Regulatory Data Sheet

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

Document Group:	40-3117-5	**Version Number:**	6.00
Issue Date:	06/22/23	**Supercedes Date:**	01/26/23

3M Scotchpak Film 9738

3M
Medical 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)
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.
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 Endocrine-Disrupting Substances
This product does not contain an ingredient at >= 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

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.

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 : Contains. *An antimony-containing catalyst is used in the manufacturing of one of the input raw materials for 3M Scotchpak 9738 (PI) backing. This antimony-containing catalyst is expected to be present at <0.1% w/w. Additionally, one of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain an antimony elemental impurity. The concentration of antimony in the pigment is expected to be less than 0.1 ppm. A second pigment used in the manufacturing of 3M Scotchpak 9738 (PI) backing also contains an antimony trace metal, with an expected antimony concentration in the pigment of <20 ppm.*

Scotchpak 9738 (PI) was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. Test results indicate that Scotchpak 9738 (PI) contains 0.35 ppm antimony (Sb).
Arsenic and (As) Compounds : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain an arsenic elemental impurity. The concentration of arsenic in the pigment is expected to be less than 0.05 ppm. A second pigment used in the manufacturing of 3M Scotchpak 9738 (PI) backing also contains an arsenic trace metal, with an expected arsenic concentration in the pigment of <9 ppm.*

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No arsenic was detected (the limit of detection is 0.01 ppm).
Asbestos : Not known to contain.
Bananas : Not known to contain.
Barium and (Ba) Compounds : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain a barium elemental impurity. The concentration of barium in the pigment is expected to be less than 10*

ppm. A second pigment used in the manufacturing of 3M Scotchpak 9738 (PI) backing also contains a barium trace metal, with an expected barium concentration in the pigment of <1 ppm.

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No barium was detected (the limit of detection is 0.01 ppm).
Beryllium and (Be) Compounds : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain a beryllium elemental impurity. The concentration of beryllium in the pigment is expected to be less than 0.05 ppm.*
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 : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain a cadmium elemental impurity. The concentration of cadmium in the pigment is expected to be less than 0.05 ppm. A second pigment used in the manufacturing of 3M Scotchpak 9738 (PI) backing also contains a cadmium trace metal, with an expected cadmium concentration in the pigment of <3 ppm.*

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No cadmium was detected (the limit of detection is 0.01 ppm).
Chromium and (Cr) Compounds : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain a chromium elemental impurity. The concentration of chromium in the pigment is expected to be less than 1 ppm. A second pigment used in the manufacturing of 3M Scotchpak 9738 (PI) backing also contains a chromium trace metal, with an expected chromium concentration in the pigment of <178 ppm.*

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No chromium was detected (the limit of detection is 0.01 ppm).
Cobalt and (Co) Compounds : Contains. *A cobalt-containing catalyst is used in the manufacturing of one of the input raw materials for 3M Scotchpak 9738 (PI) backing. This cobalt-containing catalyst is expected to be present at <0.1% w/w. Additionally, a pigment used in the manufacturing of 3M Scotchpak 9738 (PI) backing contains a cobalt trace metal, with an expected cobalt concentration in the pigment of <19 ppm.*

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No cobalt was detected (the limit of detection is 0.01 ppm).
Colophony (Rosin) (CAS 8050-09-7) : Not known to contain.
Copper and (Cu) Compounds : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain a copper elemental impurity. The concentration of copper in the pigment is expected to be less than 0.4 ppm. A second pigment used in the manufacturing of 3M Scotchpak 9738 (PI) backing also contains a copper trace metal, with an expected copper concentration in the pigment of <223 ppm.*

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No copper was detected (the limit of detection is 0.01 ppm).
Corn and/or corn derivatives : Not known to contain.
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.
Hexavalent Chromium and (Cr+6) Compounds : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing contains a hexavalent chromium trace metal, with an expected hexavalent chromium concentration in the pigment of <1 ppm.*

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No chromium was detected (the limit of detection is 0.01 ppm).
Iridium and (Ir) Compounds : Not known to contain.
Iron and (Fe) Compounds : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain an iron elemental impurity. The concentration of iron in the pigment is expected to be less than 4 ppm.*
Lead and (Pb) Compounds : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain a lead elemental impurity. The concentration of lead in the pigment is expected to be less than 0.05 ppm. A second pigment used in the manufacturing of 3M Scotchpak 9738 (PI) backing also contains a lead trace metal, with an expected lead concentration in the pigment of <8 ppm.*

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No lead was detected (the limit of detection is 0.01 ppm).
Lithium and (Li) Compounds : Not known to contain.
Materials of Human or Animal Origin : Not known to contain.
Melamine (CAS 108-78-1) : Not known to contain.
Mercury and (Hg) Compounds : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain a mercury elemental impurity. The concentration of mercury in the pigment is expected to be less than 0.01 ppm. A second pigment used in the manufacturing of 3M Scotchpak 9738 (PI) backing also contains a mercury trace metal, with an expected mercury concentration in the pigment of <0.5 ppm.*

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No mercury was detected (the limit of detection is 0.01 ppm).
Molybdenum and (Mo) Compounds : Not known to contain.
Natural Rubber Latex : Not known to contain.
Nickel and (Ni) Compounds : Contains. *A nickel-containing catalyst is used in the manufacturing of one of the input raw materials for 3M Scotchpak 9738 (PI) backing. This nickel-containing catalyst is expected to be present at <0.0000038% w/w. Additionally, a pigment used in the manufacturing of 3M Scotchpak 9738 (PI) backing also contains a nickel trace metal, with an expected nickel concentration in the pigment of <150 ppm.*

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No nickel was detected (the limit of detection is 0.01 ppm).
Nonylphenol (NP) : Not known to contain.
Nonylphenol Ethoxylates (NPE) : Not known to contain.
Nuts : 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 : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain a selenium elemental impurity. The concentration of selenium in the pigment is expected to be less than 0.05 ppm. A second pigment used in the manufacturing of 3M Scotchpak 9738 (PI) backing also contains a selenium trace metal, with an expected selenium concentration in the pigment of <26 ppm.*

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No selenium was detected (the limit of detection is 0.01 ppm).
Silver and (Ag) Compounds : Not known to contain.
Sugar, monosaccharides or disaccharides : Not known to contain.
Thallium and (Tl) Compounds : Not known to contain.
Tin and (Sn) Compounds : Contains. *A tin-containing catalyst is used in the manufacturing of one of the input raw materials for 3M Scotchpak 9738 (PI) backing. This tin-containing catalyst is expected to be present at <0.000006% w/w. Additionally, one of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain a tin elemental impurity. The concentration of tin in the pigment is expected to be less than 0.05 ppm.*

3M Scotchpak 9738 (PI) backing was subjected to ICH Q3D elemental impurities testing. Testing was completed on one lot of material for screening purposes. The testing was done with a non-validated method following USP <661.1> Metals Screen for USP 40/S2 (modified for sample weight to extract solution ratio). Control samples were included for calculated recovery. No tin was detected (the limit of detection is 0.01 ppm).
Vanadium and (V) Compounds : Not known to contain.
Zinc and (Zn) Compounds : Contains. *One of the pigments used in the manufacturing of 3M Scotchpak 9738 (PI) backing does contain a zinc elemental impurity. The concentration of zinc in the pigment is expected to be less than 5 ppm.*

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.
Perfluorooctanoic Acid (PFOA) (CAS 335-67-1) : 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, 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.