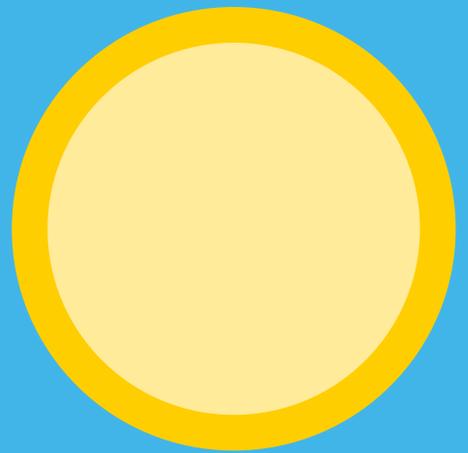
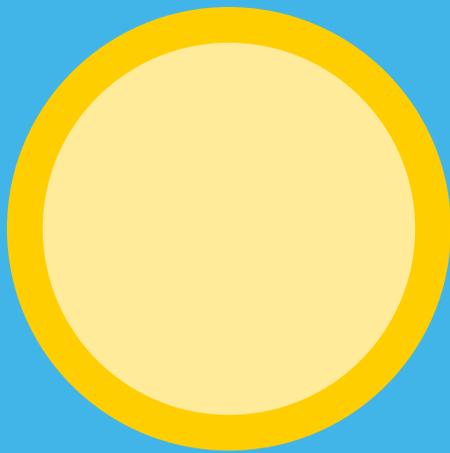
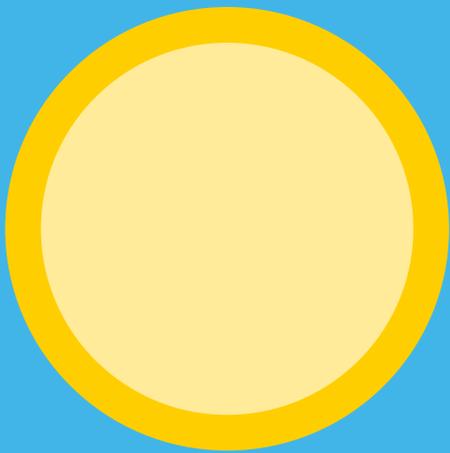
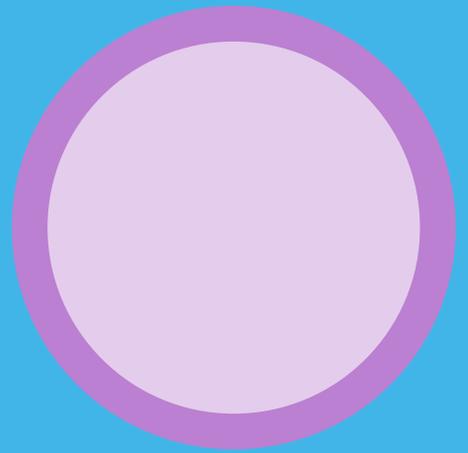
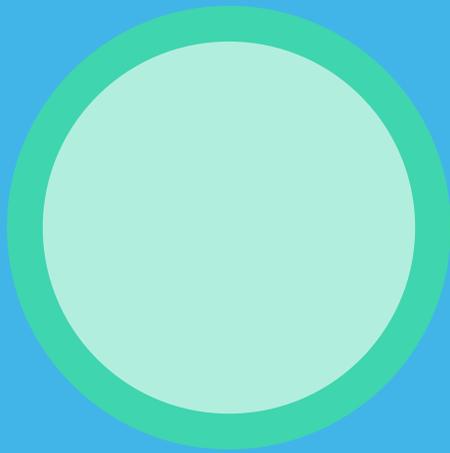
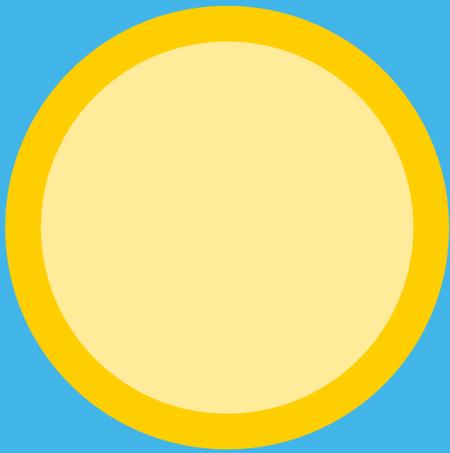
