CALIFORNIA PROPOSITION 65 AND VINYL EXAM GLOVES - FAQ

As a result of Prop 65, manufacturers selling products containing DINP in California are required to either remove DINP from their products or put a warning on their product labels by December 20, 2014. PIP is committed to quality and safety. To this end, PIP offers a line of disposable vinyl gloves that are Proposition 65 compliant. Certain compliant vinyl glove products will bear a Proposition 65 warning label. PIP is 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 DINP?
A: 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.

Q: WHAT IS PROP 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.

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 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 on all products that contain any amount of DINP. Specific product uses and limits have not been evaluated by California. Therefore the warning is required to notify customers of the chemical.

Q: WHY WAS DINP ADDED TO PROP 65 LIST?
A: A chemical can be listed if it is determined by the two independent committees of scientists and health professionals that the chemical has been clearly shown to cause cancer or birth defects or other reproductive harm. These two committees- the Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicant (DART) Identification Committee are part of OEHHA’s Science Advisory Board. 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 that contains DINP that is not identified with a Prop 65 warning after December 20, 2014 is con-
   sidered in violation of Prop 65. This is true regardless of the manufacture date. In addition, the manufacturer or
distributor remains responsible for any such 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.

   1. Manufacturers of vinyl gloves are currently seeking a replacement plasticizer for DINP. However, there is no
      guarantee that this substitute substance will not eventually be added to the Prop 65 list.

   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. PIP 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 warn-
ing 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 web-
      site and other published information related to the gloves. Medline has made available a line of vinyl gloves with
      the “Prop 65” warning statement.

Q: WHAT IS PIP DOING REGARDING PROP 65?
   A: PIP offers a line of disposable vinyl gloves that are compliant with Prop 65. If you’d like to purchase product that is
   Prop 65 complaint for distribution within the State of California please inform your PIP Representative at the time of
   order placement so that the appropriate style number is placed on your order.

Q: ONCE A CHEMICAL IS LISTED, CAN IT BE REMOVED FROM THE PROP 65 LIST?
   A: Yes. Chemicals are removed and added to the Prop 65 list throughout the year. The American Chemistry Council has
   filed a lawsuit against the California Office of Environmental Health Hazard Assessment to remove DINP from the
   Prop 65 list. The timeline associated with resolution of this lawsuit is yet to be determined.