

# CHEM FATALE



## POTENTIAL HEALTH EFFECTS OF TOXIC CHEMICALS IN FEMININE CARE PRODUCTS



WOMEN'S VOICES  
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## Potential Health Effects of Toxic Chemicals in Feminine Care Products

By Alexandra Scranton, November 2013

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**F**eminine care. Feminine hygiene. Personal cleansing products. Intimate care. No matter what you call them, these consumer products are manufactured for and marketed exclusively to women. The purpose of feminine care products is to clean, moisturize, absorb discharge or otherwise treat the sensitive skin and tissues of the vaginal area. Women are told they are necessary for personal hygiene, a “fresher feeling,” or “greater confidence,” and the companies marketing these products imply that this improved cleanliness will promote good health and increase sex appeal.<sup>1</sup>

A closer look at the impacts of these products, and the chemicals they contain, tell a much different story. Products intended for use on or in an incredibly absorbent part of a woman’s body are marketed and sold with little to no data assuring the ingredients they contain are safe. Ingredients are determined “safe,” operating under the premise that they are used on ordinary skin just like other cosmetic products. That means chemicals of concern such as carcinogens, reproductive toxins, endocrine disruptors, and allergens are being used on, or even in, the extremely permeable mucus membranes of the vaginal area.

Feminine care products are widely used by women in the United States and constitute a \$3 billion dollar industry.<sup>2</sup> The most popular feminine care products are tampons and menstrual pads, used by 70-85 percent of women<sup>3</sup>. Douches, sprays, washes, and wipes are used by a smaller percentage of women (approximately 10-40 percent), with rates considerably higher among African-American, Latina and low-income women<sup>4</sup>. This report highlights the potential health concerns related to toxic and allergenic chemicals found in feminine care products and outlines the considerable data gaps in our knowledge about them. These products, and their ingredients, require both more research, and greater scrutiny to ensure the safety of their use.

## POTENTIAL HEALTH HAZARDS ASSOCIATED WITH FEMININE CARE PRODUCTS

**Tampons:** Hazardous ingredients may include dioxins and furans (from the chlorine bleaching process), pesticide residues and unknown fragrance chemicals. Exposure concerns include cancer, reproductive harm, endocrine disruption, and allergic rash.

**Pads:** Hazardous ingredients may include dioxins and furans, pesticide residues, unknown fragrance chemicals, and adhesive chemicals such as methyl dibromoglutaronitrile. Exposure concerns include cancer, reproductive harm, and endocrine disruption. Studies link pad use to allergic rash.

**Feminine Wipes:** Hazardous ingredients may include Methylchloroisothiazolinone, Methylisothiazolinone, parabens, quaternium-15, DMDM Hydantoin and unknown fragrance chemicals. Exposure concerns include cancer and endocrine disruption. Studies link wipe use to allergic rash.

**Feminine Wash:** Hazardous ingredients may include unknown fragrance chemicals, parabens, Methylchloroisothiazolinone, Methylisothiazolinone, DMDM Hydantoin, D&C Red No.33, Ext D&C Violet #2, and FD&C Yellow #5. Exposure concerns include endocrine disruption, allergic rash, and asthma.

**Douche:** Hazardous ingredients may include unknown fragrance chemicals and the spermicide Octoxynol-9. Studies link douche use to bacterial vaginosis, pelvic inflammatory disease, cervical cancer, low-birth weight, preterm birth, HIV transmission, sexually transmitted diseases, ectopic pregnancy, chronic yeast infections, and infertility.

**Feminine deodorant** (sprays, powders and suppositories): Hazardous ingredients may include unknown fragrance chemicals, parabens, and Benzethonium Chloride. Exposure concerns include reproductive harm, endocrine disruption and allergic rash.

**Feminine anti-itch creams:** Hazardous ingredients may include unknown fragrance chemicals, parabens, Methylisothiazolinone and an active ingredient, benzocaine, a mild anesthetic. Exposure concerns include endocrine disruption, allergic rash, and unresolved itch.

## What are Feminine Care Products?

The purpose of feminine care products is to clean, moisturize, absorb discharge, or otherwise “treat” the skin and tissues of the vaginal area. According to companies marketing these products, additional benefits supposedly include removal of odor, creating a “fresh feeling,” and “boosting your confidence.”<sup>5</sup> This marketing has successfully created a \$3 billion market for feminine care products in the United States.<sup>6</sup> In this report, Women’s Voices for the Earth closely examines the potential health consequences of chemicals used in menstrual tampons, pads, douches, feminine wipes, feminine wash, feminine deodorant sprays, powders, suppositories, and feminine anti-itch creams.

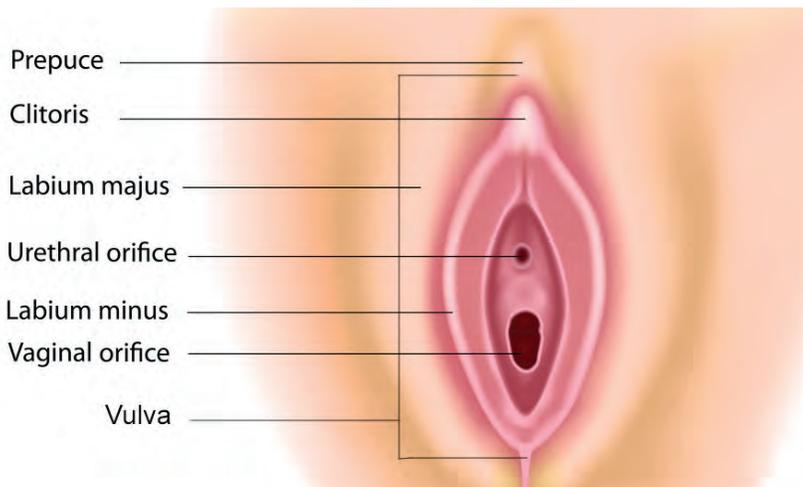
## Feminine Care Products: What makes them special?