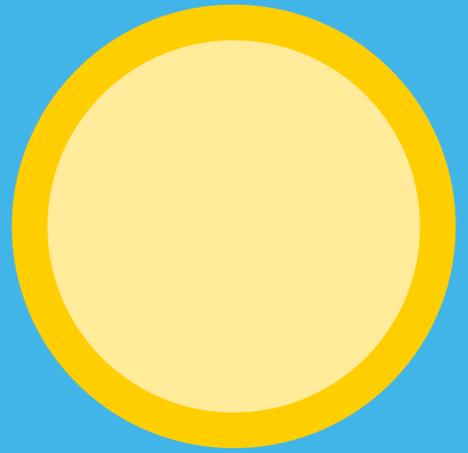
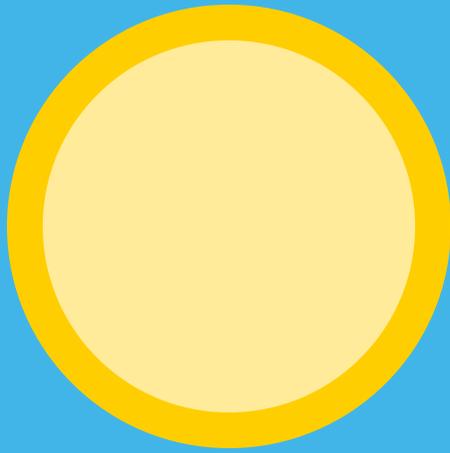
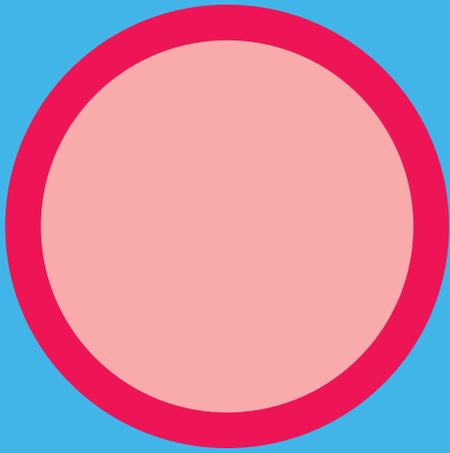
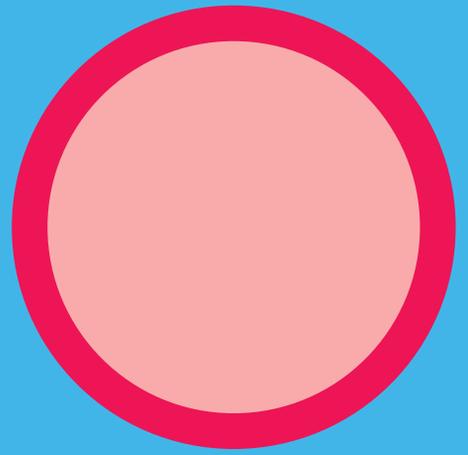
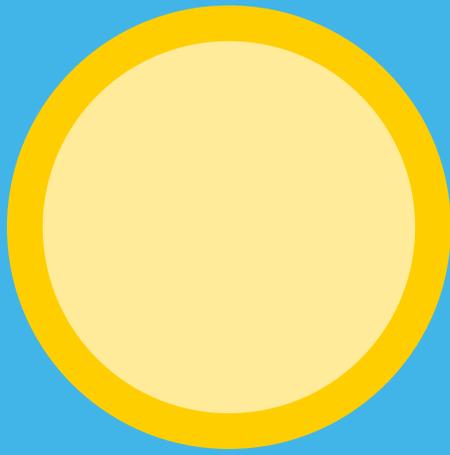
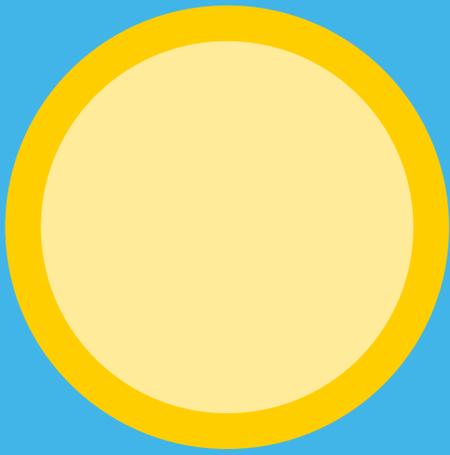


