

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS (SCCP)

Request for a scientific opinion: Presence and release of nitrosamines from children's balloons

1. Background

Nitrosamines are a class of chemical compounds with the generic chemical structure $R_2N-N=O$. They are produced under certain conditions (acidic pH, high temperature, presence of certain reducing agents) in a variety of media (products, biological systems, air, etc) when nitrates react with the so called nitrosatable substances, mainly secondary amines. They have been detected as contaminants in a number of products including foods, beer, tobacco products, rubber products, and cosmetics. There is no publicly documented case of intentional addition or functional use of nitrosamines in consumer food or non food products.

From the toxicological point of view, the genotoxic carcinogenic action of some nitrosamines in animals and their probable link with human carcinogenesis is the most relevant end point. The two most common nitrosamines, N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) are classified by IARC and the EU as category 2 carcinogens (CMR cat 2).

In the EU, specific limits have been established for the presence and release of nitrosamines and nitrosatable substances from elastomer or rubber teats (93/11/EEC) and in alkyl and alkanolamines used in cosmetics (2003/83/EEC).

Concerning rubber, the formation of nitrosamines has been shown to occur when certain types of vulcanisation accelerators are used. Publicly available information from the rubber industry indicates that nitrosamine formation can be avoided if the accelerators are replaced by others which do not contain nitrosatable substances. Recently, research in Germany and the Netherlands has shown that nitrosamines and nitrosatable compounds are released when children's rubber balloons are extracted with artificial saliva to simulate the conditions of mouth blowing of balloons by children. Similar results have shown the release of nitrosamines from condoms. Research into other types of rubber products (gloves, rubber bands, erasers) has not been reported in the public domain.

On the basis of the findings in balloons, the German Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV) and the Federal Institute for Risk Assessment (BfR) and the Dutch National Institute for Health and the Environment (RIVM) conducted risk assessments on the potential health risks from the release of nitrosamines in balloons. The conclusions of the risk assessments agreed that the release of nitrosamines from balloons at the reported levels do not pose reasons for concern provided the released amounts were relatively low and on the basis of assumptions on the amount of time children mouth balloons. The BgVV and BfR however, concluded that in the case of very high release as observed in the German study there may be reasons for concern. In light of these conclusions and the fact that nitrosamines are genotoxic carcinogens and therefore exposure should be reduced to the absolute minimum, the public administrations in both countries proceeded with precautionary measures. In the Netherlands, the authorities are to require balloons to carry a warning statement ("Warning: For safety reasons do not place in the mouth and blow only with a balloon

pump'). In Germany, limits for the content and release for nitrosamines and nitrosatable substances in rubber balloons have been proposed.

As the Commission is aware of both national measures and public authorities having urged a review of the issue, we consider that it is appropriate to seek the advice of the Scientific Committee on Consumer Products concerning any potential consumer health implications when children may be exposed to nitrosamines that are released from balloons when children put them in their mouths (to blow them or simply to mouth the blowing part of fully or partly inflated balloons) or simply when they lick them. Although specific research into the mouthing behaviour of children with balloons is lacking, published evidence shows that balloons are one of the most common toy items children above the age of 6 months and up to 4 years of age, put in their mouth (Smith A.S and B. Norris. 2003 Reducing the risk of choking hazards: mouthing behaviour of children aged 1 month to 5 years. Injury Control and Safety promotion 10:145-154).

2. Terms of Reference

The SCCP is requested to

- (1) *Critically review the evidence concerning the migration of nitrosamines from balloons and the risk assessments conducted by the RIVM and BgVV and BfR on the potential risks arising from the exposure of young children (ages 6 months to 4 years).*
- (2) *In light of its response to question 1, pronounce itself as to whether there may be reasons for concern arising from the exposure of young children to nitrosamines when young children mouth and/or lick balloons. In elaborating its point of view, the Committee is asked to take into account known/published exposures of young children to nitrosamines from other known sources of exposure (food and non food products, environment, etc) and previous or ongoing assessments of nitrosamine exposure (e.g. SCF opinions or work by EFSA panels).*
- (3) *In light of its response to question 2, assess whether a limit of nitrosamines and nitrosatable compounds can be established that will lead to exposure of young children to balloons not giving reasons for health concerns (e.g. the 0.05 mg of nitrosamines and 1.0 mg N-nitrosatable compounds per kg rubber recently proposed for balloons by the Federal Republic of Germany). In answering this question, consideration should also be given to other sources of nitrosamines and nitrosatable compounds than rubber.*
- (4) *Identify any additional investigative work that needs to be done concerning both the specific issue of nitrosamines in balloons and the presence and release of nitrosamines from other rubber or non-rubber consumer products (non-food and food) resulting in eventual consumer exposure, that would enable an integrated risk assessment to be conducted concerning the total children exposure to nitrosamine from all known sources.*