.2013

Version number 2

Revision: 14.03.2013

Trade name: Aquasil Ultra

Monophase, XLV, LV, Heavy

(Contd. of page 4)

· European waste catalogue

18 01 07 chemicals other than those mentioned in 18 01 06

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

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.	
14.7 Transport in bulk according to Anno MARPOL73/78 and the IBC Code		

15 Regulatory information

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

- · Department issuing MSDS: Analytical Research
- · Contact: HotLine for urgent technical support: +49-7531-583-333
- · * Data compared to the previous version altered.

GB

DENTSPLY Milford Safety Data Sheet

1. Product and Company Identification

Product Name	SDS Code Number
Aquasil®	578617
Substance Identity	Date of Last Revision
Aquasil, Aquasil Ultra, Aquasil Ultra Xtra, Smart Wetting® Impression Material, Aquasil	05/09/16
Ultra Cordless Tissue Managing Impression Material, Aquasil Ultimate - Tissue	
Managing Impression Material, Aquasil Ultra + Smart Wetting Impression Material	
Manufacturer:	Address
DENTSPLY Milford	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.dentsply.com
Grades or Minor Variant Identities	Information Telephone
AQUASIL MONOPHASE, AQUASIL RIGID, AQUASIL LV, AQUASIL Easy Mix PUTTY - Smart Wetting®	Number: (302) 422-4511
Impression Material, AQUASIL ULTRA MONOPHASE, AQUASIL ULTRA RIGID, AQUASIL ULTRA XLV, AQUASIL ULTRA LV, AQUASIL ULTRA HEAVY – Smart Wetting [®] Impression Material, Super Fast Set, Fast Setting	(8:00 AM – 4:30 PM
and Regular Setting – Including AQUASIL ULTRA DECA [™] Smart Wetting [®] Impression Material for Dynamic Mixing	Eastern Time)
Machines and digit Targeted Delivery Systems. AQUASIL ULTRA Xtra – Wash, Tray and DECA Tray. Aquasil Ultra	,
Cordless Tissue Managing Wash Impression Material and Aquasil Ultra Cordless Tissue Managing Tray Impression	
Material, Aquasil Ultimate Cordless Tissue Managing Wash Impression Material, Aquasil Ultra Cordless Tissue Managing Tray Impression Material, Aquasil Ultra + Smart Wetting Impression Material Fast and Regular Setting - all viscosities.	
Product Use (for Canada)	Emergency Telephone
Dental Impression Material	Number: (302) 422-4511
2 dawn ampression alandian	(8:00 AM – 4:30 PM
	Eastern Time)

2. Hazard(s) Identification



WASH HANDS THOROUGHLY AFTER HANDLING WEAR PROTECTIVE GLOVES IF ON SKIN: WASH WITH PLENTY OF SOAP AND WATER.

IF ON SKIN, WASH WITH PLENTY OF SOAP AND WATER.

IF SKIN IRRITATION OCCURS: GET MEDICAL ADVICE / ATTENTION

TAKE OFF CONTAMINATED CLOTHING AND WASH BEFORE REUSE

3. Composition/Information on Ingredients

	0		
Hazardous Components	C.A.S. Number	Exposure Limits	%
Silicon Dioxide -Crystalline	14464-46-1	0.05 mg/m^3	< than 30
Silicon Dioxide - Amorphous	68855-54-9	1.20 mg/m^3	< than 30
Hydrophobic Amorphous Fumed Silica	68909-20-6	10 mg/m^3	< than 10
Titanium Dioxide	13463-67-7	10 mg/m^3	< than 10

<u>Colorant Information</u>: The base pastes may contain fluorescent organic dyes and/or ultramarine pigments and/or inorganic iron oxides. The base pastes may also contain a red pigment known as a Red 2B Toner or a Calcium salt of a beta oxynaphthoate. The Chemical structure of all Ultramarine pigments, regardless of color, is Sodium Aluminosulfosilicate.

<u>Odorant Information:</u> This product contains Peppermint oil which may cause irritation to skin or mucosa or other allergic responses in susceptible persons.

4. First Aid Measures

Routes of	First Aid Instructions	Immediate	Delayed Effects	
Exposure		Medical Attention		
Eye	Eye Rinse opened eye for several minutes under running water. If		Not Applicable	
	symptoms persist consult physician			
Skin	Immediately wash with soap and water and rinse thoroughly	Not Applicable	Not Applicable	
Inhalation	Supply fresh air, consult physician if symptoms persist	Not Applicable	Not Applicable	
Ingestion	If symptoms persist consult physician	Not Applicable	Low order of toxicity is expected when large	

			amounts of material are ingested. Acute toxicology study in rats LD ₅₀ >2,000mg/kg.	
Other	Not Applicable	Not Applicable	Not Applicable	
Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.				

5. Fire Fighting Measures

Flame Propagation or Burning Rate	Properties Contributing to Fire Intensity:	Flammability Classification: Not Applicable	Other: Not Applicable	
(for Solids): Not Applicable	Not Applicable			
Extinguishing Media: CO ₂ , extinguishing powder, foam carbon dioxide or water Extinguishing Media to Avoid: Water with full jet.			et.	
spray. Fight larger fires with water spray or alcohol resistant foam.				
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.				
Unusual Fire and Explosion Hazards: No dangerous decomposition products known Product does not present an explosion hazard.				

