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PRESS RELEASE
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DINP – ECHA RAC concludes no classification required

Brussels, 16 March 2018 – ECHA's Risk Assessment Committee (RAC) has concluded, on March 7, that **Di-isononyl phthalate (DINP) does not warrant classification for reprotoxic effects under the EU's Classification, Labelling and Packaging (CLP) regulation**.

"RAC's robust scientific weight of evidence assessment of all relevant data resulted in the conclusion that DINP does not require classification for reproductive toxicity, neither Category 1B nor Category 2, for either fertility or development", commented European Plasticisers' manager, Michela Mastrantonio.

RAC undertook a stringent hazard assessment following the rules of the CLP regulation, with the conclusion that, given the lack of evidence of adverse effects, classification is not required. Amongst prior regulatory assessments, the ECHA evaluation of new scientific evidence - endorsed by the European Commission in 2014[1]- concluded that DINP can be safely used in all current applications. All relevant data are included in the DINP REACH registration dossiers, which were updated in 2015 and 2016.

The proposal for the classification of DINP was submitted to ECHA by Denmark in February 2015. This triggered a scientific debate on the proposal for classification including a complete re-analysis of the raw data on a key study in the dossier conducted by scientists at the Danish Technical University. Critical scientific reviews of relevant available data were provided by European Plasticisers' toxicologists as well as by leading international scientists and have been published in peer-reviewed journals (*Reproductive Toxicology*[2] and *Regulatory Toxicology and Pharmacology*[3]).

In summing up the testing and evaluations on DINP, Michela Mastrantonio further commented: "The extensive regulatory assessments of DINP over the last 20 years concluded that there is no need for hazard classification and that DINP is safe for use in current applications. We are confident this brings a strong reassuring message to the industry, the value chain and consumers on the safety and sustainability of DINP and flexible vinyl articles made with DINP".

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[1] https://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715

[2] *Reproductive Toxicology:*
P. Morfeld, Min Chen, Rainer Otter, Christine Palermo, Jessica Kemmerling, Michela Mastrantonio, 2017. "Boberg et al. (2011) – Corrigendum (2016): Further significant modifications needed". https://doi.org/10.1016/j.reprotox.2017.03.013;
J. Boberg et al (2011) -Corrigendum http://doi.org/10.1016/j.reprotox.2016.07.001 ;
J. Boberg, M. Axelstad, S. Christiansen, U. Hass 2017. Rebuttal to letter by Morfeld et al., "Boberg et al. (2011) – Corrigendum (2016): Further significant modifications needed." https://doi.org/10.1016/j.reprotox.2017.03.014

[3] *Regulatory Toxicology and Pharmacology:*
W. Dekant, J. Bridges 2016 "A quantitative weight of evidence methodology for the assessment of reproductive and developmental toxicity and its application for classification and labeling of chemicals"https://www.sciencedirect.com/science/article/pii/S0273230016302574;
W. Dekant, J. Bridges 2016 "Assessment of reproductive and developmental effects of DINP, DnHP and DCHP using quantitative weight of evidence"
https://www.sciencedirect.com/science/article/pii/S027323001630280X

Avenue E. Van Nieuwenhuyse 4, Box 1, B-1160 Brussels, Belgium
T: + 32 2 676 7260 • F: + 32 2 676 7392 • E: info@europeanplasticisers.eu
www.europeanplasticisers.eu

cefic sector group