

## **Regulatory Data Sheet**

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# **3M<sup>TM</sup>** Filtek<sup>TM</sup> One Bulk Fill Restorative

3M Oral Care Solutions Division 3M Center, St. Paul, MN 55144-1000, USA 1-888-3M HELPS (1-888-364-3577)

#### RDSs are available at www.3M.com

### **Regulations and Industry Standards**

#### SDS (US OSHA)

See Safety Data Sheet (SDS) for hazard and other regulatory data.

#### **California Proposition 65**

To the best of the manufacturer's knowledge, this product is in compliance with Proposition 65, and reasonably anticipated use of this product will not result in exposure to any Proposition 65 chemicals that would require a Proposition 65 warning. **EU CMR Directive** 

This product does not contain an ingredient at  $\geq 0.1\%$  that is classified as a Category 1 or 2 carcinogen, mutagen, or reproductive toxicant according to Annex VI (Table 3.2) of European Regulation 1272/2008 on Classification, Labelling, and Packaging of Dangerous Substances and Mixtures or that is classified by 3M or its vendors as an EU Category 1 or 2 carcinogen, mutagen, or reproductive toxicant according to the criteria of European Council Directive 67/548/EEC (the Dangerous Substances Directive).

#### **EU Food Allergens**

This product complies with Regulation (EU) 1169/2011 on the provision of food information to consumers, as there is no intentionally added component identified in Annex II of this regulation. Specifically, none of the following are intentionally added: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/L expressed as sulphur dioxide, lupin, mollusks, and/or derivatives thereof.

#### Halal

This product has not been certified Halal.

#### Kosher

This product has not been certified Kosher.

#### **US FALCPA**

This product complies with the United States Food Allergy Labeling and Consumer Protection Act of 2004, as there is no intentionally added milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and/or proteins thereof.

## **Chemicals and/or Compounds of Interest**

Arsenic and (As) Compounds : Not intentionally added. Beryllium and (Be) Compounds : Not intentionally added. Bismuth and (Bi) Compounds : Not intentionally added. Bisphenol A (BPA) (CAS 80-05-7) : Not intentionally added. Butyl Benzyl Phthalate (BBP) (CAS 85-68-7) : Not intentionally added. Cadmium and (Cd) Compounds : Not intentionally added. Colophony (Rosin) (CAS 8050-09-7) : Not intentionally added. Di(2-Ethylhexyl) Phthalate (DEHP) (CAS 117-81-7) : Not intentionally added. Dibutyl Phthalate (DBP) (CAS 84-74-2) : Not intentionally added. Dibutyl Tin Compounds : Not intentionally added. Diisodecyl Phthalate (DIDP) : Not intentionally added. Diisononyl Phthalate (DINP) : Not intentionally added. Di-n-Octyl Phthalate (DNOP) (CAS 117-84-0) : Not intentionally added. Dyes : Not intentionally added. Flavorings : Not intentionally added. Formaldehyde (CAS 50-00-0): This product contains a polymer manufactured with formaldehyde as a monomer. While residual amounts of formaldehyde might be present, the amount would be <10 ppm by weight. Hexavalent Chromium and (Cr+6) Compounds : Not intentionally added. Lead and (Pb) Compounds : Not intentionally added. Melamine (CAS 108-78-1) : Not intentionally added. Mercury and (Hg) Compounds : Not intentionally added. Natural Rubber Latex : This product is not made with natural rubber latex. Organotin Compounds : Not intentionally added. Phthalates : Not intentionally added. Selenium and (Se) Compounds : Not intentionally added. Tributyl Tin Compounds : Not intentionally added. Triphenvl Tin Compounds : Not intentionally added.

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