### Biology of the vagina: a highly permeable route of chemical exposure

Most of the chemicals used in feminine care products are also commonly found in other cosmetic products. However, feminine care products are specifically intended for use on vaginal and vulvar tissue, which are much different and more sensitive than the skin on the rest of your body. (Quick biology refresher: The vulva is the part of female genitals you can see from the outside of the body, and the vagina is the internal part which leads to the cervix.)

Vulvar and vaginal tissue are structurally different than the skin of the rest of the body. For example, these tissues are also more hydrated and more permeable than other skin. That means this area of the body is potentially more vulnerable to exposure to toxic chemicals and irritants.<sup>7</sup> In addition,

the inner parts of the vulva and the vagina are covered in mucous membranes, which serve an immune defense function, creating a barrier against pathogens which could lead to disease.<sup>8</sup> The walls of the vagina are filled with numerous blood vessels and lymphatic vessels, which allows for direct transfer of chemicals in to the circulatory system.<sup>9</sup> In fact, there is considerable interest in vaginal drug delivery systems because the vagina is such an effective site to transfer drugs directly into the blood without being metabolized first.<sup>10</sup>



Unfortunately, this feature is a distinct disadvantage when it comes to exposure to toxic chemicals, which can also be rapidly absorbed and circulated through the rest of the body. This is especially true of hormone-mimicking chemicals. One study found that a vaginally applied dose of estradiol (an estrogen proxy) resulted in systemic estradiol levels in the body 10 to 80 times greater compared to the same dose given orally.<sup>11</sup> Similarly, vaginal exposure to hormone-mimicking chemicals that may be present in feminine care products may lead to higher than expected exposures in the rest of the body. Cancer-causing chemicals in feminine care products are also a concern, but like many other women's health issues, they are woefully understudied.<sup>12</sup> There is relatively no research on the direct impact of exposure of carcinogens on the vagina. For the most part, risk factors given for vaginal cancer are vague, and concern about exposure of carcinogens to vaginal tissue is rarely, if ever, mentioned.<sup>13,14</sup> Given the potential for exposure of carcinogens to vaginal tissue from feminine care products, concern is warranted and research attention is greatly needed to assess potential risk.

### **The Self-Cleaning Vagina**

The use of feminine care products (and therefore the exposure to chemicals they contain) is a choice made by women based on their personal preferences. For the most part, such use is not medically required for good health. Unlike the skin on the rest of the body which can benefit from cleaning or rinses, a healthy vagina has an effective self-cleaning function. The vagina produces mucous which coats the surface, clearing away bacteria, viruses or other harmful substances. Excess washing of the area can interfere with this natural process, inviting potential infections to take hold. In fact, the American Public Health Association and the



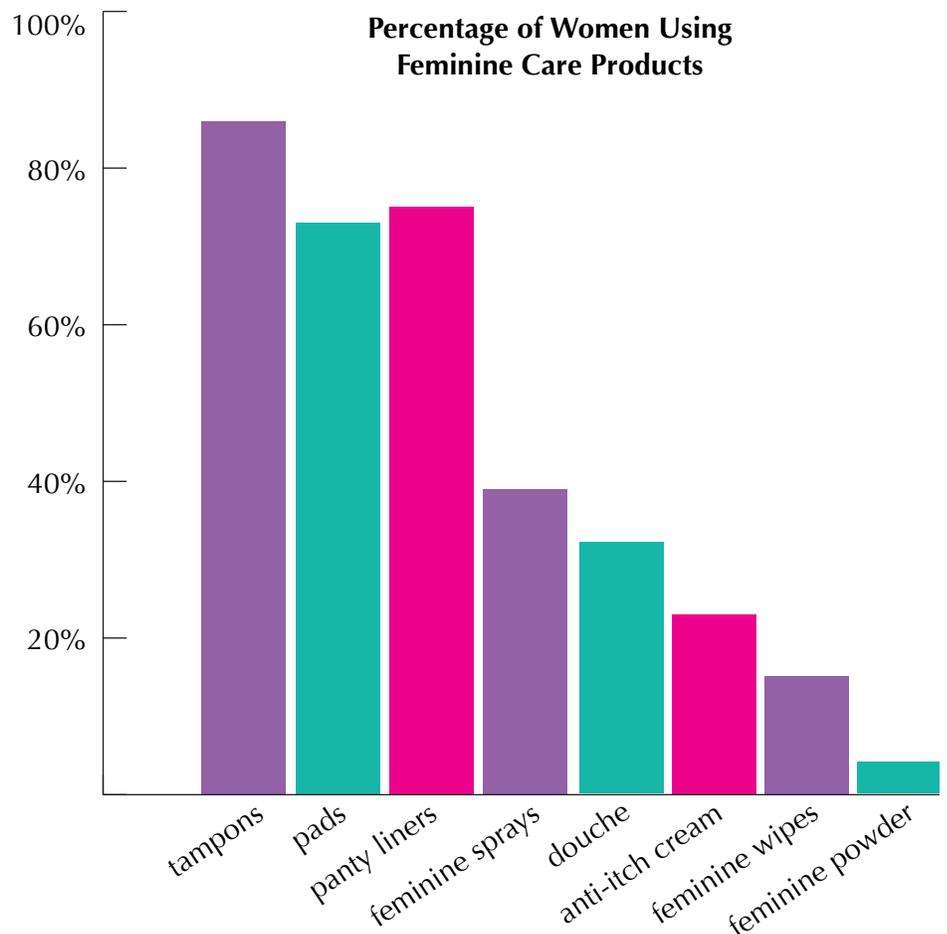
**Chemicals absorbed through the vagina are easily and effectively distributed throughout the body, without being metabolized. For example, when estrogenic drugs are administered vaginally, the resulting systemic levels of the drug in the body can be 10-80 times higher than when the very same dose is given orally.**

American College of Obstetricians and Gynecologists (ACOG) specifically recommend against intravaginal cleaning (douching) as it is both medically unnecessary and associated with adverse health outcomes such as increased bacterial infections.<sup>15,16</sup> In addition, ACOG recommends against the use of fragranced tampons and pads, as well as feminine sprays and powders, to help prevent or clear up vulvar disorders.<sup>17</sup> The decision to use feminine care products, if at all, should be made with care.

