

Statement

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WEIGHT OF EVIDENCE INDICATES THAT DINP SHOULD NOT BE LISTED ON PROP 65

WASHINGTON (December 5, 2013) – Following an announcement by the California EPA's Office of Environmental Health Hazard Assessment (OEHHA) Carcinogen Identification Committee (CIC) that the phthalate DINP should be listed as a "carcinogen," the High Phthalates Panel of the American Chemistry Council released the following statement:

"We challenge the scientific basis of California's decision. The phthalate DINP has been reviewed by multiple scientific and regulatory bodies around the world, all of which found no evidence that the very low levels people are typically exposed to cause cancer. The CIC's decision to list DINP as a Prop 65 'carcinogen' is contrary to the weight of evidence demonstrating that DINP does not cause cancer in humans. The animal data summaries cited by the CIC in the Prop 65 listing are both exaggerated and misleading.

"The Hazard Information Document (HID) prepared by OEHHA fails to present the breadth and depth of available scientific literature that demonstrates: the lack of human relevance and/or biological significance of the rodent study results; that the findings are not consistent or persistent enough to constitute evidence of carcinogenic effects; and that the proposed mechanisms for tumorigenesis are not supported by all available information.

"High phthalates, including DINP, have been reviewed by numerous scientific panels and the conclusions have been essentially the same each time: that the phthalates used in commercial products do not pose a risk to human health at typical exposure levels. Phthalates are among the most thoroughly studied family of compounds in the world and have been reviewed by multiple regulatory bodies in the United States, Europe and Australia.

"The CIC cannot make a well-considered, weight-of-evidence assessment of the available science on which to base its determination if it is only reviewing the limited and selected papers on the HID lists."

Comments and data outlining why OEHHA should not list DINP as a 'carcinogen' were submitted by chemical manufacturers, business associations and independent scientists, including comments from the American Chemistry Council outlining the following:

• DINP is REACH registered and is not listed on the REACH Candidate List, which means it can be placed on the European market without any additional authorization. Under the European Chemicals Agency's (ECHA) Classification, Labelling and Packaging (CLP) regulation, DINP is not classified as a carcinogen. Although DINP has not been reviewed by the World Health Organization (WHO) International Agency for Research on Cancer (IARC), it is not on the priority list for the agency, indicating a low degree of concern.



- The Australian Government Department recently released an evaluation on DINP, stating that "DINP is not genotoxic or carcinogenic," reaffirming the safety of its use in all current applications.ⁱ
- In August of 2013 ECHA released its final report on the re-evaluation of DINP in toys and child care articles that can be placed in the mouth. The report concludes that 'a risk from the mouthing of toys and childcare articles with DINP ... cannot be excluded if the existing restriction were lifted. However, based on the risk assessment in the report, ECHA also concludes that no further risk management measures are needed to reduce the exposure of children and adults to DINP. The risk assessment included an examination of exposure from toys and child care articles, school materials, indoor air and house dust and included a review of the available new information on the carcinogenicity of DINP.

Phthalates are the most commonly used plasticizers in the world and are categorized as high and low, depending on their molecular weight. The High Phthalate Panel of the American Chemistry Council represents the manufacturers of high phthalates, or those with 7-13 Carbon atoms in their chemical backbone, which gives them increased permanency and durability. The most common types of high phthalates include diisononyl phthalate (DINP), diisodecyl phthalate (DIDP) and dipropylheptyl phthalate (DPHP). High phthalates are commonly used in PVC products such as wire and cable, flooring, wall covering, self-adhesive films, synthetic leather, coated fabrics, roofing and automobile applications.

For a full list of comments submitted to OEHHA outlining the scientific evidence against a DINP listing on Prop 65, please visit:

http://www.oehha.ca.gov/prop65/public_meetings/100413MeetingHazIDmats.html#comments

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http://www.americanchemistry.com

The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$770 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for twelve percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.



ⁱ http://www.nicnas.gov.au/communications/publications/information-sheets/existing-chemical-info-sheets/diisononyl-phthalate-dinp-factsheet

ii http://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715