



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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3M™ ESPE™ KETAC™ CEM RADIOPAQUE PERMANENT GLASS IONOMER LUTING CEMENT

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:

16-2590-4, 26-9894-2

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3M™ ESPE™ KETAC™ CEM RADIOPAQUE POWDER

3M
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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 $\geq 0.1\%$ 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.

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.

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 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 product is not made with natural rubber latex.

Nickel and (Ni) Compounds : 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.

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

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

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3M™ ESPE™ KETAC™ CEM RADIOPAQUE LIQUID

3M
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3M Center, St. Paul, MN 55144-1000, USA
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