No Nitrosamine Risk in Condoms

There is no carcinogenic risk associated with the use of condoms. No medical or scientific evidence exists to suggest that the very minute amounts of nitrosamines in condoms pose any potential carcinogenic risk. For this reason, no regulatory body has set limits on levels of nitrosamines or nitrosatable substances in condoms.

Proksch, in his study on the toxicological evaluation of nitrosamine in condoms, concluded that ‘the risk for the induction of tumors from nitrosamines is very low.’ The abstract of his paper is reproduced in full below.


<table>
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<th>Toxicological Evaluation of Nitrosamines in Condoms</th>
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<tbody>
<tr>
<td>E. Proksch</td>
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Abstract

Volatile N-nitrosamines have been found in rubber products including gloves, balloons, toys, baby bottle teats, soothers, and condoms. N-Nitrosamines are potent carcinogens, and therefore, European legislation has limited the release of N-nitrosamines and N-nitrosatable compounds in teats and soothers to 0.01-0.1 mg/kg rubber, respectively. Previously, endogenous nitrosamine formation in the vagina has been suggested as a cause of cervical cancer. It was speculated that exogenous N-nitrosamines and N-nitrosatable compounds from condoms may also lead to genital cancer. Therefore, we reviewed the literature and calculated the risk for the induction of tumors by nitrosamines from condoms. In vitro Biaudet et al. (1997) found up to 88 ng nitrosatable compounds migrating from condoms to cervical mucous within 24 hrs. During sexual intercourse about 0.6 ng may migrate in the female genital mucous membranes because of the short contact to the condom, e.g. 10 min. Comparable amounts of nitrosamines may also migrate in the penile skin. Estimating 1500 contacts to condoms during lifetime (50 condoms/year for 30 years) this may result in the adsorption of up to 0.9 microgram nitrosamines in total. Animal studies in Syrian hamsters showed the induction of local and/or systemic tumors, in particular liver tumors, after topical application of nitrosamines to the skin or mucous membrane at a total dose of about 1 g. This dose exceeds the dose to be expected from contact with condoms by more than 1 million. Also, epidemiological studies do not support a role for condoms in the induction of cancer. The incidence of cervical cancer and liver tumors is high in developing countries, where condoms are seldom used. In addition, humans are regularly exposed to nitrosamines from food and tobacco smoke at a dose which is 1,000 to 10,000 fold higher than expected from condom use. In summary, the risk for the induction of tumors from nitrosamines in condoms is very low.

There are limits set on the levels of nitrosamines and nitrosatables in baby bottle teats and soothers. In Europe, the limit of migration of nitrosamines is 0.01mg/kg and that for nitrosatables
is 0.1mg/kg. But, baby teats and soothers, in their use, are different from condoms. In response to concerns on the carcinogenic risk of condoms due to nitrosamines, the Rubber Foundation Information Center for Natural Rubber made the following statement in their 2nd Quarter 2004 Newsletter.

### Nitrosamines in Condoms, a Risk?

The requirement for teeters is a maximum of 10 µg/kg (or 10 ppb). This means a teeter having a mass of about 5 gram is allowed to contain at most 0.05 µg nitrosamines. However, other remainders of the vulcanization process present in the rubber also can form nitrosamines when the product in service is exposed to heat. That means that sterilizing a teeter in boiling water may lead to the forming of additional nitrosamines.

For a condom this will not happen. A condom is intended to be used only once, so only the nitrosamines present after production are a potential risk. Furthermore condoms are used by adults and the sensitivity of adults is about 100 times less than that of babies. Assuming a condom containing 200 µg/kg of nitrosamines, which is a really high level, the total amount of nitrosamines in this condom having a mass of 1.5 gram is about 0.3 µg. The average daily doses attributed to normal eating and drinking is about 0.2 µg for women and 0.3 µg for men. This means that assuming the body absorbs all nitrosamines present in a condom this is about equal to a daily doses. In practice the levels of nitrosamines present in most condoms will be much lower then 200 µg/kg. Some brands remained well below the requirement for baby teeters, and not all nitrosamines present in a condom will be absorbed in the human body.

For baby teeters the situation is quite different because these are used several times a day and sucked on heavily. Assuming the requirement for teeters is a safe one as it is considered to be and taking into account that for instance barbequeing or eating fish and spinach will lead to much higher intakes of nitrosamines it is clear that normal use of condoms is safe even when these contain somewhat higher levels of nitrosamines. Professional use however may introduce somewhat more risk and for that purpose it is advisable to use condoms having a known low level of nitrosamines.