Making a Good Thing Even Better:

Removing NITROSAMINES from CONDOMS



September 2014
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Making a Good Thing Even Better:

Removing NITROSAMINES from CONDOMS

Introduction and Summary

In a country with approximately 19 million new cases of sexually transmitted infections (STIs) each year, half of them among 15–24-year-olds,¹ condoms are an essential part of protecting and promoting sexual and reproductive health for people of all ages. Condoms are the *only* product available that simultaneously protects against STIs and pregnancy, are highly effective when used correctly and consistently, and are relatively low-cost, making them an essential sexual health product for many people.

Nevertheless, even a good thing can be improved.

In 2010, the World Health Organization (WHO) and the United Nations Population Fund (UNFPA) recommended that manufacturers minimize the presence of nitrosamines, a class of carcinogenic chemicals, in male latex condoms.²

While the detectable level of nitrosamines in condoms is lower than those found in food, water, and other consumer goods – and does not diminish the health benefits, efficacy, and safety of condoms – their

presence is unnecessary and may contribute to our overall exposure to these chemicals. Since nitrosamines can be readily removed from the condom manufacturing process – and several types of condoms are already available that do not leach nitrosamines – condoms without detectable levels of nitrosamines should be the new norm.

There has been little follow up testing to see if the WHO and UNFPA recommendation has been implemented. Thus, the Reproductive Health Technologies Project (RHTP), with funding from the co-founders of a condom company and in conjunction with the Center for Environmental Health (CEH), commissioned testing to determine if condoms available in the U.S. released nitrosamines and, if so, whether those amounts exceeded international standards set for other products.

Working with CEH, RHTP analyzed the results of the condom testing and compared the level of nitrosamines released with exposure standards for nitrosamines established by the European Union (EU) and by the State of California. Our study revealed a wide

range of migration of nitrosamines in the condoms we tested, from 0 to 443 parts per billion (ppb), with a third of the condoms exceeding the EU standards and one condom exceeding California's standards. We detail our findings below.

The use of condoms should not be reduced or undermined because of the presence of nitrosamines in some condoms. Indeed, a 2001 study found that the risk of tumors from nitrosamines in condoms was exceedingly low.³ And 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.

That said, any unnecessary or extraneous exposure to nitrosamines should be minimized. Nitrosamines *can* be removed from condoms without impacting the efficacy, reliability, or safety of condoms and thus manufacturers should make every effort to eliminate nitrosamines from their products.

Reproductive Health and Chemical Exposures

Although reducing exposures to environmental toxins may seem far removed from a conventional reproductive rights agenda, it is one of the most important things we can do in the long term to protect our reproductive health and the health of our families. Mounting scientific evidence

indicates that our everyday environment – from the air we breathe to the shampoo we use – can expose us to toxic chemicals that negatively impact reproductive health and fertility.⁴ Toxic chemicals can affect our reproductive health by reducing sperm content and quality, impeding ovarian function, influencing breast and prostate development, and altering fetal development and pregnancy outcomes, to name a few.⁵

By the same token, we also want to ensure that contraceptive and other reproductive health technologies are as “green” as possible.⁶ This approach can include minimizing the environmental impacts of the processes by which contraceptives are made, marketed, delivered, and used, and it can also include reducing any potential exposures to toxins from contraceptives themselves during use or following disposal.

What Are Nitrosamines?

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.⁷ Research shows nitrosamines can damage DNA repair processes and cause human cells to mutate, potentially causing cancer.⁸

During the manufacturing process of 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.⁹ Typically, three types of nitrosamines are found in condoms: N-nitrosodimethylamine

(NDMA), N-nitrosodiethylamine (NDEA), and N-nitrosobutylamine (NDBA).¹⁰

In addition to condoms, 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.¹¹

Why Nitrosamines in Condoms May Raise Concerns

The nature of condom use is unique compared to other types of nitrosamine exposure. Oral exposure is the primary route of exposure for most nitrosamines.¹² Although some condoms are used orally, it is not the primary route of exposure during typical use.