## Who Uses Feminine Care?

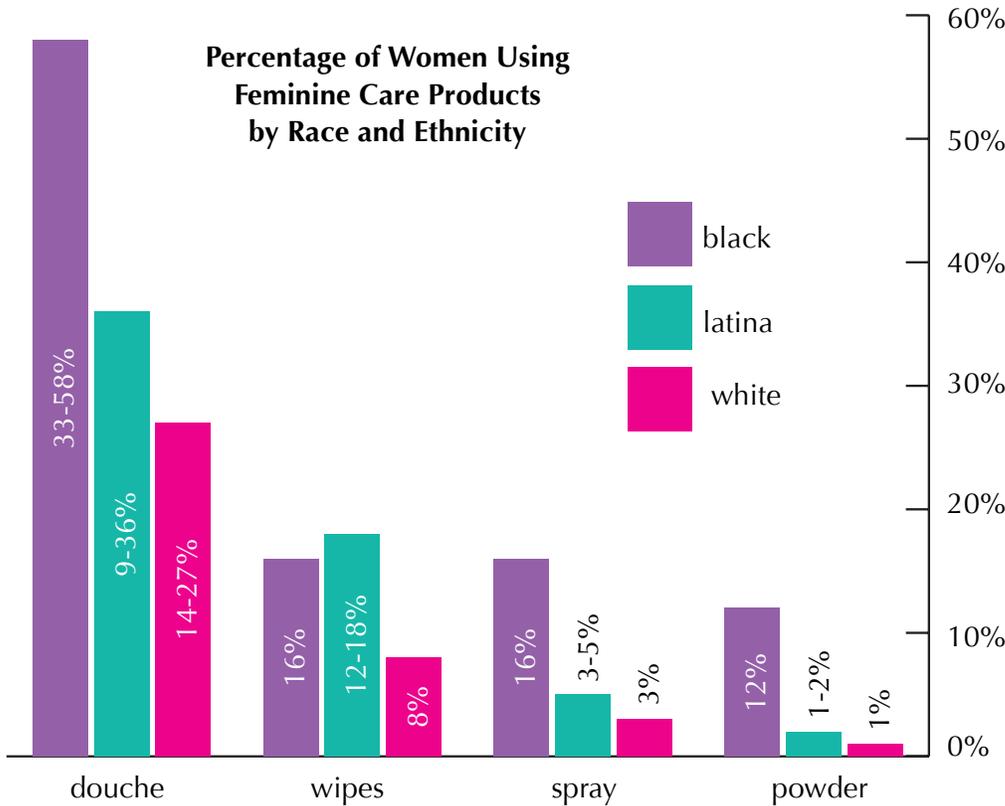
### Demographics of use of feminine care products

Only a few surveys have been conducted to assess the rates of feminine care product use in the United States. As a result, the different survey methodologies result in a fairly wide range of reported use for some products. Results from surveys conducted in the 1990s- 2000s found that: 50–86% of women use tampons; 62–73% of women use pads; 75% of women use panty liners; 4–39% of women use feminine sprays; 10–15% of women use feminine wipes; 4% of women use feminine powder; 23% of women use over-the-counter anti-itch creams; 15–32% of women douche.<sup>18,19,20</sup>





Some women are more likely to use feminine care products than others, leading to disproportionate exposure to toxic chemicals found in these products. For example, while tampons and pads are used relatively universally by most women of reproductive age, feminine “cleansing” products such as douche, sprays, and wipes are used much more commonly by black and Latina women than white women.<sup>21,22,23</sup>



**Note:** None of these studies examined feminine care products use by Asian-American or indigenous women, representing a research need for these populations.

### Age

The age of the woman influences the likelihood that she uses certain feminine care products. One study found that women over the age of 48 were significantly more likely than younger women to use feminine sprays and wipes.<sup>24</sup>

### Socio-economic Factors

Studies on douching have shown the practice to be more commonly reported among women with lower levels of education and of lower socio-economic status.<sup>25,26</sup> Women who douche are much more likely to use other feminine care products regularly as well, further increasing their exposure to harmful chemicals in these products.<sup>27</sup>



## HOW FEMININE CARE PRODUCTS ARE REGULATED

Chemicals used in feminine care products are virtually unregulated by governmental agencies in the United States. Neither the Food and Drug Administration (FDA) nor the Environmental Protection Agency (EPA) has direct authority to monitor or require safety testing for feminine care products. Products such as feminine washes, wipes, and sprays are classified as “cosmetics” and fall under the regulation of the FDA. According to the law, cosmetics, including feminine care products, sold in the United States must be free of poisonous or deleterious substances that might harm users under conditions of normal use. However, the FDA admits that it does not assess or preapprove products before they are marketed. Instead, the FDA states:

*“Companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. The law also does not require cosmetic companies to share their safety information with FDA.”<sup>28</sup>*

The FDA also recognizes the fact that it lacks the authority to require a recall of harmful products and that recalls are voluntary company actions.<sup>29</sup> In absence of FDA control, the cosmetics industry continues to police itself through an industry-funded panel called the Cosmetics Ingredient Review (CIR). Unfortunately when the CIR assesses the safety

of cosmetic ingredients, they often fail to consider the special concerns associated with exposure to sensitive vulvar and vaginal tissue or their mucous membranes.

