

Toys made of natural and synthetic rubber for children under three years of age: Release of N-nitrosamines should be as low as possible

BfR Opinion No. 005/2012 of 17 January 2011

During the manufacture of products made of natural and synthetic rubber, dithiocarbamates and thiurams are used as vulcanization accelerators which can be converted into N-nitrosamines and nitrosatable amines during the vulcanization process. Several N-nitrosamines are genotoxic carcinogens. No safe toxicological threshold value can be derived for these substances and even trace quantities of them can cause cancer. The ALARA principle (“as low as reasonably achievable”) is used to protect consumers and minimize risks by reducing exposure to N-nitrosamines to the maximum possible extent.

Consumers ingest N-nitrosamines mainly through their food, such as pickled or smoked meat and smoked fish. Another source of the intake of N-nitrosamines is passive smoking. With regard to children as a particularly sensitive population group, exposure to N-nitrosamines through teats and soothers and toys must also be considered. Toys made of natural and synthetic rubber in particular, which small children can put into their mouths, can be a specific source of N-nitrosamine exposure.

For this reason, the BfR is of the opinion that the ALARA principle should be applied to the migration limits for toys made of natural or synthetic rubber for children aged up to 36 months which are intended to, or foreseeably will be, put in the mouth. The application of the migration limits of the EU toy directive 2009/48/EC to these toys could lead to a worsening of the protection level, however. While the German Consumer Goods Ordinance allows less than 0.01 mg of N-nitrosamines per kg material to be released from these toys, the EU toy directive is to permit the release of 0.05 mg of N-nitrosamines per kg material in future.

This higher value complies with the limit value for balloons in the German Consumer Goods Ordinance for the determination of which the technologically achievable minimum release of N-nitrosamines was the decisive criterion. On the other hand, however, the lower German limit value for toys made of natural or synthetic rubber intended for children aged less than 36 months and which can be put into the mouth is based on the lower limit for pacifiers and teats. The reason for these different limit values is that small children put toys into their mouth more frequently and keep them there for longer than they do with balloons.

In the opinion of the BfR, the nationally valid, lower limit values should be maintained. According to the state of the art, the formation of carcinogenic N-nitrosamines during the manufacture of products made of natural or synthetic rubber can be widely avoided through the choice of suitable vulcanization accelerators.

The full version of this BfR Opinion is available in German on <http://www.bfr.bund.de/cm/343/spielzeug-aus-natur-und-synthesekautschuk-fuer-kinder-unter-drei-jahren-freisetzung-von-n-nitrosaminen-sollte-so-gering-wie-moeglich-sein.pdf>