Condoms are intended for close contact with the skin and with the mucous membranes of the genitalia. Mucous membranes found in genitalia are semi-permeable tissue and can be damaged, irritated, and penetrated by synthetic chemicals much more easily than the surface of the outer skin.¹³ Vaginal and vulvar tissues in particular are more sensitive and permeable than the skin on the rest of the body. Vaginal walls contain many blood and lymphatic vessels, which enable chemicals to transfer directly into the circulatory system without first being metabolized.¹⁴ Moreover, other parts of the body that come into contact with condoms – such as the head of the penis, the inner layer of the penis foreskin, the urethra, the anus, and the rectum – are also mucous membranes.

Worker Health

Concern about exposure to nitrosamines is not limited to users of condoms. Condom factory workers may also be exposed, and at much higher levels. In fact, it was an increase in the incidence of cancer among workers in the American rubber industry that first alerted scientists to the presence of nitrosamines in rubber products.¹

Condom factory workers, especially those in developing nations, are often paid low wages and are less likely to have access to health care to address any work-related health issues. Thus, protecting workers from unnecessary exposure to nitrosamines is yet another reason for condom producers to change their manufacturing processes.

¹ Proksch, 104.

We are not aware of research comparing oral and vaginal absorption of the nitrosamines found in condoms. However, some compounds, such as the hormone estradiol, are better absorbed vaginally than orally.¹⁵ In addition, researchers have shown that absorption of a type of nitrosamine not typically found in condoms was equivalent whether through the skin or orally.¹⁶ While both men and women are exposed to low levels of nitrosamines from condoms that contain the substance, it is estimated that more is absorbed through the vagina than the penis.¹⁷

Even assuming as we did in this study that 100 percent of the nitrosamines leached by a condom during use are absorbed by the vagina or rectal wall, the exposures are low compared to other sources of exposure such as food, byproducts of disinfecting our water, tobacco smoke (first- and second-hand),

and cosmetics.¹⁸ For instance, it is estimated that a woman's average daily intake of nitrosamines from food sources alone is approximately 500 ng,¹⁹ whereas the average exposure level among the condoms tested in our study was 81 ng. However, because we face regular exposure to nitrosamines from other products, anything that adds to our cumulative nitrosamine exposure raises health concerns. Thus, it is important that our lifetime exposure to nitrosamines be minimized wherever possible.

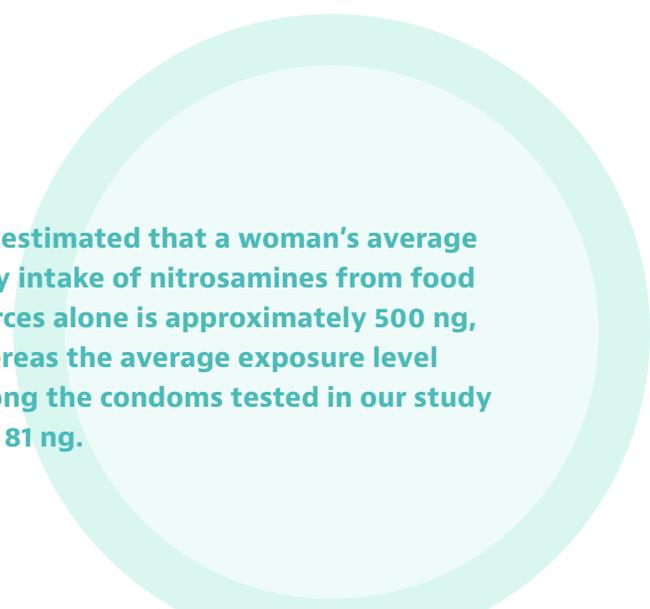
Methodology

In February 2014, we had 24²⁰ different types of latex condoms that are sold in the United States tested in accordance with BS ISO 29941:2010 to determine the amount of nitrosamines released by the condoms. The condom test ISO 29941:2010 was designed to estimate the amount of nitrosamines to which a condom user would be exposed during typical use so as to provide an

assessment of risk. This amount is to be distinguished from the total amount of nitrosamines that may be contained in a condom, which is expected to be higher than the amount released during usage.