Some feminine care products are not considered cosmetics. Tampons and pads are regulated by the Food & Drug Administration (FDA) as medical devices. Unlike cosmetics, medical devices lack any government requirement to disclose ingredients to the consumer. This makes it nearly impossible for consumers to avoid chemicals of concern found in these products. Some anti-itch creams and medicated douches are considered over-the-counter drugs, and also lack scrutiny because the FDA solely reviews the active ingredient in these kinds of drugs. Safety and compliance with regulations for other ingredients in over the counter drugs are the sole responsibility of manufacturers, meaning little or no assessment of the safety of the whole product is conducted by the FDA before a product can be sold.<sup>30</sup> Potentially harmful contaminants in products are likewise virtually unregulated and unexamined.



**In the absence of FDA control, the cosmetics industry polices itself, resulting in little government oversight of feminine care products.**

# POTENTIAL HEALTH HAZARDS ASSOCIATED WITH CHEMICALS FOUND IN FEMININE CARE PRODUCTS



## Tampons

**W**hile tampons may appear to be relatively simple devices, made with few ingredients, there is a great deal that scientists don't know about the chemicals they may contain. Most tampons are made from cotton and/or rayon or other pulp fiber. Unfortunately these substances can be contaminated with highly toxic dioxins when bleached with chlorine compounds, as well as pesticides from non-organic cotton. Exposure to dioxins and furans has been linked to cancer, reproductive harm and endocrine disruption.<sup>31</sup> FDA guidance for the marketing of tampons recommends that tampons be "...free of 2,3,7,8-tetrachlorodibenzo-p-dioxin(TCDD)/2,3,7,8-tetrachlorofuran dioxin (TCDF) and any pesticide and herbicide residues."<sup>32</sup> **Unfortunately, this recommendation is not mandatory, and testing results reveal that both dioxins and pesticide residue are found in tampons.**



**Test results show dioxins, furans and pesticide residues in tampons, which have been linked to cancer, reproductive harm and endocrine disruption. Tampons contaminated with these chemicals maintain contact with vaginal tissue for hours at a time for several days each month for women who use them.**

### Dioxin testing in tampons

In 2002, a study was published examining dioxin levels in four different brands of tampons. The study found small but detectable levels of TCDF in all four brands.<sup>33</sup> No TCDD was found in any brand, but several other toxic dioxins and furans were detected. The study concluded that the health risk from exposure to dioxins and furans from tampon use would be insignificant compared to the risk of exposure to dioxins and furans people face from eating food. The study stated that levels of dioxins and furans in tampons would have to be 100-1,000 times greater to affect human exposure levels. However, the study authors did not account for the unique and highly permeable tissues of the vagina, and how that vaginal exposure may be different or even more potent than the dietary route of exposure. Because tampons are inserted internally into the vagina, and maintain contact with vaginal tissue for hours at a time for several days each month, the direct exposure of dioxins and furans to the vagina warrants further scientific study.

### Pesticide testing in tampons

There is surprisingly little data available on the amount of pesticides in tampons. The first publically available testing of tampons commercially available in North America for pesticide residues was commissioned and published by Naturally Savvy in 2013.<sup>34</sup> This study involved testing just one brand of tampons, o.b., for pesticide residues, and tests were conducted by a third party-certified laboratory.<sup>35</sup> The following pesticides were detected:

<b>Malaoxon &amp; Malathion</b>	1ppm
<b>Dichlofluamid</b>	1ppm
<b>Mecarbam</b>	6ppm
<b>Procymidone</b>	37ppm
<b>Methidathion</b>	5ppm
<b>Fensulfothion</b>	5ppm
<b>Pyrethrum</b>	66ppm
<b>Piperonyl Butoxide</b>	1ppm

Granted, these levels are relatively low, and generally below the residue levels allowable in food. However, these data clearly contradict the FDA's recommendation that tampons be "free of pesticide residue." The pesticides detected also pose a range of potential risks. For example, the U.S. EPA has determined that Procymidone is a "probable human carcinogen," Piperonyl butoxide is a "possible human carcinogen," and that the data on Malathion is "suggestive of carcinogenicity."<sup>36</sup> The Pesticide Action Network has

labeled Malaoxon, Malathion, Mecarbam, Procymidone, Methidathion, Fensulfothion, and Pyrethrum as "Bad Actor" pesticides due to hazards including acute toxicity and possible endocrine disruption.<sup>37</sup> However, there has been no research assessing the risk of exposure directly to vaginal tissue from these toxic chemicals. These results, despite being only one study of one brand, generate valid concern about the potential for exposure to pesticides from tampons. More research is needed to determine how commonly pesticide residue is found in tampons, and what the health impacts of that exposure may be.

### **Fragrance in tampons**

Some manufacturers offer scented tampons. This is an aesthetic choice for consumers. Unfortunately, a "fragrance" is a mixture of ingredients that can include any of over 3,000 different chemicals; and the components of any one fragrance are usually kept secret by manufacturers. According to a master list of fragrance chemicals made available by the International Fragrance Association, fragrances can include chemicals which are

## **SECRET TOXIC CHEMICALS IN FRAGRANCE**

**Many feminine care products are heavily fragranced, yet the companies only disclose the generic term "fragrance" as an ingredient, even though many chemicals make up a fragrance. The International Fragrance Association's (IFRA) master list of chemicals used in fragrance includes:<sup>39</sup>**

**Carcinogens** like p-dichlorobenzene and styrene oxide;

**Endocrine disruptors** like galaxolide and tonalide (synthetic musks);

**Reproductive toxicants** like diethyl phthalate (DEP) and di-isononyl phthalate (DINP);

**Problematic disinfectants** like Triclosan and ammonium quaternary compounds; and

**Numerous allergens**

**Unfortunately, IFRA's list does not disclose which companies are using these harmful chemicals or which products they're in, and companies are legally allowed to keep fragrance ingredients a secret from consumers.<sup>40</sup>**

carcinogens, irritants, allergens, and potential endocrine disruptors.<sup>38</sup> The impact of direct exposure of these chemicals to vaginal tissue is woefully understudied. It is especially of concern that fragrance chemicals are used in scented tampons without ingredient disclosure to the consumer.

