

Assessment of nitrosamines in balloons

BfR supplementary expert opinion, 26 March 2004

The Federal Institute for Risk Assessment (BfR) and its predecessor the Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV) expressed an opinion in April 2002 and again in December 2003 on the possible risks for consumers and, more particularly, for children from N-nitrosamines and nitrosatable amines in balloons. In 2002 German regulatory authorities had detected these substances in the balloons of a Dutch supplier and notified the results of their tests to the Dutch Inspectorate for Health Protection. The Dutch National Institute for Public Health and the Environment (RIVM) then undertook a risk assessment. The German and Dutch assessments are based on different exposure assumptions.

In its assessment BfR proposed guidance values for the migration of N-nitrosamines and nitrosatable amines from balloons. In this supplementary expert opinion the Institute explains the toxicological establishment of these values and, more particularly, the mass used for the balloons and the exposure assumption which differs from that of RIVM. The expert opinions to which the following text refers can be accessed on the Internet in German on www.bfr.bund.de, Bedarfsgegenstände/Sonstige Bedarfsgegenstände.

Explanations

There is a limit value of 10 microgram per kilogram ($\mu\text{g}/\text{kg}$) elastomer for the migration of nitrosamines and of 100 $\mu\text{g}/\text{kg}$ elastomer for the migration of nitrosatable substances from teats/soothers. Assuming a teat/soother weighs 10 gram (g), then a maximum of 0.1 μg of nitrosamines and 1 μg nitrosatable substances may be taken up from it. If one applies the same requirements to balloons based on surface-related exposure, then this leads to a maximum level of 400 μg nitrosamines and 4 milligram (mg) of nitrosatable substances per kg balloon mass assuming that a child licks an area of 10 square centimetres (cm^2) and an area of 400 square decimetres (dm^2) corresponds to a balloon mass of 1 kg. However, balloons do not come into contact daily or over longer periods with the oral mucosa whereas teats/soothers may be in contact with the mucosa for hours on a regular basis.

Nitrosamines are genotoxic substances for which no limit value can be established toxicologically. Hence, the minimisation principle should be applied here. Bearing in mind the technological state of the art, BfR therefore proposed surface-related maximum levels for balloons of 0.0005 mg/dm^2 and 0.2 mg/kg for nitrosamines and 0.005 mg/dm^2 and 2 mg/kg for nitrosatable substances.

In its exposure considerations BfR assumed that a child puts a 10 cm^2 piece of a non-inflated balloon in its mouth. By contrast, the Dutch study assumes contact lasting more than an hour, five times a year, with 100 cm^2 of an inflated balloon with a median mass of 90 mg/dm^2 and a mouthpiece with a mean mass of 270 mg. No surface details were provided for the mouthpiece. The exposure of children to nitrosamines from balloons calculated in this way in the Dutch assessment was far lower than the dose of 1.5 ng NDMA/kg body weight/day which – in the case of lifelong intake – corresponds to a negligible additional cancer risk of 1:10⁶. A surface weight cannot be calculated from the RIVM data.

As testing for nitrosamines and nitrosatable substances is done with non-inflated balloon material, BfR is of the opinion that the mass of 1 kg pro 400 dm^2 relevant for this should be taken as the basis for a maximum level.

References

BGVO: Bedarfsgegenständeverordnung, Bundesgesetzblatt I, No. 20: 866-902, 1992 in the version of 7.1.1998, Bundesgesetzblatt I. No. 1: 6-36, 1998.

BfR 1999. Empfehlung XXI. Bedarfsgegenstände auf Basis von Natur- und Synthesekautschuk, as per 01.06.1999, <http://www.bfr.bund.de>

Inspectorate for Health Protection and Veterinary Public Health (2003) Report ND1TOYO1/01, *Migration of Nitrosamines and Nitrosatable Substances from Balloons*

Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers. Official Journal of the European Communities L 93/37

RIVM 2003 N-Nitrosamines in Balloons: Assessment of the health risk for children.