



Regulatory Data Sheet

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3M™ CoTran™ 9718 Backing

Product Identification Numbers

70-0002-0042-1

7100065959

3M

Medical Solutions Division

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1-888-3M HELPS (1-888-364-3577)

RDSs are available at www.3M.com

Regulations and Industry Standards

SDS (US OSHA)

This product is an article and therefore is not subject to the requirements of the US Occupational Safety and Health Administration's (OSHA) Hazardous Communications Standard 29 CFR 1910.1200(b)(6)(v) to provide a Safety Data Sheet (SDS).

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.

CONEG

This product complies with the US CONEG (Coalition of Northeastern Governors) Model Toxics in Packaging Legislation as there is no intentionally added lead, cadmium, hexavalent chromium or mercury, and the sum total concentration of these substances in the product does not exceed 100 ppm by weight. *This product is not intentionally formulated with heavy metals. Residuals that may be detected are less than 100 ppm total lead, cadmium, mercury and hexavalent chromium.*

Conflict Minerals

Conflict Minerals, which the U.S. Securities and Exchange Commission ("SEC") has defined as gold, columbite-tantalite (coltan), cassiterite, wolframite, or their derivatives (tin, tantalum, or tungsten), are not contained in or are not "necessary to the functionality or necessary to the production" of the above-listed product, as the term "necessary to the functionality or the production" is defined under the SEC's Conflict Minerals Rule. 77 Fed. Reg. 56274 (Sept. 12, 2012).

Drug Master File

A Drug Master File for this product is available upon request. Please contact the manufacturer for more information or to obtain a Letter of Authorization (LOA).

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 Endocrine-Disrupting Substances

This product does not contain an ingredient at $\geq 0.1\%$ that is classified as having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)) or, pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (Biocidal Products Regulation).

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.

EU REACH

Substances listed in Annex XIV of Regulation No 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) are not intentionally added to this product.

EU REACH

Substances listed in Annex XVII of Regulation No 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) are not intentionally added to this product.

EU REACH

This product, including any article that the product is composed of, does not contain at greater than 0.1% by weight a Substance of Very High Concern (SVHC) substance identified according to Article 59 of REACH. This declaration reflects the substances on the candidate SVHC list, effective June 2023.

EU RoHS

This product does not exceed the maximum concentration values (MCVs) set under EU Directive 2011/65/EU (RoHS recast/RoHS 2), as stated in Annex II to that directive. This means that each of the homogenous materials within this product does not exceed the following MCVs: (a) 0.1% (by weight) for lead, mercury, hexavalent chromium, polybrominated biphenyls or polybrominated diphenyl ethers; and (b) 0.01% (by weight) for cadmium.

EU RoHS Phthalates

This product does not exceed the maximum concentration values (MCVs) for phthalates set under EU Directive 2011/65/EU (RoHS recast/RoHS 2), as amended by EU 2015/863, which applies to finished EEE after July 22, 2019 for Category 1-7, 10-11 products and after July 22, 2021 for Category 8 and 9 products. This means that each of the homogeneous materials within this product does not exceed the MCV of 0.1% (by weight) for each of the following phthalates: DEHP, BBP, DBP, and DIBP.

Halal

This product has not been reviewed. However, this product does not contain a material of animal or human origin in the manufacturing process.

Kosher

This product has not been reviewed. However, this product does not contain a material of animal or human origin in the manufacturing process.

US FDA Indirect Food Additive

This product may comply with the United States Food and Drug Administration (Code of Federal Regulations) 21 CFR Regulations. Please contact 1-800-362-3550 for specific citations and limitations. *This product is composed of ingredients that are cleared by the U.S. Food and Drug Administration (FDA) for safe use as described in 21 CFR 174.5, 177.1520 (c) 2.1 & 3.1a, 178.2010 and 178.3297. This product may be used in food contact applications when the maximum use does not exceed 19.0% under conditions C-H as described in Table 2 of 21 CFR 176.170 (c) (subject to applicable restrictions as described in 21 CFR). When used in applications with a density < 0.94 and thickness > 0.051 mm (0.002 inch), this product may contact food only under conditions of use E-G as described in Table 2 of 21 CFR 176.170 (c).*

USP <232>/<233> and ICH Q3D Elemental Impurities

Data on USP<232>/<233> and ICH Q3D Elemental Impurities is available upon request for this product.

Chemicals and/or Compounds of Interest

Acrylamide (CAS 79-06-1) : Not known to contain.

Alkylphenol (AP) : Not known to contain.

Alkylphenolethoxylates (APE) : Not known to contain.

Antimony and (Sb) Compounds : Not known to contain.