## Menstrual pads

**D**uring use, menstrual pads (also called sanitary napkins) come in direct contact with vulvar skin. Thus the long exposures to chemicals that may be infused in the pad are of concern. Similar to tampons, pads are marketed in unscented and scented varieties by many manufacturers. The fragrances used in pads are almost never disclosed to consumers, meaning women are unknowingly exposed to numerous possible chemicals. The absorbent material within the pad may also have been chlorine-bleached, posing the potential for dioxin or furan exposure. If the pad includes traditionally-grown cotton, the risk of pesticide residue exposure exists as well.

Several case studies have been published examining health risks to women from use of menstrual pads.<sup>41,42,43</sup> Common symptoms of menstrual pad use include irritation and allergic rash. Many women in these studies suffered for months before a doctor's diagnosis determined the pads were causing the problem. In one case study, the fragrance present in the scented pad was found to be the causative agent of a rash.<sup>44</sup> In another case study, methyl dibromo glutaronitrile (MDBGN) was identified as the cause of the dermatitis. MDBGN was found to be a component of an adhesive used in the pad.<sup>45</sup> A third study at a single gynecological practice did not identify a chemical cause, but noted that one particular brand of pads, Always, led to the symptom of itching or burning vulva in 28 women patients.<sup>46</sup> In most cases, discontinuing use of pads, switching to unscented pads or simply changing brands led to the resolution of the rash or other symptoms.

Similar to tampons, menstrual pads are regulated as medical devices. Thus no ingredient disclosure is required to help consumers choose products, meaning it's difficult for women and their medical care providers to identify problematic ingredients. **With greater ingredient disclosure, women would be able to avoid chemicals of concern and potentially prevent adverse reactions to pads from occurring. Furthermore, this information is critical in order to ensure proper regulatory oversight of chemicals used in these products.**



**Several studies have found an association between menstrual pad use and vulvar irritation or rash. In many cases, switching to unscented pads or changing brands resolved symptoms.**

## Feminine Wipes

**F**eminine moist wipes are a convenience product designed for simple (and disposable) moist cleaning of the genital area. Moist wipes usually contain a preservative chemical in order to retain moistness and prevent bacterial growth in the package. These can be harsh or irritating to skin. The preservatives commonly used in moist wipes include:

- ▶ Methylchloroisothiazolinone
- ▶ Methylisothiazolinone
- ▶ Parabens
- ▶ Quaternium-15
- ▶ DMDM Hydantoin
- ▶ 2-Bromo-2-Nitropropane-1,3-Diol



**Feminine wipes can contain formaldehyde-releasing preservatives and parabens, both linked to increased risk of cancer. Wipes also frequently contain allergens such as Methylchloroisothiazolinone and Methylisothiazolinone (MCI/MI) which were named “Allergens of the Year” in 2013 by the American Contact Dermatitis Society.**

All of these preservatives are potential allergens which can lead to allergic contact dermatitis in the genital area, also known as anogenital dermatitis. Anogenital dermatitis is common, resulting in itching and burning, creating severe discomfort at times.<sup>47</sup> The preservatives Methylchloroisothiazolinone and Methylisothiazolinone (MCI/MI) appear to be of particular concern in wipes. Feminine care products and moist wipes frequently contain MCI/MI, which was dubbed “Allergen of the Year” in 2013 by the American Contact Dermatitis Society.<sup>48,49</sup> A study in Germany of over 1,000 patients with anogenital dermatitis, found MCI/MI exposure to be one of the most frequent problem allergens causing symptoms.<sup>50</sup> Other case studies have reported that patients with anogenital dermatitis were specifically found to be allergic to moist wipes they used which contained MCI/MI.<sup>51</sup> In most cases, discontinuing use of moist wipes resolved their itching symptoms rapidly.<sup>52</sup> The presence of strong sensitizing allergens in feminine wipes is problematic given the direct contact with sensitive vulvar skin. Moist wipes may also be frequently used by women who are already experiencing symptoms of itchiness as a way to resolve them through “better cleaning.” This approach could unfortunately worsen these symptoms for women who are sensitized to the allergenic chemicals commonly found in these products.

The use of quaternium-15 and DMDM Hydantoin in feminine care products like wipes is also concerning because these chemicals are formaldehyde-releasing preservatives. Two other formaldehyde-releasing preservatives, Polyoxymethylene Urea and Diazolidinyl urea are also found in other feminine care products such as feminine wash and deodorant.



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The formaldehyde these chemicals release in the product does an effective job of killing bacteria, but causes allergy problems for those who are sensitized to formaldehyde. Quaternium-15 was one of the top five problem allergens in a study of women suffering from vulvar dermatitis.<sup>53</sup> In addition, formaldehyde is a human carcinogen. The potential cancer-causing impact of formaldehyde exposure to vaginal tissue is virtually unstudied, but certainly concerning. Formaldehyde-releasing preservatives can also be commonly found in feminine wash. The personal care products industry appears to be starting to move away from the use of formaldehyde-releasing preservatives, beginning with a commitment from Johnson & Johnson to remove these chemicals from their products.<sup>54</sup> The removal of these potentially harmful chemicals from feminine care product should be a top priority for the entire industry.

