BASF Plasticizer Newsletter

July 2019

We have developed this newsletter to keep customers and others informed about regulatory and other issues that may affect the North American plasticizers market. We appreciate any feedback you may have and would like to know if there are special topics you would like to hear more about in future newsletters.

Manufacturer–Requested Risk Evaluations for DINP and DIDP

On May 24, 2019, US EPA received a request from the ExxonMobil Chemical Company, Evonik Corporation, and Teknor Apex, through the American Chemistry Council’s High Phthalates Panel to conduct a risk evaluation for diisononyl phthalate (DINP). A request also was received from the ExxonMobil Chemical Company, through the ACC High Phthalates Panel, to conduct a risk evaluation for diisodecyl phthalate (DIDP). More details are available through the EPA website.

Plasticizers in Vinyl Flooring

A new collaborative report from the Ecology Center, Safer Chemicals Healthy Families, the Environmental Health Strategy Center and Healthy Building Network described the results of their analysis of vinyl flooring from three major retailers. They were not able to detect ortho-phthalates in any of the products tested. Most of the flooring products were plasticized with di-2-ethylhexyl terephthalate (DOTP); some also contained dibenzoate plasticizers.

As a manufacturer of DOTP, this was positive news. In addition, they noted the high scores for DOTP in GreenScreen® hazard assessments; however, there were other incorrect or misleading comments in the report.

For example, they refer to “new research showing interaction of DOTP with hormone receptors” and the need to further test this product. This new research is a publication by Kambia, et al (2019) on in vitro and in silico testing with minor metabolites of DOTP. Screening tests such as the ones in this publication can be helpful in preliminary assessments of products, but their results must be verified by further testing in animals (in vivo). Harmon and Otter (2018) summarized existing in vitro and in vivo data for DOTP that show no evidence of adverse hormonal changes:

- No antiandrogenic effects similar to those observed with some ortho-phthalates in US EPA and other studies
- No estrogenic effects in vitro or in vivo
- Inactive in US EPA ToxCast and EDSP21 assays
- No suggestion of thyroid or adrenal gland effects from subchronic and chronic studies
- No evidence of antiandrogenic or estrogenic effects in two-generation rodent as well as developmental studies with rodents and non-rodents
In addition, a recent review by the French competent authority ANSES (French Agency for Food, Environmental and Occupational Health & Safety) under the EU RMOA (Risk management option analysis) process determined that there was “no alert... on potential endocrine disruption properties of the substance” and concluded there were no risk management measures necessary.

More detailed BASF comments on Kambia, et al., also are available.

The collaborative NGO report states that ortho-phthalates “as a class are problematic” and suggests that retailers “reduce and phase out” PVC for flooring products. We disagree with these statements. First of all, ortho-phthalates are a class of products with quite different chemical and biological performance due to the various alcohols used; the alcohols differ in carbon chain length and the degree of branching. Based on their specific structures, some ortho-phthalates are subject to global regulations due to adverse effects seen in rodents; others do not show any of these effects and are therefore not regulated. Regulating or deselecting ortho-phthalates as a whole chemical class seems unfounded, illogical, and not supported by the science.

The criticisms of PVC are not surprising, given the anti-vinyl history of some of the groups responsible for the paper. Vinyl products continue to be popular and successful due to their performance and cost advantages. BASF plasticizers such as Palatinol® DOTP and Hexamoll® DINCH also help manufacturers create new materials to meet the growing need for sustainable products.

Human Biomonitoring Update

As noted in previous newsletters, exposure data from human biomonitoring studies are important for assessing risk from materials used in consumer and industrial applications. A new study (Nehring, et al., 2019) has been published on human urinary metabolites of di-2-ethylhexyl adipate (DEHA or DOA). The data from the study were used to develop a new biomonitoring method for DEHA. The validity of the method was confirmed in a small study with human volunteers and with German and Brazilian pilot populations. The abstract is available using this link.

EU medical device consultation

As noted in the last newsletter, the EU Scientific Committee on Health, Environment, and Emerging Risks (SCHEER) on March 18th published the Preliminary Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates that are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties. Recently, the minutes of a public meeting on April 4th and slides from the public presentations (including BASF’s) were made available.

Hearing on Phthalates in Medical Devices
In a related issue, ECHA has submitted a recommendation to the European Commission to amend Authorisation List (Annex XIV of REACH) entries by adding the endocrine disrupting properties of DEHP, BBP, DBP, and DIBP. Once the Commission decides on the amendment, some previously exempted uses will require authorisation. As a consequence, the press release notes “some uses of DEHP (e.g. in food contact materials or medical devices) that will no longer fall under the ‘generic exemptions from the authorisation requirement’ as it has now been identified as an SVHC also because of hazards to the environment.”

ECHA Press Release.

If you have questions, contact Patrick Harmon at patrick.harmon@basf.com.

3 Nehring, A; Bury, D; Kling, H-W; Weiss, T; Bruning, T; Koch, HM. Determination of human urinary metabolites of the plasticizer di(2-ethylhexyl) adipate (DEHA) by online-SPE-HPLC-MS/MS, J Chromatography B, 2019, 1124, 239-246.