

# BASF Plasticizer Newsletter

September 2018

*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.*

## Issues and Important Topics

### ACC Response to American Academy of Pediatrics Policy Statement

The American Academy of Pediatrics (AAP) recently published a [policy statement](#) on food additives and children's health (Trasande, Shaffer, and Sathyanarayana, **2018**. Food Additives and Child Health. *Pediatrics*, **142** (2), August 2018.) The statement focused on food additives such as phthalates and the "generally recognized as safe" (GRAS) program. The American Chemistry Council (ACC) has published a [response](#) to this policy statement. The ACC blog corrects some of the misinformation in the AAP article and also includes good information on the benefits of plastics in food packaging.

### DEHP for Red Blood Cell Storage Containers

An [editorial](#) in the journal *Transfusion* provides a helpful update on the status of replacing DEHP in bags used for red blood cell storage (Almizraq and Acker, **2018**, *Transfusion*, **58**, 1089–1092). Hexamoll® DINCH® and DOTP (e.g., Palatinol® DOTP) were described as giving promising results as alternatives to DEHP for red blood cell storage.

## Regulatory Actions

### California Proposition 65

Proposition 65, a regulation that requires the labeling of all products sold in California containing carcinogens or reproductive and developmental toxins, was revised in 2016 and became effective August 30, 2018. Although the regulation did not change which products require warnings, it did change the required language of the warnings. In addition to the updated language, the new warnings require the listing of at least one substance driving the warning. BASF has elected to use the Safety Data Sheets (SDS) to convey warnings for industrial products and has completed a multi-year project to update the impacted SDS's.

## EU Community Rolling Action Plans (CoRAP)

As noted in previous newsletters, important plasticizers will be reviewed as part of the European REACH Community Rolling Action Plans (CoRAP). As a follow up to Registration, Member States can nominate substances for evaluation to determine whether they pose an actual risk to humans and/or the environment.

What happens after the evaluation? If the Member State considers further information is necessary to clarify a potential risk caused by the substance, it may draft a decision specifying additional data requirements. The registrants of that substance will have an opportunity to provide comments on the draft decision. A final decision on this action is made between ECHA and the Member State, or by the European Commission if no agreement is reached. The decision will contain a deadline by which the registrants must submit the requested information. It may also be that no further action or request for information is needed because the risks are considered to be sufficiently under control with the measures already in place.

After the additional information is received, the Member State has 12 months to reach a conclusion or to decide to request more information. There are three possible conclusions: 1) EU-wide risk management measures are needed, 2) national level actions are needed, or 3) the risks are sufficiently under control with measures that are already in place.<sup>1</sup>

Several updates to the schedule have been made; please see the attached table for the current plan:

### **EU Community Rolling Action Plan (CoRAP) - updated 3-21-2018**

Evaluation Year	Product	Status	Justification*
2013	TOTM (triethylhexyl trimellitate)	Information requested	Suspected PBT
2014	Di-C9-11-branched and linear alkyl phthalate	Ongoing	Suspected CMR
2014	DUP (branched and linear)	Ongoing	Suspected CMR
2014	DTDP (di-C11-14 (C13 rich) branched alkyl phthalate)	Ongoing	Suspected CMR
2014	DEP (diethyl phthalate)	Completed (conclusion: not ED)	Suspected endocrine disruptor (ED)
2019	DPHP (dipropyl heptyl phthalate)	Not started	Potential ED
2019	Diethyleneglycol dibenzoate	Not started	Suspected reprotox
2019	Dipropyleneglycol dibenzoate	Not started	Suspected reprotox
2020	DEHA (diethylhexyl adipate)	Not started	Suspected CMR
2020	L9TM (trinonyl trimellitate)	Not started	Suspected reprotox, ED, PBT/vPvB

PBT - Persistent, bioaccumulative, toxic

CMR - carcinogen, mutagen, reproductive toxin

vPvB - Very persistent, very bioaccumulative

\*other justifications include use, exposure, and high production volumes

<sup>1</sup> Taken from *Questions and Answers Regarding CoRAP and Substance Evaluation*, ECHA-11-QA-03-EN, November 2011. See also <http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan> for more information.

