Reproductive Health Technologies Project
Where reproductive health, politics, policy and practice meet

Frequently Asked Questions: Condoms and Nitrosamines

The Reproductive Health Technologies Project (RHTP) and the Center for Environmental Health (CEH) released a report, *Making a Good Thing Even Better: Removing Nitrosamines from Condoms [link to report]*, analyzing the results of testing we had performed on a variety of condoms available in the United States.

1. What are nitrosamines and why are they in some condoms?

Nitrosamines are a class of chemical compounds that form when nitrates and amino acids combine. About 300 types of nitrosamines have been tested and 90 percent have been found to be carcinogenic.[i]

Nitrosamines are found in a variety of rubber products including balloons, gloves, baby bottle nipples, and pacifiers, as well as in some processed meats such as hot dogs and cooked bacon, some types of cheese, drinking water, and tobacco smoke.[ii]

In condoms, nitrosamines can form in small quantities when nitrogen oxides in the air interact with residue from chemicals used to speed up the rubber manufacturing process.[iii] Typically, three types of nitrosamines are found in condoms: N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA), and N-nitrosobutylamine (NDBA).[iv]

2. Why did RHTP and CEH commission the testing of condoms?

No governing body has set specific limits for the levels of nitrosamines in condoms, but in 2010 the World Health Organization (WHO) and the United Nations Population Fund (UNFPA) recommended that manufacturers minimize the presence of nitrosamines in male latex condoms.

There has been little follow-up testing to see if the WHO and UNFPA recommendation has been implemented. Thus RHTP, in partnership with CEH, commissioned testing to determine if condoms available in the U.S. released nitrosamines.

In February 2014, RHTP and CEH had 24 different types of latex condoms that are sold in the United States tested in accordance with BS ISO 29941:2010, a test that was designed specifically to determine the amount of nitrosamines released by condoms during typical use. Since there are no regulatory standards for nitrosamines in condoms, we used the regulatory standard for certain rubber toys set by the European Union (EU) as a proxy to determine whether the level of nitrosamines released from condoms might pose a risk to human health.

3. What did the report find?

The good news: Of the condoms we tested, almost one-third did not release any detectable levels of nitrosamines, including some well-known brands with large market shares.

Approximately another third released levels that fall below the EU standard, meaning that some nitrosamines were detected but at low levels.

The remaining third exceeded the EU threshold, some by twice as much. But of those, the makers of half have already indicated to RHTP that they are aware of the issue and taking steps to monitor and reduce the levels of nitrosamines in their products.

4. Should people stop using condoms?

NO! Condoms are safe and effective and are the *only* product available that simultaneously protect against sexually transmitted infections (STIs), including HIV/AIDS, and pregnancy. They are also low-cost and widely available. As a result, condoms are an essential sexual health product for many people. The presence of nitrosamines in some condoms should not reduce or undermine condom use.

5. Will using condoms cause cancer?

Determining the risk of cancer is very complex and our report did not attempt to make that assessment. However, a 2001 study found that the risk of tumors from nitrosamines in condoms was exceedingly low.[v] To put the potential risk in perspective, the average level of nitrosamines in our daily food is *five times* higher than the average exposure to nitrosamines from using a condom one time.

What we do know is that the health benefits of condoms – including pregnancy prevention, HIV/AIDS prevention, and protection from a wide range of other STIs including the Human Papillomavirus (HPV), which can cause cervical cancer – far outweigh the potential health risks of exposure to nitrosamines that some condoms on the market may pose.

6. If the risk of cancer from condoms is low, why did RHTP and CEH publish this report?

While exposure to nitrosamines from condoms is quite low relative to other sources of exposure, their presence in condoms is unnecessary and can be readily removed. Thus, they should be. Because we are exposed to nitrosamines from food, drinking water, and a wide range of consumer products, it is important to eliminate exposures to the substance wherever possible.

7. Are there condoms with undetectable levels of nitrosamines on the market?

Yes! Of the condoms we tested, almost one-third did not release any detectable levels of nitrosamines, including some well-known brands with large market shares. In our report [link to report] we list the condoms we tested and the amount of nitrosamines detected so consumers can make an informed choice. However, we only tested a small number of condoms and do not draw conclusions about nitrosamines in any other products. Moreover, our findings are only accurate as of the time of testing (February 2014).

We are optimistic that condom manufacturers, once aware of the issue, will start to mitigate the presence of nitrosamines in their products. Indeed, prior to releasing this report, we notified the companies whose condoms we tested of their individual product results and asked those whose condoms released nitrosamines to make a pledge by February 27, 2015 to eliminate nitrosamines from their products. Encouragingly, we learned that several have already begun to change their

products to reduce or eliminate nitrosamines. We look forward to continuing to work with condom manufacturers to make condoms even better.

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[i] The WHO Prequalification Programme for Condoms. A Workshop for Male Latex Condom Manufacturers - Session 7, Handout 3. http://www.path.org/publications/files/RH_condom_wrkshp_session7_en.pdf.

[ii] *Id.*

[iii] Department of Health and Human Services. Report on Carcinogens, Twelfth Edition. http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/nitrosamines.pdf. Published 2011. Accessed September 12, 2014; Toxicological evaluation, *supra* note 3.

[iv] Selin E. Environmental Guidelines and Regulations for Nitrosamines: A Policy Summary (hereinafter Environmental Guidelines). February 2014. CO_2 Technology Centre Mongstad. http://www.tcmda.com/Global/Aminrapporter/MIT%20nitrosamines%20report%20final.pdf.

[v] Proksch E. Toxicological evaluation of nitrosamines in condoms (hereinafter Toxicological evaluation).. *Int. J. Hyg. Environ. Health*. 2001;204:103-110.