



## Regulatory Data Sheet

Copyright, 2016, 3M Company.

All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, 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:** 29-1348-1  
**Issue Date:** 05/22/16

**Version Number:** 1.00  
**Supersedes Date:** Initial Issue

# PARADIGM™ NANO HYBRID UNIVERSAL RESTORATIVE

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

3M RDSs are available at [www.3M.com](http://www.3M.com)

## Regulations and Industry Standards

### SDS (US OSHA)

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

### 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.

### 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 EU Directive 2000/13/EC as amended by 2003/89/EC and 2007/68/EC on Labeling, Presentation and Advertising of Foodstuffs, as there is no intentionally added component identified in Annex IIIa of these directives. Specifically, 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 sulfur dioxide, lupin, mollusks, and/or derivatives thereof, are not intentionally added.

### Halal

This product has not been certified Halal.

### Kosher

This product has not been certified Kosher.

## California Proposition 65

To the best of 3M'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.

## Chemicals and/or Compounds of Interest

**Arsenic and (As) Compounds** : This chemical or chemical compound is not intentionally added.

**Beryllium and (Be) Compounds** : This chemical or chemical compound is not intentionally added.

**Bismuth and (Bi) Compounds** : This chemical or chemical compound is not intentionally added.

**Bisphenol A (BPA)** : This chemical or chemical compound is not intentionally added.

**Butyl Benzyl Phthalate (BBP)** : This chemical or chemical compound is not intentionally added.

**Cadmium and (Cd) Compounds** : This chemical or chemical compound is not intentionally added.

**Chromium and (Cr) Compounds** : This chemical or chemical compound is not intentionally added.

**Colophony (Rosin)** : This chemical or chemical compound is not intentionally added.

**Dibutyl Phthalate (DBP)** : This chemical or chemical compound is not intentionally added.

**Dibutyl Tin Compounds** : This chemical or chemical compound is not intentionally added.

**Di(2-Ethylhexyl) Phthalate (DEHP)** : This chemical or chemical compound is not intentionally added.

**Diisodecyl Phthalate (DIDP)** : This chemical or chemical compound is not intentionally added.

**Diisononyl Phthalate (DINP)** : This chemical or chemical compound is not intentionally added.

**Di-n-Octyl Phthalate (DNOP)** : This chemical or chemical compound is not intentionally added.

**Dyes** : This chemical or chemical compound is not intentionally added.

**Flavorings** : This chemical or chemical compound is not intentionally added.

**Formaldehyde** : 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** : This chemical or chemical compound is not intentionally added.

**Lead and (Pb) Compounds** : This chemical or chemical compound is not intentionally added.

**Melamine** : This chemical or chemical compound is not intentionally added.

**Mercury and (Hg) Compounds** : This chemical or chemical compound is not intentionally added.

**Natural Rubber Latex** : This product is not made with natural rubber latex

**Nickel and (Ni) Compounds** : This chemical or chemical compound is not intentionally added.

**Organotin Compounds** : This product is known to contain this chemical or chemical compound.

**Phthalates** : This chemical or chemical compound is not intentionally added.

**Selenium and (Se) Compounds** : This chemical or chemical compound is not intentionally added.

**Tributyl Tin Compounds** : This chemical or chemical compound is not intentionally added.

**Triphenyl Tin Compounds** : This chemical or chemical compound is not intentionally added.

**Zinc and (Zn) Compounds** : This chemical or chemical compound is not intentionally added.

**Disclaimers:** The information provided in this document related to material content represents 3M's knowledge and belief, which may be based in whole or in part on information provided by suppliers to 3M. This is intended to answer commonly asked questions about 3M 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 3M 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, 3M's entire liability and Buyer's exclusive remedy, will be at 3M'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 3M. 3M 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.