

Regulatory Data Sheet

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

Document Group: 09-0298-1 **Version Number:** 1.00

Issue Date: 09/28/17 **Supercedes Date:** Initial Issue

3M Unitek Multi-Cure Glass Ionomer Band Cement (712-050)

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:

07-6196-5, 07-6217-9

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

Document Group: 07-6196-5 **Version Number:** 3.00 **Issue Date:** 03/30/22 **Supercedes Date:** 09/09/21

3MTM UnitekTM Multi-Cure Glass Ionomer Orthodontic Band **Cement Powder (712-051)**

3MOral 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 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.

Halal

This product has not been certified Halal.

Kosher

This product has not been certified Kosher.

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.

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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. Chromium and (Cr) 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. **Di(Methoxyethyl) Phthalate (DMEP) (CAS 117-82-8)**: Not intentionally added.

Dibutyl Phthalate (DBP) (CAS 84-74-2): Not intentionally added.

Dibutyl Tin Compounds: Not intentionally added.

Diisobutyl Phthalate (DIBP) (CAS 84-69-5): 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: Contains.

Flavorings: Not intentionally added.

Formaldehyde (CAS 50-00-0): Not intentionally added.

Gluten: Not intentionally added.

Hexavalent Chromium and (Cr+6) Compounds: Not intentionally added.

Lead and (Pb) Compounds: Not intentionally added.

Materials of Human or Animal Origin: 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.

Nickel and (Ni) Compounds: Not intentionally added.

Nuts: Not intentionally added.

Organotin Compounds: Not intentionally added.

Phthalates: Not intentionally added.

Selenium and (Se) Compounds: Not intentionally added.
Tributyl Tin Compounds: Not intentionally added.
Triphenyl Tin Compounds: Not intentionally added.
Zinc and (Zn) Compounds: Not intentionally added.

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

 Document Group:
 07-6217-9
 Version Number:
 2.00

 Issue Date:
 09/09/21
 Supercedes Date:
 11/04/16

3MTM UnitekTM Multi-Cure Glass Ionomer Orthodontic Band Cement Liquid (712-052)

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.

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 >= 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

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Flavorings: Contains.

Formaldehyde (CAS 50-00-0): Not intentionally added.

Gluten: Not intentionally added.

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Lead and (Pb) Compounds: Not intentionally added.

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