Parabens, used as preservatives in feminine care products, are also problematic. Parabens are commonly found in feminine wipes, feminine washes, and vaginal creams. Similar to MCI/MI, parabens are one of the allergens commonly causing reactions in patients with anogenital dermatitis.<sup>55</sup> Yet in the U.S., the Cosmetic Ingredient Review (CIR) determined parabens are safe to use in all cosmetic products including feminine care products.<sup>56</sup> Their review included just one study addressing irritation to mucous membranes. **This single study was conducted by industry scientists in 1980 on six rabbits, and was never published in a peer-reviewed journal.**<sup>57</sup> **Yet the CIR considered this to be enough data to establish that parabens are not irritating to mucous membranes, and thus safe to use in feminine care products.**

Parabens are also of concern because they have been shown to have estrogenic properties.<sup>58</sup> Parabens have been detected in breast cancer tissue, and there is concern that their presence may be connected to the disease.<sup>59</sup> Higher levels of parabens in a woman's urine has also been associated with ovarian aging, which leads to reduced fertility.<sup>60</sup> Certainly, more research is needed to better understand the effects of parabens on women's health. Their inclusion in feminine care products, where vaginal contact and absorption seems inevitable, must be examined.

**Note:** *The most recent statistics from 2001-2004 cited in this report indicate that 10-15 percent of women report using feminine wipes. However, these data may be outdated. In recent years, the disposable wipes market has had significant growth, including the personal care wipes sector which increased 15 percent between 2009 and 2010 alone, and continued growth is expected.<sup>61</sup> Thus usage of feminine care wipes may well have increased since the data were last reported.*

## Feminine Wash

**F**eminine wash is similar to many other types of liquid body wash, differing mostly from a marketing perspective. The product is sold to women specifically as a wash for the genital area. However, the instructions for use found most bottles of feminine wash state the product is “for external use only.” Feminine wash is meant to be distinguished from douche products for example, which have applicators to facilitate internal vaginal cleansing. However, given the reality of feminine wash and how it is used, it is extremely unlikely that some internal vaginal exposure would not occur from regular use.



**Two dyes commonly found in feminine washes are regulated by the FDA as safe “for external use only.” However, given the reality of feminine wash and how it is used, it is extremely unlikely that some internal vaginal exposure would not occur from regular use.**

Given that reality, it is especially concerning that ingredients are frequently included in feminine washes which are not approved for use on mucous membranes (which cover both the inner vulva and the vagina). Perhaps the best example of this are color dyes added to feminine washes for aesthetic appeal. Color dyes (color additives) in cosmetics are regulated by the U.S. Food and Drug Administration (FDA). Two commonly found colorants in feminine wash are D&C Red No. 33 and Ext. D&C Violet #2. The FDA clearly states that D&C Red No. 33 and Ext. Violet #2 may be safely used only in cosmetics that are “externally applied.” FDA explains this designation this way:

*“Externally applied cosmetics: This term does not apply to the lips or any body surface covered by mucous membrane. For instance, if a color additive is approved for use in externally applied cosmetics, you may not use it in products such as lipsticks unless the regulation specifically permits this use [21 CFR 70.3 (v)].”*

Having a label on feminine wash that states the product is “for external use only” may be a legal way of allowing these colorants to be used, but it does little to prevent vaginal mucous membranes from actually being adversely impacted by these color additive ingredients. Another color additive of concern found in feminine wash is FD&C Yellow #5. While this color has been approved for use on both externally and internally applied cosmetics, there is specific warning language that is required for its use in certain prescription drugs. The regulations state:

*“(3) For prescription drugs for human use containing FD&C Yellow No. 5 that are administered orally, nasally, vaginally, or rectally, or for use in the area of the eye, the labeling required by § 201.100(d) of this chapter shall, in addition to the label statement required under paragraph (c)(2) of this section, bear the warning statement “This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the*

*overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.” This warning statement shall appear in the “Precautions” section of the labeling.”*

No such warning, however, is required for feminine care products which may be administered vaginally, contrary to the above policy. Since color additives in feminine wash are merely added for aesthetic reasons, this exposure seems unnecessary and should be carefully considered.

## Douche

**D**ouching is the practice of cleaning the vagina with water or some form of liquid solution. Women have been douching for centuries for a variety of reasons, using a variety of different formulas.<sup>62</sup> Today there are a number of douche products on the market, and there are also some women who make their own solutions from ingredients such as vinegar and water. Studies show that the most common reason women douche is for personal “cleanliness.”<sup>63</sup> Douching, however, appears to have the opposite effect and actually interferes with the vagina’s inherent ability to keep clean.

A healthy vagina maintains a complex and interdependent community of bacteria (the vaginal microbiome) which support a natural defense to harmful pathogens that can lead to disease. Douching can disrupt this microbiome, by altering both the vaginal pH and changing the proportions and types of bacteria in the vagina. Regular douching has been associated in numerous studies with an increased risk of bacterial vaginosis, which occurs when the balance is upset and there is an overgrowth of certain microorganisms in the vagina.<sup>64</sup> Other studies link douching to pelvic inflammatory disease, cervical cancer, low-birth weight, preterm birth, HIV transmission, sexually transmitted diseases, ectopic pregnancy, chronic yeast infections, and infertility.<sup>65</sup>

