



CALIFORNIA PROPOSITION 65 AND VINYL EXAM GLOVES

FAQs

DINP (Diisononyl phthalate) is a phthalate plasticizer used to manufacture many vinyl (polyvinyl chloride/PVC) products, including electrical wire, coated fabrics, automotive parts, vinyl flooring, footwear, and medical examination gloves, to make them pliable.

The California Office of Environmental Health Hazard Assessment (“OEHHA”) has added DINP to the Proposition 65 list of chemicals “known to the State of California to cause cancer.”

Importantly, OEHHA itself has stated that the mere listing of a substance does not mean a product containing that substance is in “violation of any product-safety standards.” Moreover, numerous governmental regulatory bodies, including the Consumer Product Safety Commission and the European Chemicals Agency, have stated that DINP poses no threat to human health at typical exposure levels. Members of California’s Cancer Identification Committee, which made the decision to list DINP, have expressed the opinion that a chemical shown to cause cancer in laboratory animals can be listed as a carcinogen regardless of whether there is evidence that the chemical causes cancer in humans.

As a result of Prop 65 and the listing of DINP, manufacturers selling products containing DINP in California are required to either remove DINP from their products, put a warning on DINP-containing products or be prepared to prove by a preponderance of the scientific evidence that exposures to DINP from the products is at a level sufficiently low that the exposures pose no significant risk of cancer in humans.

As of this date, OEHHA is considering a “safe harbor” no significant risk exposure level, which would establish a threshold exposure level at which warnings would and would not be required. For the present, Medline has added warning labels to all of our vinyl glove products. Medline is committed to quality and safety. We are aggressively exploring viable alternatives to DINP that would deliver users the same level of quality, performance, and cost.

The following information is provided to help our customers understand this important issue.

Q: What is Proposition 65?

A: Enacted in 1986, Prop 65 is a California state law intended to reduce or eliminate exposure to certain substances. It is comprised of a list of substances that the State of California recognizes as causing cancer and/or birth defects.

The entire list of substances can be viewed online by visiting the webpage of the California Office of Environmental Health Hazard Assessment (OEHHA):

http://oehha.ca.gov/prop65/prop65_list/newlist.html.



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Q: Do vinyl gloves containing DINP pose a health risk?

A: There is substantial scientific and medical evidence that vinyl gloves are safe and serve a valuable role in the medical and industrial glove market. Vinyl exam gloves are regulated at the federal level by the FDA as medical devices that require Premarket submissions (510(k)) prior to commercial distribution. The exam gloves have FDA cleared 510(k)s that demonstrate that they meet all product-safety standards without the requirements of a carcinogen warning on the product labeling. At the state level, California requires the carcinogen warning for all exposures to listed chemicals, including DINP, unless the company causing the exposure can meet a very high scientific burden of proving that the exposure is below the “no significant risk level.”

California has not evaluated vinyl gloves or specific uses, nor has it set a “no significant risk level.” Therefore, acting conservatively, Medline is including the warning to ensure compliance.

Q: How was DINP added to CA Prop 65 list?

A: A chemical can be listed if it is determined by the Carcinogen Identification Committee (CIC) that the chemical has been clearly shown to cause cancer, or by the Developmental and Reproductive Toxicant (DART) Identification Committee that the chemical has been clearly shown to cause birth defects or reproductive harm. The CIC made the determination that DINP is carcinogenic based on evidence from studies in rats and mice as well as through structural activity comparisons with other phthalates, including DEHP that has been classified by IARC and the US EPA as a carcinogen.

Q: How long will this affect products containing DINP?

A: Any product exposure to DINP after December 20, 2014 must be preceded by a clear and reasonable warning or the manufacturer, distributor or retailer risks being in violation of Prop 65. This is true regardless of the manufacture date of the product. In addition, the manufacturer or distributor may be responsible for non-compliant product that is resold at any time in the future within California. This exposure extends along the entire distribution chain, with the retailer, distributor, importer and manufacturer all being subject to possible penalties.

Q: What are the options?

A: Once a chemical is placed on the Prop 65 list, a seller of a product that causes an exposure to that chemical must either; 1. remove the given product from the California market, 2. Reformulate the product so as to remove the chemical, 3. establish that the exposure level to humans is below the No Significant Risk Level (NSRL) and/or the Maximum Allowable Dose Levels (MADLs), or 4. provide a clear and reasonable warning that the product contains a listed substance. Manufacturers of vinyl gloves are currently seeking a replacement plasticizer for DINP.

However, there is no guarantee a satisfactory substitute will be found, and no guarantee that any substitute substance will not eventually be added to the Prop 65 list.



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2. At the moment, OEHHA has not established an NSRL for DINP. Companies whose products create a low level of exposure may develop and establish their own NSRL's, although the scientific threshold for doing so is quite rigorous and the process quite complex. The High Phthalates Panel of the American Chemistry Council has indicated that it plans to develop a resource to assist in estimating potential exposure levels to DINP from vinyl consumer products. Medline is actively involved with the industry to help estimate the potential exposure level and establish safe harbor limits for the chemical.

3. A product containing a listed chemical may continue to be sold in California if it includes a warning using the “safe harbor” language, and if it is presented in a clear and reasonable manner. For DINP the safe harbor warning would read “WARNING: This product contains a chemical known to the State of California to cause cancer.” Such a warning must be prominently placed on the labeling in a conspicuous fashion so as to allow it to be read by an ordinary user under customary conditions of purchase or use. The statement may also appear on the website and other published information related to the gloves. Medline has made available a line of vinyl gloves with the “Prop 65” warning statement.