The condoms we selected for testing varied by color, flavor, feature (i.e., warming or tingling sensation), texture (i.e., ribbed), and thickness (i.e., ultrathin). We also chose condoms based on high in-store availability, large number of units sold in the United States according to the market research company IRI, and with input from issue and industry experts. In addition, we tested condoms that were previously found to have higher levels of nitrosamines and condoms that are marketed as "organic" or "natural." We acquired the selected condoms by purchasing them from retail pharmacy chains or ordering them from online condom vendors and then shipped them to the Tun Abdul Razak Research Centre laboratory for testing, with one exception. Pre-market samples of Sustain condoms were shipped directly from the company to the laboratory for testing as they were not yet available for purchase at the time.

No governing body has set limits for the levels of nitrosamines in condoms. Nevertheless, as mentioned above, in 2010, the WHO and UNFPA issued guidelines for male latex condoms that included a recommendation that manufacturers take steps to minimize nitrosamines in their products.²¹ These guidelines did not set specific limits for nitrosamines but did provide anticipatory guidance on how to reduce or eliminate nitrosamines from the manufacturing process.²²



It is estimated that a woman's average daily intake of nitrosamines from food sources alone is approximately 500 ng, whereas the average exposure level among the condoms tested in our study was 81 ng.

As a proxy for determining whether the level of nitrosamines released from condoms might pose a risk to human health, we compared the level of nitrosamines released during the testing to two different regulatory standards.

Because the test used to determine the level of nitrosamines released was a migration test (how much leached during a specified time period) as opposed to how much was contained in condoms, we used regulatory standards that likewise were based on migration rather than on content.²³ The first standard used for comparison was the EU's EN 71-12 (nitrosamines in toys made of elastomers).²⁴ This standard sets a limit of .05 milligrams of migratable nitrosamines/ per kilogram of toy material, or 50 ppb, calculated as a sum of all migratable nitrosamines.²⁵

The second standard used for comparison was California's Safe Drinking Water and Toxic Enforcement Act of 1986, also known as Proposition 65. While not targeted solely to nitrosamines, Proposition 65 seeks to reduce or eliminate exposures to chemicals that cause cancer, birth defects, or reproductive harm by requiring warnings in advance of those exposures.²⁶ Under Proposition 65, the Office of Environmental Health Hazards Assessment (OEHHA) calculates the daily exposure to certain nitrosamines that would result in one excess cancer case per 100,000 people exposed.²⁷ This is called the no significant risk level (NSRL). The NSRLs (in micrograms (mg) per day) for the three types of nitrosamines found in condoms are: .02 mg for NDEA; .04 mg for NDMA; and .06 mg for NDBA.²⁸



The good news is that almost one-third of the condoms tested (7 out of 23) did not release any detectable nitrosamines.

We recognize that the comparison of nitrosamines released in testing to these standards is not perfect. For one, the EU standard is targeted to children, a population that may be at higher risk because of rapid developmental changes. Moreover, the standard is primarily concerned with oral exposure. Likewise, under Proposition 65, the studies used for calculating the maximum allowable dose level (MADL) for nitrosamines are based on oral exposure from drinking water.²⁹ While condoms are sometimes used for oral sex, a more common exposure is dermal or epithelial,³⁰ as noted above.

Results

The study revealed a wide range of migration of nitrosamines in condoms, from 0 to 443 ppb (Figure 1). Sixteen of the 23 condoms³¹ released at least one type of nitrosamine. NDBA was the most common nitrosamine detected, but NDEA – considered the most potent as demonstrated by the low NSRL under Proposition 65 – was detected at the highest levels. One of the condoms tested released more than 300 ppb of NDEA. Special features of the condom (i.e., flavor, color, or thickness) did not seem to affect the level of nitrosamines released.

