



Regulatory Data Sheet

Copyright, 2025, Solventum. All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing Solventum products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from Solventum, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

This Regulatory Data Sheet is provided as a courtesy in response to a customer request.

Document Group:	28-0649-5	Version Number:	4.00
Issue Date:	11/10/25	Supersedes Date:	06/11/25

Filtek™ Z500 Universal Restorative (8020, 8021)

Solventum
Dental Solutions
Solventum US LLC, 12930 IH 10 West, San Antonio, TX 78249
1-855-423-6725

RDSs are available at [Solventum.com](https://www.solventum.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 CMRs

This product does not contain an ingredient at $\geq 0.1\%$ that is classified as a Category 1A or 1B carcinogen, mutagen, or reproductive toxicant according to Annex VI 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 a Category 1A or 1B carcinogen, mutagen, or reproductive toxicant according to the criteria laid out in European Regulation 1272/2008 on Classification, Labelling, and Packaging of Dangerous Substances and Mixtures.

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.

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, sesame and/or proteins thereof.

Chemicals and/or Compounds of Interest

Arsenic and (As) Compounds : Not known to contain.

Beryllium and (Be) Compounds : Not known to contain.

Bismuth and (Bi) Compounds : Not known to contain.
Bisphenol A (BPA) (CAS 80-05-7) : Not known to contain.
Butyl Benzyl Phthalate (BBP) (CAS 85-68-7) : Not known to contain.
Cadmium and (Cd) Compounds : Not known to contain.
Chromium and (Cr) Compounds : Not known to contain.
Colophony (Rosin) (CAS 8050-09-7) : Not known to contain.
Di(2-Ethylhexyl) Phthalate (DEHP) (CAS 117-81-7) : Not known to contain.
Dibutyl Phthalate (DBP) (CAS 84-74-2) : Not known to contain.
Dibutyl Tin Compounds : Not known to contain.
Diisodecyl Phthalate (DIDP) : Not known to contain.
Diisononyl Phthalate (DINP) : Not known to contain.
Di-n-Octyl Phthalate (DNOP) (CAS 117-84-0) : Not known to contain.
Dyes : Not known to contain.
Flavorings : Not known to contain.
Formaldehyde (CAS 50-00-0) : Not known to contain.
Hexavalent Chromium and (Cr+6) Compounds : Not known to contain.
Lead and (Pb) Compounds : Not known to contain.
Melamine (CAS 108-78-1) : Not known to contain.
Mercury and (Hg) Compounds : Not known to contain.
Natural Rubber Latex : This product is not made with natural rubber latex.
Nickel and (Ni) Compounds : Not known to contain.
Organotin Compounds : Not known to contain.
Phthalates : Not known to contain.
Selenium and (Se) Compounds : Not known to contain.
Tributyl Tin Compounds : Not known to contain.
Triphenyl Tin Compounds : Not known to contain.
Zinc and (Zn) Compounds : Not known to contain.

Definitions

Note: all Definitions take Disclaimers into account and apply to the “Chemicals and/or Compounds of Interest” and/or “Per and poly-fluoroalkyl Substances (PFAS)” sections only

Terms	Definitions
Contains*	Present based on composition information disclosed by 3M suppliers, analytical testing, or both.
Not known to contain*	1. Analytical measurement for presence is not currently available; 2. If measurement is possible, a) The material has not been identified or disclosed to 3M and b) The material has not been specifically quantified or detected; OR c) Based on information from raw material suppliers, possible presence as an impurity or by-product at or below regulatory thresholds (e.g., 0.1 or 0.01 %)
Intentionally added**	Desired in the final product to provide a specific characteristic, appearance, or quality and/or to perform a specific function.
Not intentionally added**	By-product(s), impurity(ies) and/or unintended artifact(s) resulting from the formulation and/or manufacture of a material.
By-product***	A chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.
Impurity***	A chemical substance which is unintentionally present with another chemical substance (e.g., residuals, catalysts, process solvents).

*Terms apply to the Chemicals and/or Compounds of Interest Section only (if section is present)

**Terms apply to the PFAS Section only (if section is present)

***Terms apply to both the Chemicals and/or Compounds of Interest and PFAS Sections (if section(s) are present)

Disclaimers: The information provided in this document related to material content represents Solventum's knowledge and belief, which may be based in whole or in part on information provided by suppliers to Solventum. This is intended to answer commonly asked questions about Solventum products and is not intended to be a comprehensive listing of all substances that may be of interest or that may be regulated in this or other Solventum products, nor is it intended to be a comprehensive summary of any and all regulations that may apply to this product. Where substances are listed, their listing does not infer or constitute a judgment as to their safety, environmental or health impacts. Information is supplied upon the condition that the persons receiving the same will make their own determination as to its suitability for their purposes prior to use. Customers are encouraged to consult with legal and regulatory experts to determine applicable regulations in light of intended use of the product.

Limitation of Remedies and Liability: In the event any Product is proven not to conform with the information in this document, then to the extent permitted by law, Solventum's entire liability and Buyer's exclusive remedy, will be at Solventum's option either: (i) replacement of Product with a conforming product, or (ii) refund of the purchase price paid by Buyer for each non-conforming Product, within a reasonable time after written notification of said non-conformance and return of said Product to Solventum. Solventum shall not under any circumstances be liable for direct, incidental, special, or consequential damages (including but not limited to loss of profits, revenue, or business) related to or arising out of this certification, including, the use, misuse or inability to use the Product. Unless stated otherwise in writing, the foregoing language cannot be waived, modified, or supplemented in any manner whatsoever.