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).

071815190
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 Application of the substance / the preparation Dental impression material

1.4 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.

(Contd. on page 2)
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.
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.
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

<table>
<thead>
<tr>
<th>kinematic:</th>
<th>Not determined.</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Solvent content:</td>
<td>0.0%</td>
</tr>
<tr>
<td>· Organic solvents:</td>
<td>0.0%</td>
</tr>
<tr>
<td>· Solids content:</td>
<td>40%</td>
</tr>
<tr>
<td>· 9.2 Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

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)
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
- 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 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>Aquasil®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance Identity</td>
<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>
</tr>
<tr>
<td>SDS Code Number</td>
<td>578617</td>
</tr>
<tr>
<td>Date of Last Revision</td>
<td>05/09/16</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>DENTSPLY Milford</td>
</tr>
<tr>
<td>Address</td>
<td>38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.dentsply.com">http://www.dentsply.com</a></td>
</tr>
<tr>
<td>Information Telephone Number</td>
<td>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</td>
</tr>
<tr>
<td>Emergency Telephone Number</td>
<td>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</td>
</tr>
<tr>
<td>Product Use (for Canada)</td>
<td>Dental Impression Material</td>
</tr>
</tbody>
</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 Aluminosilicate.

**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>
5. Fire Fighting Measures

Flame Propagation or Burning Rate (for Solids): Not Applicable
Properties Contributing to Fire Intensity: Not Applicable
Flammability Classification: Not Applicable
Other: Not Applicable

Extinguishing Media: CO₂, extinguishing powder, foam carbon dioxide or water spray. Fight larger fires with water spray or alcohol resistant foam.
Extinguishing Media to Avoid: Water with full jet.

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

<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>Skin</td>
<td>The glove material has to be impermeable and resistant to the product.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Not Required</td>
<td>Not Required</td>
</tr>
<tr>
<td>Body Protection</td>
<td>Protective work clothing</td>
<td>Not Required</td>
</tr>
<tr>
<td>Occupational Exposure Limits</td>
<td>Not Applicable</td>
<td>Engineering Controls: Not Applicable</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

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.
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 class 1 (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 method change product classification? No

DOT Hazard Class: 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.