6. Accidental Release Measures

(Containment Techniques: Material is a paste and as such will not flow.		
S	Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container.		
A	Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.		
I	Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages.

8. Exposure Control / Personal Protection









Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective Equipment for
Measures	Measures	
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation Not Required		Not Applicable
Body Protection Protective work clothing		Not Applicable
Occupational Exposure Limits: Not Applicable		Engineering Controls: Not Applicable

9. Physical and Chemical Characteristics

Appearance: Various colored pastes, may be high viscosity	Odor: Peppermint odor.			
Normal Physical State: Material is available in several viscosities. It varies from a very high viscosity liquid		Melting Point: Not Applicable		
(Paste) to a more runny material.				
Specific Gravity: Varies from 1.1 g/cm ³ to 1.5 g/cm ³	Solubility in Water: Not soluble	pH: Not Applicable		
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): N A		
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not Applicable,		
	LEL: Not Applicable UEL: Not Applicable	Product will not autoignite.		
Other: Not Applicable	•	-		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong oxidizing materials.			
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use.			
Hazardous Polymerization: ☐May Occur ☐May Not Occur ☐ Conditions to Avoid: None known			
Stability? Stable Unstable	Conditions to Avoid: None known		

11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product may irritate the skin and mucous membranes. The unpolymerized product may cause irritation to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: No sensitizing effects known.

Emergency Ov	Emergency Overview: Material may be mildly irritating to eyes.				
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health Effect(s)	
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)		Target Organ(s)
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Not Applicable
Skin	Material may be an irritant	Single & Repeated	Moderate	Irritation or possible allergic response.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is probably not	Not Applicable	Mild	Low order of toxicity is expected when	Not Applicable
	harmful if swallowed			large amounts of material are ingested.	
				Acute toxicology study in rats LD ₅₀	

				>2,000mg/kg.	
Other	Not Applicable				
Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.					
Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in					
compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					
Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard Classification Ratings (Scale 0-4), Health = 0, Fire = 1, Reactivity = 0					

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

13.Disposal Considerations

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

Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations

Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

14.Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment	DOT Hazard Class: Not Applicable	UN Number: Not Applicable
method change product classification? No		

15.Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations: CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

<u>Section 313 Toxic Chemicals</u>: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.

<u>U.S. State Regulations California Proposition 65:</u> This product does not contain any chemicals, which are on the California Proposition 65 list.

<u>International Regulations: Canadian Environmental Protection Act:</u>

This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation.

European Inventory of New and Existing Chemicals Substances (EINECS):

This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products.

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

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

DENTSPLY Milford Safety Data Sheet

1. Product and Company Identification

Product Name	SDS Code Number
Aquasil®	578617
Substance Identity	Date of Last Revision
Aquasil, Aquasil Ultra, Aquasil Ultra Xtra, Smart Wetting® Impression Material, Aquasil	05/09/16
Ultra Cordless Tissue Managing Impression Material, Aquasil Ultimate - Tissue	
Managing Impression Material, Aquasil Ultra + Smart Wetting Impression Material	
Manufacturer:	Address
DENTSPLY Milford	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.dentsply.com
Grades or Minor Variant Identities	Information Telephone
AQUASIL MONOPHASE, AQUASIL RIGID, AQUASIL LV, AQUASIL Easy Mix PUTTY - Smart Wetting®	Number: (302) 422-4511
Impression Material, AQUASIL ULTRA MONOPHASE, AQUASIL ULTRA RIGID, AQUASIL ULTRA XLV, AQUASIL ULTRA LV, AQUASIL ULTRA HEAVY – Smart Wetting [®] Impression Material, Super Fast Set, Fast Setting	(8:00 AM – 4:30 PM
and Regular Setting – Including AQUASIL ULTRA DECA [™] Smart Wetting ® Impression Material for Dynamic Mixing	Eastern Time)
Machines and digit® Targeted Delivery Systems. AQUASIL ULTRA Xtra – Wash, Tray and DECA Tray. Aquasil Ultra	
Cordless Tissue Managing Wash Impression Material and Aquasil Ultra Cordless Tissue Managing Tray Impression	
Material, Aquasil Ultimate Cordless Tissue Managing Wash Impression Material, Aquasil Ultra Cordless Tissue Managing Tray Impression Material, Aquasil Ultra + Smart Wetting Impression Material Fast and Regular Setting - all viscosities.	
Product Use (for Canada)	Emergency Telephone
Dental Impression Material	Number: (302) 422-4511
Dental impression Material	(8:00 AM – 4:30 PM
	Eastern Time)

2. Hazard(s) Identification



WASH HANDS THOROUGHLY AFTER HANDLING WEAR PROTECTIVE GLOVES IF ON SKIN: WASH WITH PLENTY OF SOAP AND WATER.

IF ON SKIN: WASH WITH PLENTY OF SOAP AND WATER.

