Contact allergens in toys: Health assessment of nickel and fragrances

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About 10% of all children are sensitised to nickel. Even to fragrances, a not inconsiderable proportion of children (roughly 2%) are sensitised. In case of renewed contact with the allergen, sensitised persons can react with a contact allergy. Contact allergy means: the skin reacts to allergen substances with redness, blistering and wetness and even with more severe inflammation. The sensitisation persists for life. Acquired contact allergy is not curable; only the symptoms but not the causes can be treated. It is therefore important that contact with allergen substances and/or elements such as nickel or certain fragrances is, already in childhood, avoided to the greatest extent possible.

The results of the Federal Control Plan 2010 on nickel release from toys prove that children’s dermal exposure to nickel from toys can be substantial. High nickel exposure carries a correspondingly increased risk of sensitisation or of elicitation a contact allergy. The release of nickel from products with direct prolonged skin contact is limited by the REACH regulation. Examples include jewellery and various metal applications in clothing textiles. In contrast, the European Toy Directive does not lay down a threshold value limiting nickel release from toys for skin contact. The BfR is of the opinion that the limit for nickel release specified in the REACH regulation should also apply to toys consisting of metal alloys and which come into intensive contact with the skin for extended periods of time. The EU Commission has now confirmed in its “Explanatory Guidance Document” on the Toy Directive, that the limit value of the REACH-Regulation has to be applied to according toys.

As regards fragrances in toys, the situation is different. The use of 55 allergenic fragrances and fragrance ingredients is banned in accordance with the new EU Toy Directive, while 11 additional fragrances must be declared due to their allergenic potential. However, trace amounts of these banned substances up to 100 mg per kg of toy material are permitted in toys. In the view of the BfR, this limit is too high. The institute holds that the 55 banned allergenic fragrances should not be detectable in toys. Information gathered in the area of cosmetic products show that such contaminations do not reflect good manufacturing practice, since such substances are not contained in perfume oils. For the 11 fragrances that must by law be declared it is recommended that the declaration threshold is lowered from currently 100 mg per kg of toy material to 10 mg per kg. Toys for children under 3 years of age and toys which, due to their size, children can put in their mouth should, in the opinion of the BfR, not contain any fragrances.

Liquid and pasty toy materials which, like finger paint or play dough, come into direct contact with the skin contain preservatives to prevent germ growth. Many preservatives are known for their sensitisation properties. For this reason, the use of preservatives in such toys should be subject to the same requirements as those that apply to preservatives in cosmetic products.

The full version of this BfR Opinion is available in German on http://www.bfr.bund.de/cm/343/kontaktallergene-in-spielzeug-gesundheitliche-bewertung-von-nickel-und-duftstoffen.pdf

* the updated opinion replaces the BfR information No. 029/2010 from 6 April 2010