Figure 1: Nitrosamines Migrating from Condoms* (ng/g or ppb)

Condom	NDMA	NDEA	NDBA
Billy Boy—Beaded Lot D420721	Not Detected	4	Not Detected
Durex—Avanti Bare Lot 0010657782	Not Detected	Not Detected	11
Durex—Extra Sensitive, Extra Lubricated Lot 0010870147	Not Detected	Not Detected	Not Detected
FC2—Female Condom Lot F5416	Not Detected	Not Detected	Not Detected
Glyde—Blueberry [†] Lot BB15961	37	Not Detected	55
LifeStyles—Flavors and Colors, Strawberry Lot 106571916	Not Detected	Not Detected	Not Detected
LifeStyles—Skyn, Original Lot 1302120722	Not Detected	Not Detected	Not Detected
LifeStyles—UltraLubePlus Lot 1211080916	Not Detected	Not Detected	Not Detected
NüVo—Nude Lot 1206/09	18	Not Detected	40
One—Glowing Pleasures [‡] Lot 13N714	22	Not Detected	40
Playboy—Lubricated [§] Lot NWSA10-101104	15	340	88
Sir Richard's—UltraThin Lot 10N3716	36	Not Detected	97
Sustain—Proto TP/RD/PS/05/2013 Lot TRL3026	Not Detected	Not Detected	Not Detected
Trojan—ENZ Lot TT3150XZ3 02	7	19	4
Trojan—Her Pleasure Sensations Lot TT2353UZ1312	7	31	5
Trojan—Intensified Charged Orgasmic Pleasure Lot TT1335BZ1311	Not Detected	3	4
Trojan—Magnum, Large Size Condoms, Ecstasy, Ultrasmooth Lubricant Lot TT3163CC	5	27	11
Trojan—Magnum, Large Size Condoms, Lubricated Lot TT3216ZZ1308	2	12	6
Trojan—Magnum, Large Size Condoms, XL, Lubricated Lot TT3101YC	13	67	63
Trojan—Pleasures, Extended Lot TT3152TE	Not Detected	8	8
Trojan—Pleasures, Fire and Ice Lot TT3151ZZ709	Not Detected	11	Not Detected
Trojan—Sensitivity, Bareskin Lot CZ2319L3	Not Detected	Not Detected	Not Detected
Trojan—Ultra Ribbed Lot TT3173UZ1512	20	48	14

* These results are accurate as of the time of testing (February 2014) and do not necessarily reflect the nitrosamine levels of these products as currently available for sale. Testing samples were procured in December 2013.

† The makers of the Glyde Blueberry condom have informed RHTP that the condom tested in this study was produced in February 2011 and indicated that they changed their manufacturing process in 2013 to reduce the level of nitrosamines in their product to fall below current regulatory standards. However, as of the time of publication, they had not provided evidence to RHTP to substantiate that claim.

‡ The makers of One Glowing Pleasures condom have informed RHTP that testing in early 2014 of the One Classic Select condom, which uses the same latex formulation and processing parameters as the Glowing Pleasures condom (aside from the addition of a glow pigment to the latter), showed that the Classic Select released less than 10 ppb of nitrosamines. They have added Glowing Pleasures to the list for their next round of analysis, but that testing had not occurred as of the time of publication.

§ The makers of the Playboy Lubricated condom have provided evidence to RHTP that they have implemented changes to the manufacturing process of all their condom lines, which has resulted in nitrosamine levels that fall below the EU standards (on file with authors). However, because the newer versions of their products have not yet been imported to the U.S., our testing results for this condom are relevant to current market conditions as of the time of publication of this report. Playboy has not indicated when the new versions will become available for sale in the U.S.

The good news is that almost one-third of the condoms tested (7 out of 23) did not release any detectable nitrosamines, including the only female condom available in the United States (Figure 2).

Figure 2: Tested Condoms with No Detectable* Nitrosamine Migration

Condom	NDMA	NDEA	NDBA
Durex—Extra Sensitive, Extra Lubricated Lot 0010870147	Not Detected	Not Detected	Not Detected
FC2—Female Condom Lot F5416	Not Detected	Not Detected	Not Detected
LifeStyles—Flavors and Colors, Strawberry Lot 106571916	Not Detected	Not Detected	Not Detected
LifeStyles—Skyn, Original Lot 1302120722	Not Detected	Not Detected	Not Detected
LifeStyles—UltraLubePlus Lot 1211080916	Not Detected	Not Detected	Not Detected
Sustain—Proto TP/RD/PS/05/2013 Lot TRL3026	Not Detected	Not Detected	Not Detected
Trojan—Sensitivity, Bareskin Lot CZ2319L3	Not Detected	Not Detected	Not Detected

*The limit of detection was taken as 1-2 ng/g.