Studies have not identified particular chemicals found in douches as the reason for these adverse effects, as it appears any type of physical washing of the vagina can upset the vaginal microbiome. There are, however, some chemicals found in commercially available douches that are of concern. Octoxynol-9 is one chemical frequently found in douches. Octoxynol-9 is a potent contraceptive drug, which effectively kills sperm. (However, douches containing Octoxynol-9 are not considered contraceptives, nor are they required to have any caution labeling to this effect.) Use of Octoxynol-9 in spermicides has been associated with genital irritation and increased vaginal discharge.<sup>66</sup> There are only a few studies that have assessed reproductive toxicity of Octoxynol-9, and they have conflicting results. In one study, Octoxynol-9 exposure to pregnant rats was associated with skeletal deformities (most notably extra ribs), whereas another study on rats found no developmental malformations from exposure.<sup>67,68</sup> In any case, the potential risk posed by Octoxynol-9, in addition to the risks of douching

**Douches commonly include fragrance, which can be made of hundreds of different undisclosed chemicals, some quite toxic, and some certainly associated with allergies—all of which come into direct internal contact with absorptive vaginal mucous membranes.**



itself, make it an inappropriate chemical to include in these products. Douches also commonly include fragrance, which can be made of hundreds of different chemicals, some quite toxic, and some certainly associated with allergies. Fragranced douche thus creates an unnecessary and potentially harmful vaginal exposure to unknown fragrance allergens, irritants and toxic chemicals. For all of these reasons, the American Public Health Association specifically recommends against douching and encourages health care providers to educate their patients on the hazards of the practice.<sup>69</sup>

## Feminine Deodorant (sprays, powders and suppositories)

**F**eminine deodorant sprays are one feminine care product with a known history of adverse effects. When they were initially marketed in the late 1960s, numerous women reported adverse effects, such as burning, rashes and other allergic reactions from their use.<sup>70</sup> This caught the attention of the FDA, which in the 1970s instituted additional labeling regulations for feminine sprays to help prevent adverse effects from use of these products. The labels for feminine deodorant sprays now must state:

*“Caution--For external use only. Spray at least 8 inches from skin. Do not apply to broken, irritated, or itching skin. Persistent, unusual odor or discharge may indicate conditions for which a physician should be consulted. Discontinue use immediately if rash, irritation, or discomfort develops.”*

Similar to feminine wash, the caution that this product is “for external use only” does relatively little to prevent the highly likely scenario that internal vaginal skin will be affected by the product. Feminine deodorant powders and deodorant suppositories are also similar products marketed to women to control or mask genital odor. One problematic chemical that is commonly found in all of these deodorant products is Benzethonium Chloride. This chemical is a powerful disinfectant. In Europe, Benzethonium Chloride is only allowed in rinse-off cosmetic products at a maximum level of 0.1%. The most recent European safety assessment determined that that it could not guarantee safety of use of Benzethonium Chloride in leave-on products due to potential concerns about both maternal and embryo toxicity.<sup>71</sup> In Japan and Canada, regulations specifically restrict Benzethonium Chloride from being used in products applied to mucous membranes.<sup>72,73</sup> In the U.S., the Cosmetic Ingredient Review (CIR) established a safety level of 0.5% Benzethonium Chloride in cosmetics, and allows use in both rinse-off and leave on products of all kinds, including feminine care.<sup>74</sup>

Interestingly, the CIR’s assessment does state that studies found that 0.2% Benzethonium Chloride applied in a foam serves as an effective spermicide. No caution labeling to this effect is required however on feminine care products containing Benzethonium Chloride which are not contraceptive products. Presumably, anyone using these products who is also trying



**Benzethonium Chloride, a preservative, is commonly used in feminine deodorant sprays, powders and suppositories sold in the United States. This same chemical is restricted from use for leave-on products or products that contact mucous membranes in Canada, Japan and the European Union due to safety concerns.**

to get pregnant should be made aware of the presence of this chemical. Benzethonium Chloride appears to be an inappropriate chemical for feminine care products and deserves further investigation.

## Over-the-counter Anti-itch Creams

**F**eminine anti-itch creams are marketed to women to help soothe symptoms of genital itching, which can be caused by numerous factors. Most anti-itch creams are considered “over-the-counter drugs,” meaning that the FDA may review and approve them, but primarily is concerned with only the active ingredient. However, for many of these products, the manufacturer remains largely responsible for ensuring safety and compliance with regulations. These products are commonly used with some studies reporting that up to 23 percent of women use anti-itch creams.<sup>75</sup> Vulvar and vaginal itch is one of the most common health care problems for women in the United States, and the commonly associated condition vaginitis, is a frequent reason for patient visits to gynecologists.<sup>76</sup>

Vaginitis is responsible for between five and ten million patient visits each year in the U.S., at an estimated health care cost of \$1-3 billion.<sup>77,78</sup> These numbers likely underestimate the number of women suffering from itch symptoms given that studies have shown many women opt to “self-treat” their symptoms with over-the-counter products, in an effort to avoid costly medical visits.<sup>79</sup>

This is problematic because anti-itch creams commonly contain allergens or irritants, which can actually serve to exacerbate the very symptoms that women are attempting to treat. One common chemical found in anti-itch creams is benzocaine. Benzocaine is a mild anesthetic, thus it relieves itch by temporarily numbing the affected area. Some women, however, are allergic to benzocaine. In dermatology studies of patients with vulvar and anogenital dermatitis, benzocaine is identified as one of the most common allergens causing symptoms.<sup>80,81</sup> **Other problematic chemicals found in anti-itch creams include parabens and fragrance, both of which may also induce the very itching symptoms that these creams are purported to soothe.** Surprisingly little research has been conducted to appropriately assess either the efficacy or the side effects of these over the counter drugs. Greater attention and scrutiny is needed to protect and aid women who are seeking solutions for these conditions.



**Anti-itch creams commonly contain chemicals that are either allergens or irritants, and can actually serve to exacerbate the very symptoms that women are attempting to treat.**

**T**he good news is that there are steps that you can take to reduce your exposure to chemicals in feminine care products in the short term, and policies you can support to protect public health for the long term.

