

## Bisphenol A in dummies - BfR study results

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The Federal Institute for Risk Assessment examined 18 dummies from various manufacturers and brands made of latex and silicone for bisphenol A. The goal was to determine how much bisphenol A is released from dummies during use. The release of 0.2 µg bisphenol A per dummy and hour was only detected in one dummy. This level is deemed to be safe. None of the other 17 dummies released any bisphenol A. In the opinion of BfR bisphenol A is generally undesirable in dummies and also avoidable. What prompted the BfR studies were analytical results published in September by environmental associations.

BfR examined 18 dummies from various manufacturers and brands made of latex and silicone for the release of bisphenol A. According to BfR estimates, the dummies examined cover around 70 % of the manufacturers on the German market. The analytical results were used to determine whether the release of bisphenol A from baby dummies could constitute a health risk. In line with the test standard for toys that may be placed in the mouth, the latex and silicone parts of the dummies were shaken in an artificial saliva solution for one hour in a special apparatus. The aim is to assess the impact of chewing and sucking on the release of substances from the dummy material. In order to increase the sensitivity of the assay, only 50 ml of the saliva solution was used per dummy instead of the prescribed 100 ml. Pretests on the impact of boiling on the release of bisphenol A did not reveal any clear trend., As it is assumed that boiling can reduce the levels of water-soluble substances like bisphenol A the dummies were not boiled in advance. Furthermore, not all manufacturers stipulate boiling prior to first-time use.

The determination of bisphenol A in the artificial saliva solution was done with HPLC and two different detection methods (MS and fluorescence detection). With these analytical methods the release of bisphenol A can be reliably detected from an amount of 0.3 µg per litre saliva solution equivalent to 0.015 µg (= 0.000015 mg) per dummy (detection limit) and determined quantitatively from 1 µg per litre saliva solution equivalent to 0.05 µg per dummy (determination limit).

No migration of bisphenol A in saliva solution was detected in 17 samples. In one sample of the migration test 4 µg per litre bisphenol A was observed which equals 0.2 µg per dummy and hour. The results obtained with the two different detection systems correlate very well. The analytical results also confirm the findings of the long-term studies under conditions far more stringent than the actual conditions of use (shaking over a period of five days with 50% ethanol at 40 °C, see BfR Information No. 037/2009 of 26 October 2009).

The BfR study results also correlate with the findings of other laboratories like the Austrian AGES. The values published by the environmental associations Global 2000 on the release of bisphenol A from dummies could not, therefore, be confirmed.

Assuming that an infant weighing 4.5 kg uses a dummy 12 hours a day, this would mean the exhausting of 1 % of tolerable daily intake. This result does not give any cause for health concerns.

As, according to information from the manufacturers, no bisphenol A is used in the production of latex and silicone dummies, the presence of bisphenol A in the soft parts of the dummy is unexpected. The levels of bisphenol A in the dummy mouth shields do not correspond to the available data either. BfR points out that the results of the environmental associations

were obtained with a multi-method that does indicate the presence of bisphenol A in the materials but that it would be desirable to validate these study results with another suitable specific analytical method.

It must be clarified how bisphenol A might reach the baby dummies. BfR is of the opinion that bisphenol A in baby dummies is generally undesirable and also avoidable.