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

Asbestos : Not known to contain.

Barium and (Ba) Compounds : Contains. *This material does contain a trace amount of barium (0.02 ppm).*

Bisphenol A (BPA) (CAS 80-05-7) : Not known to contain.

Butyl Benzyl Phthalate (BBP) (CAS 85-68-7) : Not known to contain.

Butylated Hydroxytoluene (BHT) (128-37-0) : Not known to contain.

Cadmium and (Cd) Compounds : Not known to contain.

Chromium and (Cr) Compounds : Not known to contain.

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

Colophony (Rosin) (CAS 8050-09-7) : Not known to contain.

Copper and (Cu) Compounds : Contains. *This material does contain a trace amount of copper (0.16 ppm).*

Di(2-Ethylhexyl) Phthalate (DEHP) (CAS 117-81-7) : Not known to contain.

Di(Methoxyethyl) Phthalate (DMEP) (CAS 117-82-8) : Not known to contain.

Dibutyl Phthalate (DBP) (CAS 84-74-2) : Not known to contain.

Diisobutyl Phthalate (DIBP) (CAS 84-69-5) : Not known to contain.

Diisodecyl Phthalate (DIDP) : Not known to contain.

Diisononyl Phthalate (DINP) : Not known to contain.

Dimethylacetamide (CAS 127-19-5) : Not known to contain.

Di-n-Octyl Phthalate (DNOP) (CAS 117-84-0) : Not known to contain.

Dioxins and Furans : Not known to contain.

Formaldehyde (CAS 50-00-0) : Not known to contain.

Genetically Modified Organisms (GMOs) : Not known to contain.

Gluten : Not known to contain.

Gold and (Au) Compounds : Not known to contain.

Halogenated Flame Retardants : Not known to contain.

Iridium and (Ir) Compounds : Not known to contain.

Iron and (Fe) Compounds : Not known to contain.

Lead and (Pb) Compounds : Not known to contain.

Lithium and (Li) Compounds : Not known to contain.

Materials of Human or Animal Origin : Contains. *This product is made from a resin that contains one or more raw materials that originated in whole or in part from animal sources. The animal-sourced raw material(s) have been chemically altered from their original structure and have undergone significant chemical processing. Because of this modification and processing, the animal-sourced raw material(s) used are expected to comply with USDA/APHIS Title 9 CFR, EMEA/410/01 Revision 3, EU Regulation 1774/2002/EC, Directive 2000/6/EC and Commission Directive 2003/32/EC. As such, this product is not expected to pose a risk with respect to transmissible spongiform encephalopathies (TSE-BSE).*

Melamine (CAS 108-78-1) : Not known to contain.

Mercury and (Hg) Compounds : Not known to contain.

Molybdenum and (Mo) Compounds : Not known to contain.

Natural Rubber Latex : Not known to contain.

Nickel and (Ni) Compounds : Contains. *This material does contain a trace amount of nickel (0.07 ppm).*

Nonylphenol (NP) : Not known to contain.

Nonylphenol Ethoxylates (NPE) : Not known to contain.

Nuts : Not known to contain.

Organotin Compounds : Not known to contain.

Osmium and (Os) Compounds : Not known to contain.

Ozone Depleting Chemicals (ODCs) : Not known to contain.

Palladium and (Pd) Compounds : Not known to contain.

Phthalates : Not known to contain.

Platinum and (Pt) Compounds : Not known to contain.

Polyvinyl Chloride (PVC) : Not known to contain.
Rhodium and (Rh) Compounds : Not known to contain.
Ruthenium and (Ru) Compounds : Not known to contain.
Selenium and (Se) Compounds : Not known to contain.
Silver and (Ag) Compounds : Not known to contain.
Sugar, monosaccharides or disaccharides : Not known to contain.
Sulfur and (S) Compounds : Not known to contain.
Thallium and (Tl) Compounds : Not known to contain.
Tin and (Sn) Compounds : Contains. *This material does contain a trace amount of tin (0.02 ppm).*
Tributyl Tin Compounds : Not known to contain.
Vanadium and (V) Compounds : Not known to contain.
Zinc and (Zn) Compounds : Contains.

Per- and Polyfluoroalkyl Substances (PFAS)

PFAS refers to a broad range of thousands of materials with varying properties and characteristics, which may include high resistance to oil, water, temperature, chemicals, and fire, which makes certain PFAS critical to the functioning of many modern products.

Chlorofluorocarbons (CFCs) : Not intentionally added.
Hydrochlorofluorocarbons (HCFCs) : Not intentionally added.

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, <ul style="list-style-type: none"> 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 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.