This SDS packet was issued with item:
071815190

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

071815182
1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Aquasil Ultra
Monophase, XLY, LV, Heavy

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

No further relevant information available.

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:
- Department Analytical Research / Research & Development for technical information
- Department 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.
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 28.03.2013
Version number 2
Revision: 14.03.2013

Trade name: Aquasil Ultra
Monophase, XLV, LV, Heavy

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)
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 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

pH-value: Not applicable.

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.

Vapour pressure: Not applicable.

Density at 20 °C: 1.2 g/cm³

Solubility in / Miscibility with
Water: Insoluble

Viscosity:
dynamic: Not determined.
Trade name: Aquasil Ultra
Monophase, XLV, LV, Heavy

| kinematic: | Not determined. |
| Solvent content: | Organic solvents: 0.0% |
| Solids content: | 40% |
| 9.2 Other information | 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.
Trade name: Aquasil Ultra
Monophase, XLV, LV, Heavy

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: 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 Annex II of MARPOL73/78 and the IBC Code
  - Not applicable.

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.
1. Product and Company Identification

<table>
<thead>
<tr>
<th>Product Name</th>
<th>SDS Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquasil®</td>
<td>578617</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance Identity</th>
<th>Date of Last Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquasil, Aquasil Ultra, Aquasil Ultra Xtra, Smart Wetting® Impression Material, Aquasil Ultra Cordless Tissue Managing Impression Material, Aquasil Ultimate - Tissue Managing Impression Material, Aquasil Ultra + Smart Wetting Impression Material</td>
<td>05/09/16</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>DENTSPLY Milford</td>
<td>38 West Clarke Avenue Milford DE 19963-1805</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grades or Minor Variant Identities</th>
<th>Information Telephone Number: (302) 422-4511</th>
</tr>
</thead>
</table>

2. Hazard(s) Identification

**WARNING**

CAUSES SKIN IRRITATION

WASH HANDS THOROUGHLY AFTER HANDLING
WEAR PROTECTIVE GLOVES
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

<table>
<thead>
<tr>
<th>Hazardous Components</th>
<th>C.A.S. Number</th>
<th>Exposure Limits</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon Dioxide -Crystalline</td>
<td>14464-46-1</td>
<td>0.05 mg/m³</td>
<td>&lt; than 30</td>
</tr>
<tr>
<td>Silicon Dioxide - Amorphous</td>
<td>68855-54-9</td>
<td>1.20 mg/m³</td>
<td>&lt; than 30</td>
</tr>
<tr>
<td>Hydrophobic Amorphous Fumed Silica</td>
<td>68909-20-6</td>
<td>10 mg/m³</td>
<td>&lt; than 10</td>
</tr>
<tr>
<td>Titanium Dioxide</td>
<td>13463-67-7</td>
<td>10 mg/m³</td>
<td>&lt; than 10</td>
</tr>
</tbody>
</table>

**Colorant Information:** 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.

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

4. First Aid Measures

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

5. Fire Fighting Measures

<table>
<thead>
<tr>
<th>Flame Propagation or Burning Rate (for Solids): Not Applicable</th>
<th>Properties Contributing to Fire Intensity: Not Applicable</th>
<th>Flammability Classification: Not Applicable</th>
<th>Other: Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extinguishing Media: CO₂, extinguishing powder, foam carbon dioxide or water spray.</td>
<td>Extinguishing Media to Avoid: Water with full jet.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unusual Fire and Explosion Hazards: No dangerous decomposition products known.  - Product does not present an explosion hazard.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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. |
| 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

<table>
<thead>
<tr>
<th>Individual Protection Measures</th>
<th>Personal Protective Equipment for Normal Use</th>
<th>Personal Protective Equipment for Emergencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye/Face</td>
<td>Safety Glasses</td>
<td>Not Required</td>
</tr>
<tr>
<td>Eye/Face</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td>Safety Glasses</td>
<td>Not Required</td>
</tr>
<tr>
<td>Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td>Safety Glasses</td>
<td>Not Required</td>
</tr>
<tr>
<td>Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body Protection</td>
<td>Protective work clothing</td>
<td>Not Required</td>
</tr>
<tr>
<td>Body Protection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupational Exposure Limits: Not Applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 viscosities. It varies from a very high viscosity liquid (Paste) to a more runny material. |
| Specific Gravity: Varies from 1.1 g/cm³ to 1.5 g/cm³ |
| 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 LEL: Not Applicable UEL: Not Applicable |
| Autoignition Temperature: Not Applicable, Product will not autoignite. |
| Other: Not Applicable |

10. Stability and Reactivity Data

| Incompatibility (Materials to Avoid): Strong oxidizing materials. |
| Hazardous Polymerization: ☐ May Occur ☑ May Not Occur Conditions to Avoid: None known |
| Stability: ☑ Stable ☐ Unstable Conditions to Avoid: None known |

11. Toxicological Information

<table>
<thead>
<tr>
<th>Routes of Exposure</th>
<th>Signs and Symptoms</th>
<th>Single, Repeated, or Lifetime Exposure</th>
<th>Severity (Mild, Moderate, Severe)</th>
<th>Acute and Chronic Health Effect(s)</th>
<th>Target Organ(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye</td>
<td>Material can cause irritation.</td>
<td>Single</td>
<td>Moderate</td>
<td>Irritation and possible corneal damage</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin</td>
<td>Material may be an irritant</td>
<td>Single &amp; Repeated</td>
<td>Not Applicable</td>
<td>Irritation or possible allergic response.</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Not Applicable</td>
<td>Single</td>
<td>Not Applicable</td>
<td></td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Material is probably not harmful if swallowed</td>
<td>Single</td>
<td>Not Applicable</td>
<td>Low order of toxicity is expected when large amounts of material are ingested.</td>
<td>Acute toxicology study in rats LD50</td>
</tr>
<tr>
<td>Other</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.
12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class I (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

Do Changes in Quantities, packaging, or shipment method change product classification? No

DOT Shipping Name: Not Regulated

DOT Hazard Class: Not Applicable

Packing Group: Not Applicable

UN Number: Not Applicable

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.

Section 313 Toxic Chemicals: 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.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.

International Regulations: Canadian Environmental Protection Act:

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.