

Flexible PVC used for flooring and other household items contributes to a healthy and hygienic indoor environment – no good evidence that phthalates contribute to the causation of asthma

Brussels 18 September

Some European media have reported about the findings of a study by Whyatt et. al, available online in *Environmental Health Perspectives*. It shows an association between childhood asthma and prenatal exposure to two phthalates BBzP (Butylbenzylphthalate) and DnBP (Di-(n-butyl)phthalate) based on the respective urinary metabolites..

In public and media debates, scientific rigor and factual accuracy is essential to avoid making unjustified, generic claims when referring to the effects of any substance, and in order to ensure consumer safety is based on precise information.

Health of children and pregnant women is of paramount importance and the safety of plasticisers is the number one priority for the Plasticisers Industry represented by ECPI. REACH, the European regulation on chemicals, strictly regulates the safe use of plasticisers in flexible PVC applications.

With regard to the study it is therefore important to note that:

- The recent study reports an association between exposure to two phthalates and asthma incidence in children. Association does not mean causation. The conclusion of the paper indicates that further investigation is required to prove the legitimacy of the key results of the study, which are in any case not aligned with the existing literature.¹
- The results of the recently published study by Whyatt et al. (2014) are a variance to a study published by Bertelsen et. al (2013): Bertelsen and coworkers did not identify any association between urinary concentrations of BBzP or DnBP) in a cross-sectional analysis on a cohort in Norway, where degradation products of 11 plasticisers were measured in one first morning void collected from 2001 through 2004 from 623 10-year-old Norwegian children, i.e. a cohort that was double the size of the subgroup analyzed by Whyatt.
- Hoppin et al. (2013) published results in another study urinary phthalate metabolites and allergic symptoms (hay fever, rhinitis, allergy, wheeze, asthma) and sensitization from participants ≥ 6 years of age in the National Health and Nutrition Examination Survey (NHANES) 2005–2006. In this cross-sectional analysis of a nationally representative sample, MBzP a degradation product of BBzP but not MBP, the degradation product of DnBP, was positively associated with allergic symptoms and sensitisation in adults, but there was no strong evidence for associations between phthalates and allergy in children 6–17 years of

In addition, Dearman et. al. (2009) concluded that the doses of phthalates encountered in the home are unlikely to be a major factor contributing to the increased incidence of asthma and allergy. Furthermore the Scientific Committee on Health and Environmental Risks (SCHER, 2007) reported that there is no evidence of skin or respiratory sensitisation for phthalates. Based on the lack of mechanistic support and taking into account the low exposure level of phthalates by inhalation, the SCHER concluded that there is no consistent scientific evidence which indicates phthalates as high concern chemicals in indoor air.



¹ In a review on indoor chemicals and the development of allergic disease, Nielsen et al. (2007), concluded that 'there is little evidence that the indoor chemicals evaluated (including phthalates) possess important effects.



age. It should be mentioned that MBP is also a degradation product of BBzP, therefore the association to one metabolite without the link to the other is ambiguous. Interestingly, in children the authors report high molecular weight phthalate metabolites to be inversely associated with asthma and hay fever. Also, for Monoethylphthalate (MEP), the degradation product of Di(ethyl)phthalate (DEP), an inverse association with allergic sensitization in adults was reported.

- There are open questions regarding the control of confounding factors in the study published by Whyatt et al., therefore, as the authors already themselves state in their publication, the findings need to be interpreted with caution.
- Three of the four phthalates (DEP, DEHP, BBzP, DnBP) studied by Whyatt et al. are already undergoing REACH Authorisation and in particular BBzP and DnBP, which are the only two phthalates that have been related to asthma by Whyatt, will be taken out of the European Market by February 2015.
- This publication is another example of reported associations of exposure to chemicals of daily life with symptoms where scientifically it is hard to find an explanation as a clear mechanistic relationship and the mode of action are missing.

With regard to the articles published on this subject by the media:

The word "plasticisers", including phthalates, groups together a very large and diverse number of substances with different molecular structures, applications, classification and legal requirements. Extending the concerns expressed on two phthalates to all phthalates is simply not correct. Not all phthalates are the same.

For more facts, please visit our website: <u>www.plasticisers.org</u>

About EPCI: The European Council for Plasticisers and Intermediates is a Brussels-based trade association representing the common interests of European manufacturers of plasticisers, alcohols and acids. Member companies are BASF, Deza, Evonik, ExxonMobil, Grupa Azoty and Perstorp. ECPI is a sector group of Cefic, the European Chemical Industry Council, which represents the interests of the European chemical industry.

Contact: Dr Stéphane Content: Manager, ECPI. Tel: +32 2 792 7260 | Email: <u>info@ecpi.org</u> <u>www.plasticisers.org</u>



Avenue E Van Nieuwenhuyse 4, Box 2, B-1160 Brussels, Belgium Tel: +32 2 676 72 60 Fax: +32 2 676 73 92 VAT 412.849.915 www.plasticisers.org