



# Statement

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## **ECHA RAC CONCLUDES THAT DINP DOES NOT WARRANT CLASSIFICATION FOR REPRODUCTIVE TOXICITY**

*ECHA's recent announcement followed a proposal by Denmark in February 2015 to reexamine DINP.*

WASHINGTON (July 9, 2018) – *The European Chemicals Agency's (ECHA) Risk Assessment Committee (RAC) recently [published its full opinion](#), confirming the conclusion from its March 2018 meeting that di-isononyl phthalate (DINP) does not warrant classification for reproductive and developmental toxicity effects under the European Union's Classification, Labelling and Packaging regulation. The CLP regulation is the EU implementation of the UN Globally Harmonized System (GHS).*

*The RAC opinion rejected by consensus the proposed classification of DINP as a reproductive toxicant category 1B (Development) and Category 2 (Fertility) and concluded “**no classification for DINP for either effects on sexual function and fertility, or for developmental toxicity is warranted.**” The ruling followed an extensive evaluation of existing toxicity data on DINP, including two reproductive (fertility) toxicity studies, 13 developmental toxicity studies, 15 repeat-dose toxicity studies – all in animals – and eight epidemiological studies in humans. The American Chemistry Council's (ACC) [High Phthalates Panel](#) issued the following statement about ECHA's conclusion:*

“The panel fully supports thorough scientific examination of chemicals to help ensure they are used safely. ECHA's conclusion that DINP warrants no classification for reproductive and developmental toxicity provides additional support for the safety of DINP in current applications.

“The conclusion brings to a close a regulatory process that lasted more than three years from the original registry of intent from Denmark and included public consultation and a year-long assessment of the proposal by a RAC rapporteur and co-rapporteur, culminating in a conclusion by the full RAC in March 2018 and publication of the full opinion in June 2018.

“High molecular weight (HMW) phthalates such as DINP have been used safely in consumer and commercial products for more than 50 years to enhance durability, flexibility and performance. Phthalates are primarily used to make polyvinyl chloride (PVC or vinyl) flexible and are used in hundreds of products in our homes, hospitals, cars and businesses. DINP is one of the most tested

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substances in commerce and multiple government agencies in North America, Europe and Australia have extensively reviewed the scientific data about its safety and have concluded DINP is safe for use in current applications.”

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*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 \$768 billion enterprise and a key element of the nation's economy. It is among the largest exporters in the nation, accounting for fourteen percent of all U.S. goods 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.*

