



L.D. Caulk Division
38 West Clarke Avenue
Milford, DE 19963-1805
(302) 422-4511

Re: DENTSPLY Caulk Dental Impression Material, Aquasil Ultra Monophase Smart-Wetting® Impression Material, Item 678773, Lot 070108.

To Whom It May Concern:

Dear Sir or Madam:

DENTSPLY Caulk has determined it necessary to remove the above noted lot of Aquasil Ultra Monophase Impression Material from all European Union locations to where the product lot was distributed.

Aquasil Ultra Smart Wetting® Monophase Regular Set Impression Material is a universal use, quadrafunctional hydrophilic silicone, medium body, elastomeric impression material with excellent hydrophilic properties, dimensional accuracy, high tear strength, and resistance to permanent deformation. It improves both wetting on the tooth surface and model detail reproduction.

The lot in question, Lot 070108, was comprised of 3567 units, Item 678773. Each unit includes 4-cartridges of the dental impression material. A total of 426 units of item 678773 from this lot were distributed into European Union Member States. DENTSPLY Caulk has determined it necessary to remove all product lot units from the market, including the 426 units shipped into the European Union.

Our investigation, which includes observation from dental professionals as well as internal product testing, has determined that the specific product lot will likely not perform as indicated in the Directions For Use. In clinical usage, the product has a minimum mouth removal time of 5-minutes. After placement in the mouth, this lot of material will typically take much longer than normal to reach a set stage, and may not set to the hardness level typically associated with this product. In order to avoid any clinical issues this may present to our dentist customers; we are recalling this one lot of material from the market

The investigation also determined that while the product will likely not set in the time specified or to the hardness level typically associated with this product, it does not present a safety issue to the dentist or patient. As is stated in the included documentation, the investigation into the product lot slow setting issue did not identify a significant risk to the public health. It is believed that the possibility of injury is unlikely and that the impression material would likely be removed from the mouth fully intact, precluding possible injury, incident or adverse health consequence.

This report is being made by DENTSPLY Caulk without prejudice and does not imply any admission of liability for any related incident or its consequences

Best regards,

Manager, Quality Assurance and Regulatory Affairs
DENTSPLY Caulk