

EVALUATION OF NEW SCIENTIFIC EVIDENCE CONCERNING THE PHTHALATES DINP AND DIDP

SUMMARY

The European Chemicals Agency (ECHA), at the request of the European Commission, has reviewed the scientific evidence on the risks posed by articles containing the phthalates DINP¹ and DIDP².

Based on an existing restriction, these phthalates cannot be used in toys and childcare articles which can be placed in the mouth by children. In its draft report, ECHA concludes that the existing restriction is justified and that no further risk reduction measures are needed to reduce the exposure of children to DINP and DIDP. In addition, the draft report finds that there may be a potential risk - although associated with substantial uncertainties - to adults from the use of sex toys containing these phthalates.

ECHA invites interested parties to provide their comments on the draft report by 31 July 2012. In particular, ECHA welcomes any relevant new scientific evidence that was not assessed in the draft report.

Against the above background, ECHA's Committee for Risk Assessment (RAC) has been requested to provide a scientific opinion on the draft report, taking into account comments from this public consultation.

BACKGROUND

DINP and DIDP are mainly used to make PVC soft and flexible. Examples of such flexible PVC articles are electrical wire, vinyl flooring, synthetic leather, and swimming pools. The other 5% is used in non-PVC applications such as rubbers, adhesives, sealants, paints and lacquers, textile inks and lubricants.

The phthalates DINP, DIDP and DNOP are restricted in toys and childcare articles which can be placed in the mouth by children in accordance with entry 52 of Annex XVII to the REACH Regulation. Also the phthalates DEHP, DBP and BBP are restricted in toys and childcare articles in accordance with entry 51 of Annex XVII to REACH (but without the condition "which can be placed in the mouth by children"). According to both restriction entries, the measures had to be re-evaluated in the light of new scientific information, and if justified, modified.

¹ DINP is a trivial name for di-"isononyl" phthalate (CAS No 28553-12-0) and for 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (CAS No 68515-48-0).

² DIDP is a trivial name for di-"isodecyl" phthalate (CAS No 26761-40-0) and for 1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (CAS No 68515-49-1).

In a first phase, upon request by the European Commission, ECHA completed review reports for all of the above phthalates. The six reports were published in July 2010 on ECHA's website.

In a second phase, the European Commission requested ECHA "to review and analyse new scientific information, if any, coming from the registration dossiers with a view to completing the assessment of information already included in the existing review reports and, as appropriate, revise the ECHA conclusions, including the need or not for further actions on these three non-classified phthalates under REACH." (14 December 2010). The need to update the first phase assessments and conclusions was limited to the reports concerning DINP and DIDP.³

CONCLUSIONS OF ECHA'S REVIEW

The draft review report is based on ECHA's review of the latest scientific evidence concerning DINP and DIDP. It contains a hazard assessment, exposure assessment for consumers (exposure from direct contact with articles, the indoor environment and food, as well as exposure estimates from bio-monitoring data); and a risk characterization. On the basis of these assessments, ECHA drew the following conclusions in its draft review report.

Children

Based on the risk assessment in the draft review report, it is concluded that the existing restriction on DINP and DIDP in toys and childcare articles which can be placed in the mouth by children (restriction entry 52 in Annex XVII to REACH) is justified. In case the existing restriction for toys and childcare articles which can be placed in the mouth by children would not be in place, there would be a risk for liver toxicity from the mouthing of toys and childcare articles by children of 0-12 months old.

It is not anticipated that mouthing of erasers containing DINP or DIDP would lead to a considerable risk for children. Furthermore, no risk is expected from combined exposure⁴ to DINP and DIDP for children exposed via food and the indoor environment.

Based on the risk assessment in this report, it can be concluded that no further risk management measures are needed to reduce the exposure of children to DINP and DIDP.

Adults

Based on the risk assessment in the draft review report, it is concluded that there is a potential risk for liver toxicity in the adult population related to the use of sex toys containing DINP and in particular when containing DIDP. There are, however, substantial uncertainties

³ As indicated, ECHA has also published review reports for the other substances covered by entries 51 and 52 in the first phase. There was no need completing the assessment in the existing review reports for these other phthalates. Indeed, DEHP, DBP, BBP, and DIBP are included in Annex XIV, and a restriction proposal on DEHP, DBP, BBP and DIBP has been submitted by Denmark on 14 April 2011. Therefore, the scope was limited to further review of the information on entry 52 phthalates, i.e. DINP, DIDP and DNOP. As far as DNOP is concerned, no REACH registration dossier has been submitted so far to ECHA. This supports the information in the ECHA review report on DNOP from July 2010 that on the one hand there seems to be confusion around the substance identity of DNOP, and on the other hand there seems to be no commercial market in the EU for DNOP. Therefore, ECHA did not conduct any further evaluation of DNOP. ECHA considers that the conclusions drawn in the published review report are still valid, i.e. that there is no new information available that would justify the re-examination of the current restriction on DNOP.

⁴ "Combined exposure" includes all routes, pathways, and sources of exposure to multiple chemicals.

with regards to exposure duration and migration rates of the phthalates from sex toys. Additional data to reduce these uncertainties would be welcomed.

Dermal exposure from for instance PVC garments is not anticipated to result in a risk for the adult population and the developing foetus in pregnant women, although exposure might lead to a considerable body burden in some individuals. Exposure to DINP and DIDP from food and the indoor environment are not very significant in the adult population, which is confirmed by the exposure estimates based on the available biomonitoring data.

COMMENTS BY 31 JULY 2012

ECHA invites interested parties to give their comments by 31 July 2012 via the webform on ECHA's website (see below). In particular, ECHA welcomes relevant new scientific information that was not included in the draft review report.

The comments from public consultation will be made available to ECHA's Committee for Risk Assessment (RAC). The Committee has been requested to provide a scientific opinion on the draft review report, taking into account comments from the public consultation. ECHA will finalise the review report taking into consideration the opinion by RAC and the comments received in public consultation.

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