



Regulatory Data Sheet

Copyright, 2023, 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:	11-1594-8	Version Number:	14.01
Issue Date:	06/26/23	Supersedes Date:	06/22/23

3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex (0.7% available iodine) and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation 8630, 8635

Product Identification Numbers

70-2007-7456-3, 70-2007-7458-9, 70-2011-7323-7, 70-2011-7324-5
7100018326, 7100020799, 7100115636, 7100115635

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)

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.

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 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.

Chemicals and/or Compounds of Interest

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

Alkylphenol (AP) : Not known to contain.

Alkylphenoethoxylates (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.

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.

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

Crystalline Silica : 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.

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

Halogenated Flame Retardants : 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.

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

Naphthalene (CAS 91-20-3) : Not known to contain.

Natural Rubber Latex : Not known to contain.

Nonylphenol (NP) : Not known to contain.

Nonylphenol Ethoxylates (NPE) : Not known to contain.

Phthalates : Not known to contain.

Polyvinyl Chloride (PVC) : Not known to contain.

Zinc and (Zn) Compounds : 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.

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*	<ol style="list-style-type: none"> Analytical measurement for presence is not currently available; If measurement is possible, <ol style="list-style-type: none"> The material has not been identified or disclosed to 3M and The material has not been specifically quantified or detected; OR 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.