

Regulatory Data Sheet

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

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3MTM FiltekTM Universal Restorative - all shades

ID Number(s):

70-2014-0755-1, 70-2014-0756-9, 70-2014-0757-7, 70-2014-0758-5, 70-2014-0759-3, 70-2014-0760-1

7100187397, 7100187396, 7100187410, 7100187411, 7100187412, 7100187415

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

This product is a kit or a multipart product which consists of multiple, independently packaged components. An RDS for each of these components is included. Please do not separate the component RDSs from this cover page. The document numbers of the RDSs for components of this product are:

39-3531-9, 40-4251-1

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

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3MTM FiltekTM Universal Restorative - All Shades Except Pink Opaquer

Product Identification Numbers

70-2014-2284-0, 70-2014-2285-7 7100333364, 7100333363

3M

Dental Solutions 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 CMRs**

This product does not contain an ingredient at >= 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.

Halal

This product has not been certified Halal.

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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 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.

Cobalt and (Co) Compounds: Not known to contain.

Colombony (Posin) (CAS 8050 00 7): 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: Not known to contain. Organotin Compounds: Not known to contain.

Phthalates: Not known to contain.

Selenium and (Se) Compounds: Not known to contain. Tin and (Sn) Compounds: Not known to contain. Tributyl Tin Compounds: Not known to contain. Triphenyl Tin 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*	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	By-product(s), impurity(ies) and/or unintended artifact(s) resulting from the formulation and/or
added**	manufacture of a material.

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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)

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^{**}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)



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

 Document Group:
 40-4251-1
 Version Number:
 1.01

 Issue Date:
 03/18/19
 Supercedes Date:
 03/08/19

3MTM FiltekTM Universal Restorative - Shade Pink Opaquer

Product Identification Numbers

70-2014-0708-0, 70-2014-0718-9, 70-2014-0728-8, 70-2014-0738-7 7100186754, 7100186777, 7100186755, 7100187394

3M

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

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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 >= 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.

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Kosher

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Chemicals and/or Compounds of Interest

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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.

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.

Dves: This chemical or chemical compound is not intentionally added.

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

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

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

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.

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