## Classification and Labelling – DINP

Denmark in 2017 proposed classification of diisononyl phthalate (DINP) as toxic to reproduction, Category 1B (presumed reproductive toxicant). In March 2018, the ECHA Risk Assessment Committee (RAC) rejected this proposal and agreed on "no classification" of DINP for the reproductive hazard endpoint.

## **Sustainability**

### Quantifying sustainability

Sustainable development has been defined as the balance of economic success, ecological protection and social responsibility. To effectively manage sustainability, a company must be able to measure or otherwise quantify sustainability in each of these pillars. See the following [link](#) for more information on BASF's methodologies for quantifying sustainability.

### GC3 Sustainable Chemistry Alliance and Sustainable Chemistry R&D Act of 2018

U.S. Senators Chris Coons (D-Del.) and Susan Collins (R-Maine) reintroduced the *Sustainable Chemistry Research and Development Act of 2018* on July 30, 2018. This bipartisan bill "encourages the development of new and innovative chemicals, products and processes with an improved environmental footprint through efficient use of resources, reducing or eliminating exposure to hazardous substances, or otherwise minimizing harm to human health and the environment." Please see the [press release](#) for more information. The bill is supported by the GC3 Sustainable Chemistry Alliance, the American Chemistry Council, BASF, and other companies.

## **New Publications**

### Human biomonitoring

Human biomonitoring data are essential for measuring exposure and performing risk assessments. A new paper was recently published on the metabolism and kinetics of TOTM (tri-2-ethylhexyl trimellitate) following oral administration in humans. Metabolites of TOTM in blood and urine were determined and may be used for future human exposure studies.

Hoellerer, et al., **2018**. Human metabolism and kinetics of tri-(2-ethylhexyl) trimellitate (TEHTM) after oral administration. *Arch Tox*, 12 July 2018.

### Hexamoll® DINCH® - no evidence of obesogenic properties

An earlier *in vitro* study by Campioli et al.<sup>2</sup> suggested Hexamoll® DINCH® might alter fat storage in adipocytes resulting in obesity. In a new publication by BASF scientists, data from studies with Hexamoll® DINCH® were reviewed for evidence of deposition in fat, changes in

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<sup>2</sup> Campioli, et al., **2015**. Cyclohexane-1,2-dicarboxylic acid diisononyl ester and metabolite effects on rat epididymal stromal vascular fraction differentiation of adipose tissue. *Environ. Res.* **140**, 145–156.

body weight, or changes in serum chemistry reflecting altered metabolic status. The evaluation concluded that “comprehensive *in vivo* data do not show any evidence of Hexamoll® DINCH® altering fat metabolism or having obesogenic properties.”

Langsch, et al., **2018**. Hexamoll® DINCH: Lack of *in vivo* evidence for obesogenic properties. *Tox Letters*, **288**, 99 – 110.

#### Plasticizers in food contact applications

Staff at US FDA reported on their analysis of plasticizers in various commercial food packaging and processing materials. In the paper, they described the following findings and observations: “Nine different plasticizers including three phthalates, diethylhexyl phthalate (DEHP), diisononyl phthalate (DINP), and diisodecyl phthalate (DIDP), were identified in the products tested. The plasticizer concentrations ranged from 1- 53% depending on the types of food contact materials and the type of plasticizer. Overall, it appears that manufacturers are switching away from phthalates as their primary plasticizer to alternate compounds such as ESBO, ATBC, DEHT [DOTP], DINCH [e.g., Hexamoll® DINCH®], DEHA and DINA.”

Carlos, de Jager, and Begley, **2018**. Investigation of the primary plasticizers present in polyvinyl chloride (PVC) products currently authorized as food contact materials. *Food Add. Contam.: Part A*, **35**, 1214 – 1222.

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