Seven of the 23 condoms tested released enough nitrosamines to exceed the level set by the EU for toys intended for use by the mouth or by children under the age of three (Figure 3). Of those seven, migration from three was greater than two times the EU standard, suggesting the level of nitrosamines released by these condoms may be high enough to warrant concern and quick action by the manufacturers to reduce nitrosamines in those products.

Figure 3: Total Migration of Nitrosamines from Condoms that Exceeded the EU Standard for Nitrosamines in Toys for Children Under Three

Condom	NDMA	NDEA	NDBA	Total Nitrosamines
Glyde—Blueberry Lot BB15961	37	Not Detected	55	92
Nuvo—Nude Lot 1206/09	18	Not Detected	40	58
One—Glowing Pleasures Lot 13N714	22	Not Detected	40	62
Playboy—Lubricated Lot NWXA10-101104	15	340	88	443
Sir Richard’s—UltraThin Lot 10N3716	36	Not Detected	97	133
Trojan—Magnum, Large Size Condoms, XL, Lubricated Lot TT3101YC	13	67	63	143
Trojan—Ultra Ribbed Lot TT3173UZ1512	20	48	14	82

The study data suggest that one condom, Playboy’s Lubricated, released enough nitrosamines to exceed both the EU standard and California’s Proposition 65. The amount of NDEA detected in this condom (340 ng/g) multiplied by the weight of the condom (1.5 g)

The proven health benefits of condoms – including HIV, STI, and pregnancy prevention – far outweigh the potential health risks of exposure to nitrosamines from the use of some condoms on the market.

gives an exposure of 510 ng per use (340 ng/g x 1.5 g = 510 ng of exposure per use or .51 micrograms of exposure per use). With an estimated average number of uses per year of 50, average daily exposure would then be 69 ng (.07 micrograms), more than three times the NSRL.

Discussion

Though the testing found that some condoms contain levels of nitrosamines that raise concerns, the results do not suggest that consumers should be discouraged from using condoms. As noted above, the proven health benefits of condoms – including HIV, STI, and pregnancy prevention – far outweigh the potential health risks of exposure to nitrosamines from the use of some condoms on the market.

RHTP and CEH recognize that some people with an anti-condom agenda or a sensationalist bent may seek to distort the results of this study and erroneously claim that condoms cause cancer. Anyone who does so – be it the media, politicians, or advocates – is acting irresponsibly and not in the best interests of public health. Our perspective on this issue is similar to that on contaminants in breast milk. The presence of chemicals in breast milk should not discourage women from breastfeeding their children. On the contrary, the health benefits of breast milk are indisputable, even when the potential for exposure to environmental toxins exists. Likewise, condoms are still the best way for

people to protect themselves from HIV/AIDS and other STIs.

That said, any unnecessary or extraneous exposure to nitrosamines should be minimized. There is no functional use of nitrosamines in condoms and there are several options for removing them. The WHO/UNFPA guidelines advise manufacturers that nitrosamines can be reduced by adequately leaching condoms, by using minimum amounts of accelerators, or by choosing alternative accelerators.³²

Furthermore, our testing results revealed that a good number of condoms already on the market either released low or undetectable levels of nitrosamines. Thus, it is possible to manufacture quality condoms on a large scale with little to no nitrosamines.

Market change is also achievable. For instance, several years ago when Germany's biggest erotica company, Beate Uhse, found out that its chocolate-flavored condoms contained high levels of nitrosamines, the company banned the condoms from its sales line.³³ And some of the condom makers in this study have already begun to change their products to reduce or eliminate nitrosamines. We applaud the actions of those who have proactively sought to ensure that their products are as safe as possible and who have followed the precautionary principle of reducing consumer exposure to potentially harmful substances.

In order to encourage other manufacturers to follow suit, we have informed the makers of the products we tested of our results. For those whose condoms released nitrosamines, we asked them to make a pledge by February 27, 2015 to eliminate nitrosamines from their products. We will publish an update in the

spring of 2015 on any commitments or other progress made.

