

October 1, 2009

Statement concerning the test results of BUND and Global 2000 on Bisphenol A (BPA) in pacifiers

Residual levels don't give any information about potential migration

The test results on BPA content measured in pacifiers published by BUND and Global 2000 need to be validated by the responsible authorities urgently in order to avoid any unnecessary concern. The results are in direct contrast to the existing data and experience concerning Polycarbonate. They also don't comply with the knowledge about the intrinsic characteristics of the materials in the test:

- the intermediate BPA is completely converted during the production of polycarbonate to become the polymer; in the end product only technically unavoidable trace levels of BPA may be present
- the published levels of residual BPA in polycarbonate-based products in the market are far below the levels published in the study
- regularly used silicone and latex do not normally contain BPA

For the assessment of the safe use of a product, no matter what kind of material it is made of, it is the migration of substances that is relevant, not the residual or total content. Only migration studies can deliver these data. The large number of studies that investigated migration from polycarbonate in food contact applications shows only trace levels of migration, which are far below the safety limits set by the authorities.

The Austrian food safety authority (AGES) states in this context: In the various baby bottles migration tests of the authority "none of the tests reported any BPA in the migration solution." ... "The levels of BPA in the soft part of pacifiers reported by the laboratory that did the testing for Global 2000 are surprising, as BPA is not used for the production of the soft parts of the pacifier. AGES has become active and executed its own testing on BPA in pacifiers. BPA was measured, with the first set of measured levels being 10fold below the levels reported by Global 2000. Further testing is necessary to validate the analytical results. It must also be clarified by which route BPA may have entered the teat. However, for the assessment of a potential health effect the migration level is essential, to understand whether, and to which amount, under normal conditions of use, a child may take in BPA from the soft part of a pacifier. "

<http://www.ages.at/ages/ernaehrungssicherheit/thema-ernaehrung/bisphenol-a-und-babyflaeschchen/>

The results of a recently published study of the German Umweltbundesamt (UBA) together with the university Erlangen-Nürnberg, which was part of the children-environmental-survey initiative by UBA, show that the BPA exposure of children in Germany is two orders of magnitude below the level defined as safe for a daily lifelong intake (TDI – tolerable daily intake) by the European Food Safety Authority (EFSA) (Becker et.al., International Journal of Hygiene and Environmental Health, 2009).

http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B7GVY-4X4RCPD-1&_user=81649&_rdoc=1&_fmt=&_orig=search&_sort=d&_docanchor=&view=c&_acct=C000000717&_version=1&_urlVersion=0&_userid=81649&md5=360a723d653b36c19e23488bd5102270

The authorities responsible for Health in Germany (BfR; Bundesinstitut für Risikobewertung) and Europe (EFSA) confirm, that products made from materials based on BPA such as Polycarbonate can be used safely by the consumers.

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Additional information:

The soft part of a pacifier (the teat) is normally made from Latex or Silicone. These materials normally do not contain any BPA. The hard part, to which the teat is fixed (shield) can be made from different materials (incl. e.g. polycarbonate, polypropylene etc.), like as well the ring which some pacifiers have on the "outside". Migration of substances from the hard shield into the soft teat is difficult to imagine. No specific information is available about this question, as it has to our knowledge not yet been investigated.

In order to assess the potential exposure of the baby to substances the materials are made from, the measuring of migration is essential, i.e. the potential "travel" of a substance from the material. As far as can be seen from the published documents, the test did not measure migration, but content of substances in the material. Measuring took place in mechanically granulated solution. However, the content of a substance in a solution of mechanically destroyed material does not say anything about a potential migration of a substance. In addition, in context with the already existing data about residual levels of BPA in Polycarbonate, the levels published in this study appear incomprehensibly high. Other materials or unusual methods should also be considered as potential reason.

Regarding potential migration of BPA from polycarbonate baby bottles we would like to refer to the published assessments of the responsible authorities in Europe (EFSA) and the EU member states, as well as to published scientific migration studies like e.g. Ehlert, 2008, or Brede, 2003 – both also defined the amount of technically unavoidable trace levels of BPA in the polycarbonate.

The German Bundesinstitut für Risikobewertung (BfR) issued several opinions on the safety of polycarbonate and stated. "After thorough assessment of all studies, especially BPA low dose studies, the BfR concludes in its scientific assessment, that there is no health risk for babies and small children from the normal use of polycarbonate bottles." "The official food safety control could not detect any BPA in the content of bottles heating the content under normal household use conditions. The BfR does not see any danger for babies from the use of polycarbonate baby bottles. Therefore, there is no need to stop using Polycarbonate baby bottles." (BfR, Januar, 2007, repeated in later statements 2008 and 2009).

The Swiss, French and other national food safety authority investigations came to the same results.

EFSA, the European food safety authority, investigated the realistic exposure levels (exposition) for babies and small children, and noted, that the measurable BPA-levels are very low and far below the safety limits set by the authorities.