



Regulatory Data Sheet

Copyright, 2024, 3M Company.

All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

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

Document Group: 10-5846-0
Issue Date: 09/16/24

Version Number: 22.00
Supersedes Date: 07/10/24

3M™ Tegaderm™ Transparent Film Dressing 1610, 1614, 1616, 1622, 1624, 1626, 1627, 1628, 1629, 1630, 1650, 1655

3M
Medical Surgical (MedSurg)
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.

China RoHS

This product or part does not exceed the maximum concentration values (MCVs) in China RoHS GB/T 26572-2011 (Requirements of Concentration limits for certain restricted substances in electrical and electronic products), which means that each of the homogeneous materials within this product is below the following MCVs: (a) 0.1% (by weight) for lead and its compounds, mercury and its compounds, hexavalent chromium and its compounds, polybrominated biphenyls or polybrominated diphenyl ethers; and (b) 0.01% (by weight) for cadmium and its compounds.

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.

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).

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 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 known to be contained in 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 2024.

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.

Lacey Act

As a company committed to compliance and sustainability, a standard part of 3M's supplier practices and arrangements is to require its suppliers to comply with all applicable laws affecting the manufacture of products for 3M. This includes the U.S. Animal and Plant Health Inspection Service (APHIS) Lacey Act amendments of May 22, 2008. We are monitoring APHIS's efforts in establishing phase-in timelines for import declarations on particular products, and are gathering information from our supply chains to support the necessary import declarations.

Chemicals and/or Compounds of Interest

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.

Azocolorants and Azodyes : Not known to contain.

Biocides/Preservatives : Biocides/preservatives are not intentionally added for the purpose of protecting the product from the growth of microorganisms.

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.

Chlorinated Paraffins, Short Chain : 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.

Crystalline Silica : Not known to contain.

Decabromodiphenyl Ether (Deca-BDE) (CAS 1163-19-5) : 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.

Flame Retardants (not PBB or PBDE) : Not known to contain.

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

Halogenated Flame Retardants : Not known to contain.

Hexabromo Cyclo-Dodecane (HBCD) : Not known to contain.

Hexabromobenzene (CAS 87-82-1) : Not known to contain.

Hexachlorobenzene (CAS 118-74-1) : Not known to contain.

Hexavalent Chromium and (Cr+6) Compounds : Not known to contain.

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

Materials of Human or Animal Origin : Not known to contain.

Medium-chained chlorinated paraffins, C14-C17 (MCCP) : Not known to contain.

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

Musk Xylene (CAS 81-15-2) : Not known to contain.

Nanomaterial : Nanomaterial is not intentionally added in this product. Nanomaterial is manufactured or naturally occurring solid particles for which at least 1% by weight of the primary particles are between approximately 1 and 100 nanometers in at least one external dimension.

Natural Rubber Latex : This product is not made with natural rubber latex.

N-Nitrosamines : Not known to contain.

Organotin Compounds : Not known to contain.

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

Pentachlorophenol (87-86-5) : Not known to contain.

Phthalates : Not known to contain.

Polybrominated Biphenyls (PBB) : Not known to contain.

Polybrominated Diphenylethers (PBDE) : Not known to contain.

Polychlorinated Biphenyls (PCBs) : Not known to contain.

Polycyclic Aromatic Hydrocarbons (PAHs) : Not known to contain.

Polyvinyl Chloride (PVC) : Not known to contain.

Radioactive Substance : Not known to contain.

Silicone : Contains.

Tetrabromobisphenol A (TBBA) (CAS 79-94-7) : Not known to contain.

Tris(1 chloro-2-propyl) phosphate (TCPP) (CAS 13674-84-5) : Not known to contain.

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.

Per- and polyfluoroalkyl substances (PFAS) : Not intentionally added.

Perfluorooctanesulfonic Acid (PFOS) (CAS 1763-23-1) : 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.