Bisphenol A in dummies

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The Federal Institute for Risk Assessment (BfR) examined dummies made of latex and silicone for bisphenol A. The goal was more particularly to determine how much bisphenol A migrates from the dummies during use. So far, no release of bisphenol A had been detected under the most diverse conditions. As, according to information from the manufacturers, no bisphenol A is used in the production of the latex and silicon parts, there is a need for further research to clarify how the substance reached the dummies. In the opinion of BfR bisphenol A is generally to be avoided and is undesirable in dummies. What prompted the BfR studies were analytical results published in September by environmental associations.

The Federal Institute for Risk Assessment examined dummies made of latex and silicone for bisphenol A. To this end, the soft dummy parts of products of various manufacturers and brands from the retail trade were tested.

BfR determined the levels of bisphenol A in the dummy parts. The first step involved using the same method as had been used by the laboratory commissioned by the environmental associations. The previous findings of BfR are unable to confirm the levels published by the environmental associations. No bisphenol A could be detected in one-third of the samples. The levels measured in the other samples were far lower than the levels published by the environmental associations. BfR is currently in the process of checking and validating these analytical results with a second method.

BfR also measured how much bisphenol A dissolves in saliva during use under realistic conditions as only this amount can be ingested by an infant (release). These data are necessary for estimating whether baby dummies can constitute a health risk. No release of bisphenol A from the dummies could be detected. The studies were conducted with an artificial saliva solution in line with the test standard for toys that may be put in the mouth.

In another study series the release of bisphenol A was determined using 50% ethanol at 40°C and this solution was shaken for five days. These conditions are far more stringent than the actual conditions of use. This analytical method can detect the release of bisphenol A from an amount of 0.25 microgram per dummy (detection limit). Even after five days under these far more stringent test conditions, it was not possible to detect any release of the substance. Assuming that 0.25 microgram bisphenol A are, in fact, digested by an infant weighing 4.5 kilogram in the space of five days, the tolerable daily intake would only be exhausted to less than 1 percent.

The environmental associations have also submitted data on the release of bisphenol A from baby dummies. They indicate levels of up to 10 microgram per liter artificial saliva. The indication of these analytical results does not, however, permit any statements about the amount of bisphenol A released from each dummy which could be ingested by an infant (exposure).

According to information from the manufacturers, bisphenol A is not used in the production of the latex and silicone parts of dummies. BfR is of the opinion that the substance is to be avoided and is undesirable in dummies. At the present time, it is not clear how bisphenol A could reach the baby dummies. BfR is to examine this issue in further studies. Particularly as the presence of bisphenol A in the soft dummy parts is unexpected, BfR believes it is neces-
sary to validate the analytical values on the level and release of the substance with another analytical method.