



Questions and Answers: DINP and Prop 65

About DINP

Diisononyl phthalate (DINP) is used to soften or “plasticize” vinyl. DINP is a general purpose plasticizer used in a multitude of vinyl products that demand flexibility, durability and specific functionality. While DINP’s primary function is as a softener, it is also used in sealants, paints and lubricants. The benefits of DINP in vinyl are evident in products manufactured by the automobile, wire and cable, roofing and flooring industries.

On December 20, 2013, the California Office of Environmental Health Hazard Assessment (OEHHA) added DINP to California’s Proposition 65 list as “known to the State to cause cancer.”

Q: What exactly is California Proposition 65?

A: Proposition 65 (Prop 65) is the original name for the initiative that became California’s Safe Drinking Water and Toxic Enforcement Act of 1986. This law was enacted directly by California’s voters when it appeared as an initiative on an election ballot. The law is administered by OEHHA, which is a part of the California Environmental Protection Agency (Cal/EPA).

Q: What does Prop 65 Require?

A: Under Prop 65, the Governor of California must issue an annual list of substances “known to the State” to cause cancer, birth defects or reproductive harm. Currently, there are almost 900 substances on this list, including additives or ingredients in food and many common household products, naturally occurring substances, ethyl alcohol in alcoholic beverages, aspirin, and many prescription drugs.

Prop 65 requires anyone doing business in California to label a product if human exposure to a listed substance in the product is expected to be at a level above the established “safe harbor” level for that substance.

Q: What is a “safe harbor” level for a substance?

A: For substances that are listed as causing cancer, the “safe harbor” level is called a “no significant risk level” (NSRL). An NSRL is defined as the level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the substance over a 70-year lifetime. In other words, a person exposed to the substance at the “no significant risk level” for 70 years would not have more than a “one in 100,000” chance of developing cancer as a result of that exposure. A business has a “safe harbor” from Prop 65 warning requirements if exposure to a substance occurs at or below the NSRL.

Q: Does DINP meet the requirements for listing?

A: Prop 65 provides specific scientific criteria to determine if a substance is “known to the State” to cause cancer or reproductive toxicity. In December 2013, a committee of scientific experts appointed by the Governor and known as the Carcinogen Identification Committee (CIC) reviewed the scientific evidence on DINP and comments from the public. Based on that review, the CIC recommended that OEHHA list DINP. The High Phthalates Panel of the American Chemistry Council believes the weight-of-evidence is that, while high doses of DINP cause tumors in rodents, the specific tumor types are widely known to be not relevant to human cancer hazard assessment. On June 9, 2014, ACC filed a lawsuit against OEHHA challenging the listing of DINP as a chemical known to cause cancer pursuant to Prop 65.

Q: Would DINP be banned by a Prop 65 listing?

A: No. As stated by OEHHA, Prop 65 “does not ban or restrict the use of any given chemical.” It is not a restriction on use; it is primarily a labeling requirement that applies in certain instances. Prop 65 is a California law and this listing does not affect other U.S. states or regulations in other countries.

Q: Does a Prop 65 listing mean that DINP is unsafe?

A: No. A Prop 65 listing is not a safety determination. Indeed, according to OEHHA, the purpose of Prop 65 is to notify consumers that they may be exposed to a listed substance, but a Prop 65 product warning label does not mean that a product is in “violation of any product-safety standards.”

As noted above, the State may develop a No Significant Risk Level (NSRL) that would be a “safe harbor” level establishing the level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the substance over a 70-year lifetime.

Q: Will products containing DINP need to be labeled in California?

A: If exposure is below the calculated NSRL, Prop 65 warning labels will not be required for these products.

The American Chemistry Council High Phthalates Panel plans to develop a resource to assist in estimating potential exposures to DINP from vinyl consumer products.

Q: When will the warning requirement for DINP be in effect?

A: DINP was added to the list of chemicals known to the State of California to cause cancer on December 20, 2013. The warning requirement becomes effective a year from that date, December 20, 2014.

Q: What have other regulatory agencies said about DINP?

A: DINP has been thoroughly studied and reviewed by a number of government scientific agencies and regulatory bodies in the United States and Europe, including:

- European Chemicals Agency (ECHA) (2013)
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of the Australian Government Department of Health and Ageing (2012)
- National Toxicology Program’s Center for the Evaluation of Risks to Human Reproduction (2003)
- European Chemicals Bureau (2003)
- Consumer Product Safety Commission (CPSC) (the Chronic Hazard Advisory Panel on DINP in 2001 and the CPSC staff in 2002)
- EU’s Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

The conclusions of these agencies have been essentially the same: DINP does not pose a risk to human health at typical exposure levels.

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