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**DANISH MINISTRY
OF THE ENVIRONMENT**

European Commission
Health and Consumer Protection Directorate-General
Unit B3 'Product and Service Safety'
Att.: Ms. Meglena Kuneva
Office B232 06/101, B-1040 Brussels

Minister
for the environment
J.nr. MST-604-00013

December 13 2007

Nitrosamines in balloons

Dear Ms. Meglena Kuneva,

I am contacting you because the Danish Environmental Protection Agency has made an investigation on chemical substances in balloons.

Among other things four balloons were tested for the migration of nitrosamines and nitrosatable substances. Some nitrosamines are carcinogenic and nitrosatable substances are substances that can produce nitrosamine. The four balloons tested for migration showed release of nitrosamines and nitrosatable substances. A copy of the report is enclosed.

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At present there are no legal limitations of the migration of these substances from balloons in EU. Germany has national limits for the migration, and the Netherlands has national limits for the concentrations in balloons. The migrations of nitrosamines from the four balloons were below the German migration limit, but for three of the four balloons the migration of nitrosatable substances were above the German migration limit.

The Danish Environmental Protection Agency made a risk assessment, which shows that a child weighing 15 kg can suck on a balloon 5 hours during one year without any added risk under these circumstances. The evaluation is based on animal experiments (RIVM 1989)¹ showing that the additional cancer risk of 1:10⁶ for lifetime exposure to nitrosamines was associated with the intake in the range of 0.25-3 ng/kg bw per day. The risk associated with migration of nitrosamines from balloons is therefore very low. However, I believe that children should not be exposed to carcinogenic substances from toys at all. SCCP also states in their evaluation of migration of these substances from balloons that the rubber industry has indicated that formations of these can be avoided. Therefore I ask you to take up this important issue and initiate setting up migration limits for nitrosa-

¹ CEN/TC 52/WG 9 N 174 April 2005

mines and nitrosatable substances in the Toys Safety Directive as this is under revision now.

I hope that you are agreeing with me in this matter and I am looking forward to get a response from you.

Yours sincerely,

Troels Lund Poulsen