IF SKIN IRRITATION OCCURS: GET MEDICAL ADVICE / ATTENTION

TAKE OFF CONTAMINATED CLOTHING AND WASH BEFORE REUSE

3. Composition/Information on Ingredients

	0		
Hazardous Components	C.A.S. Number	Exposure Limits	%
Silicon Dioxide -Crystalline	14464-46-1	0.05 mg/m^3	< than 30
Silicon Dioxide - Amorphous	68855-54-9	1.20 mg/m^3	< than 30
Hydrophobic Amorphous Fumed Silica	68909-20-6	10 mg/m^3	< than 10
Titanium Dioxide	13463-67-7	10 mg/m^3	< than 10

<u>Colorant Information</u>: The base pastes may contain fluorescent organic dyes and/or ultramarine pigments and/or inorganic iron oxides. The base pastes may also contain a red pigment known as a Red 2B Toner or a Calcium salt of a beta oxynaphthoate. The Chemical structure of all Ultramarine pigments, regardless of color, is Sodium Aluminosulfosilicate.

<u>Odorant Information:</u> This product contains Peppermint oil which may cause irritation to skin or mucosa or other allergic responses in susceptible persons.

4. First Aid Measures

	TO I HIST THE TYPE WAS ALL OF			
Routes of	First Aid Instructions	Immediate	Delayed Effects	
Exposure		Medical Attention		
Eye	Rinse opened eye for several minutes under running water. If	Not Applicable	Not Applicable	
symptoms persist consult physician				
Skin	Immediately wash with soap and water and rinse thoroughly	Not Applicable	Not Applicable	
Inhalation	Supply fresh air, consult physician if symptoms persist	Not Applicable	Not Applicable	
Ingestion	If symptoms persist consult physician	Not Applicable	Low order of toxicity is expected when large	

			amounts of material are ingested. Acute toxicology study in rats LD ₅₀ >2,000mg/kg.
Other	Not Applicable	Not Applicable	Not Applicable
Note to Physicians (Treating Testing and Monitoring): Treat symptomatically			

5. Fire Fighting Measures

Flame Propagation or Burning Rate	Properties Contributing to Fire Intensity:	Flammability Classification: Not Applicable	Other: Not Applicable	
(for Solids): Not Applicable	Not Applicable			
Extinguishing Media: CO ₂ , extinguishing powder, foam carbon dioxide or water Extinguishing Media to Avoid: Water with full jet.				
spray. Fight larger fires with water spray or alcohol resistant foam.				
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.				
Unusual Fire and Explosion Hazards: No dangerous decomposition products known Product does not present an explosion hazard.				

6. Accidental Release Measures

Containment Techniques: Material is a paste and as such will not flow.		
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container.		
Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.		
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages.

8. Exposure Control / Personal Protection









Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective Equipment for
Measures		Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Not Required	Not Applicable
Body Protection Protective work clothing		Not Applicable
Occupational Exposure Lim	Engineering Controls: Not Applicable	

9. Physical and Chemical Characteristics

Appearance: Various colored pastes, may be high viscosity paste or runny. Catalyst is white to grey-colored. Odor: Peppermint odor.			
Normal Physical State: Material is available in several visco	Melting Point: Not Applicable		
(Paste) to a more runny material.	(Paste) to a more runny material.		
Specific Gravity: Varies from 1.1 g/cm ³ to 1.5 g/cm ³ Solubility in Water: Not soluble pH: Not Applicable			
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): N A	
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not Applicable,	
	LEL: Not Applicable UEL: Not Applicable	Product will not autoignite.	
Other: Not Applicable		-	

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong oxidizing materials.		
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use.		
Hazardous Polymerization: ☐May Occur ☐May Not Occur	Conditions to Avoid: None known	
Stability? Stable ☐ Unstable Conditions to Avoid: None known		

11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product may irritate the skin and mucous membranes. The unpolymerized product may cause irritation to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: No sensitizing effects known.

Emergency Overview: Material may be mildly irritating to eyes

		Material may be finding to eyes.			
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health Effect(s)	
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)		Target Organ(s)
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Not Applicable
Skin	Material may be an irritant	Single & Repeated	Moderate	Irritation or possible allergic response.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is probably not harmful if swallowed	Not Applicable	cable Mild Low order of toxicity is expected when large amounts of material are ingested. Acute toxicology study in rats LD ₅₀		

				>2,000mg/kg.		
Other	Not Applicable					
Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.						
Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in						
compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.						
Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.						
NFPA Hazard Classification Ratings (Scale 0-4), Health = 0, Fire = 1, Reactivity = 0						

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

13.Disposal Considerations

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

Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations

Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

14.Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable	
Do Changes in Quantities, packaging, or shipment	DOT Hazard Class: Not Applicable	UN Number: Not Applicable	
method change product classification? No			

15.Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations: CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

<u>Section 313 Toxic Chemicals</u>: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.

<u>U.S. State Regulations California Proposition 65:</u> This product does not contain any chemicals, which are on the California Proposition 65 list.

<u>International Regulations: Canadian Environmental Protection Act:</u>

This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation.

European Inventory of New and Existing Chemicals Substances (EINECS):

This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products.

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

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.