In that same spirit, we urge large-volume purchasers – including public purchasers like community and family planning health clinics, bilateral organizations such as the United States Agency for International Development (USAID) and the Department for International Development (DFID), and large multilateral organizations like the WHO and UNFPA involved in setting guidelines and quality assurance – to encourage condom manufacturers to eliminate nitrosamines and to purchase brands that release undetectable levels of nitrosamines.

Conclusion

Women and men deserve safe and effective contraceptive options that do not harm or contribute to harming their health or the environment. Although our exposure to nitrosamines from some condoms is minimal compared to other sources, nitrosamines can be removed from condoms without impacting the efficacy, reliability, or safety of condoms and, thus, they should be.



Endnotes

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- 20 Planned Parenthood Federation of America (PPFA), which owns one of the condoms we tested – PROPER ATTIRE’s Basic condom – has informed RHTP that it secured a commitment from its manufacturer in May 2014 to phase out nitrosamine levels to below the limits of detection after 12 months. PPFA also has provided evidence to RHTP that condoms produced using its new manufacturing process release nitrosamines at levels that fall below the limits set by the EU and California (on file with authors). Therefore, we have omitted from the reported findings the results of our testing of what is now an outdated version of PROPER ATTIRE’s Basic condom.
- 21 WHO/UNFPA Male Latex Condom Specification, *supra* note 2 at 28 and 122.
- 22 *Id.*
- 23 The U.S. Food and Drug Administration regulates the level of nitrosamines in baby bottles and nipples, but that standard is based on nitrosamine content, not exposure, and thus was not applicable to the testing we had done on condoms. See U.S. Food and Drug Administration, CPG Sec. 500.450 Volatile N-Nitrosamines in Rubber Baby Bottle Nipples (2005).
- 24 EN 71-12 (June 2013). This standard was set for toys made of elastomers intended for use by children less than three years old or intended to be put in the mouth.
- 25 *Id.*
- 26 Cal. Health and Safety Code §§ 252495-25249.13. <http://oehha.ca.gov/prop65/law/p65law72003.html>.
- 27 *Id.* Under California law, if daily exposure (averaged over a lifetime) exceeds the “No Significant Risk Level” (NSRL), the company selling the product must provide a warning to potential consumers.
- 28 See Office of Environmental Health Hazard Assessment. No Significant Risk Levels (NSRLs) for Carcinogens and Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity. <http://www.oehha.ca.gov/Prop65/pdf/safeharbor070113.pdf>. Published July 2013. Accessed September 12, 2014.
- 29 Risk Specific Intake Levels For Proposition 65 Carcinogen, N-Nitrosodimethylamine, Reproductive Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services (Oct. 1, 1988); Risk Specific Intake Levels For Proposition 65 Carcinogen, N-Nitrosodiethylamine, Reproductive Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services (Oct. 1, 1988); Risk Specific Intake Levels For Proposition 65 Carcinogen, N-Nitroso-n-Dibutylamine, Reproductive Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services (Nov. 1, 1988).
- 30 Epithelial tissue refers to the tissue that covers the whole surface of the body including the lining of internal and external body surfaces. See Department of Biodiversity & Conservation Biology, University of the Western Cape, Epithelial Tissues, http://www.botany.uwc.ac.za/sci_ed/grade10/mammal/epithelial.htm. Accessed September 12, 2014.
- 31 Because our results for PROPER ATTIRE are no longer relevant, see *supra* note 20, we are reporting our findings on 23 of the 24 condoms tested.
- 32 WHO/UNFPA Male Latex Condom Specification, *supra* note 2 at 28 and 122.
- 33 German Study Says Condoms Contain Cancer-Causing Chemical. <http://www.dw.de/german-study-says-condoms-contain-cancer-causing-chemical/a-1220847>. Published May 29, 2004. Accessed September 12, 2014.

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Mission

The mission of the Reproductive Health Technologies Project is to advance the ability of every woman of any age to achieve full reproductive freedom with access to the safest, most effective, appropriate and acceptable technologies for ensuring her own health and controlling her fertility.

The Center for Environmental Health protects people from toxic chemicals by working with communities, consumers, workers, government, and the private sector to demand and support business practices that are safe for public health and the environment.