### Personal Alternatives

- ▶ Reduce your use of feminine care products
- ▶ Eliminate use of products that may be unnecessary to a healthy vagina
- ▶ Choose unscented products where available (particularly tampons and pads)
- ▶ Choose chlorine-free bleached or unbleached cotton tampons and pads
- ▶ Try reusable, washable menstrual pads
- ▶ Try switching brands of products you believe may be associated with allergic symptoms (and if you do switch – call the company’s 1-800 customer service to tell them why!)
- ▶ Read the labels of products (where available) to avoid problematic chemicals discussed in this report
- ▶ Look for brands that disclose all ingredients, including fragrance ingredients
- ▶ Talk with your health care provider about how the use of feminine care products may be affecting your health
- ▶ Tell the FDA if you have had any concerns about or reactions to a feminine care product – Call 1-800-332-1088 or fill out a consumer reporting form available at: <http://www.fda.gov/Safety/MedWatch/default.htm>

## Recommended Federal and Corporate Policy Changes

### Federal Legislation

The Safe Cosmetics and Personal Care Products Act (H.R. 1385 introduced in the 113th Congress), is a bill to improve regulation of cosmetic and personal care products to better ensure these products are safe for consumers to use. The bill requires safety testing and the phasing out of ingredients linked to cancer, birth defects and developmental harm. Cosmetic companies would be required to disclose fragrance ingredients on product labels and company websites. The bill would grant greater authority and resources to the FDA for improved regulation and oversight of cosmetic product safety.

### Food and Drug Administration (FDA) Oversight

The Food and Drug Administration should increase oversight and attention to the regulation and review of feminine care products in light of their unique exposure route to sensitive and permeable vaginal skin. Concerns



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regarding appropriate use of colorants, the applicability of “for external use only” language, and potential warning language on common allergens, especially in anti-itch products, should be considered and addressed.

### **Improved Ingredient Screening Processes and Policies for Products**

Manufacturers should create and implement improved ingredient safety screens to rule out ingredients which may pose unnecessary health risks. Specifically, companies should institute policies to eliminate the use of carcinogens, mutagens, reproductive toxins and endocrine disruptors from feminine care products. Additional screening should be conducted for feminine care products to ensure safety of use on mucous membranes.

### **Ingredient Disclosure Policies**

Manufacturers should disclose all ingredients and additives used in tampons and menstrual pads and all ingredients present in fragrances used in other feminine care products. Additionally, all ingredients which are identified as allergens should be highlighted for product users, in order to help them avoid the ingredients which are problematic for them.

### **Increase Research**

More research is needed from the scientific community to better understand the potential effects of chemical exposure on vaginal and vulvar tissue. Health disparities for feminine care products users based on race, age, and socio-economics should also be examined. Further surveys of product use are also needed to fill data gaps for unstudied demographic groups such as Asian-American and indigenous women.

### **How Can You Help?**

**J**oin Women’s Voices for the Earth to learn more about how you can support policies that protect us from toxic chemical exposure. Visit [www.womensvoices.org](http://www.womensvoices.org)

Use your voice! Share this report and associated materials with friends and family and discuss your concerns about toxic chemicals used in personal care products.

## Chemicals of Concern in Feminine Care Products

**T**his list includes chemicals of concern that are discussed in this report. This list is not exhaustive, other problematic chemicals not on this list may also be found in feminine care products and deserve greater examination.

CHEMICAL NAME	FUNCTION	POTENTIAL HEALTH EFFECTS	FOUND IN
Benzethonium Chloride	Preservative, spermicide	Not for use on mucous membranes, maternal and embryotoxicity	Deodorant powders and suppositories, feminine wash
Benzocaine	Mild anesthetic	Allergic rash, dermatitis	Anti-itch creams
Butylparaben	Preservative	Endocrine disruption, increased risk of breast cancer, allergic rash	Wipes
D&C Red 33	Colorant (dye)	Not for use on mucous membranes	Feminine wash
Diazolidinyl urea	Preservative	Releases formaldehyde, allergic rash, cancer	Feminine wash, douche
Dioxins and Furans	Contaminant from bleaching process	Cancer, endocrine disruption, reproductive toxicity	Tampons (not disclosed on label)
DMDM Hydantoin	Preservative	Releases formaldehyde, allergic rash, cancer	Wipes, feminine wash
Ethylparaben	Preservative	Endocrine disruption, increased risk of breast cancer, allergic rash	Wipes
Ext. Violet 2	Colorant (dye)	Not for use on mucous membranes	Feminine wash
FD&C Yellow No.5	Colorant (dye)	Allergic reactions including bronchial asthma	Feminine wash
Fragrance	Fragrance	Contains undisclosed chemicals of unknown toxicity, likely to contain allergens, allergic rash, endocrine disruption, cancer	Wipes, feminine wash, tampons, pads, douche, deodorant, anti-itch creams
Methylchloroisothiazolinone	Preservative	Allergic rash	Feminine wash
Methylisothiazolinone	Preservative	Allergic rash	Wipes, feminine wash, anti-itch cream
Methylparaben	Preservative	Endocrine disruption, increased risk of breast cancer, allergic rash	Wipes, deodorant, anti-itch creams
Octoxynol 9	Spermicide	Genital irritation, increased vaginal discharge, potential reproductive toxicity	Douche
Pesticide residues	Contaminant of traditionally grown cotton	Cancer, endocrine disruption, acute toxicity	Tampons (not disclosed on label)
Polyoxymethylene Urea	Preservative	Releases formaldehyde, allergic rash, cancer	Deodorant powder
Propylparaben	Preservative	Endocrine disruption, increased risk of breast cancer, allergic rash	Wipes, anti-itch creams
Quaternium-15	Preservative	Releases formaldehyde, allergic rash, cancer	Wipes, feminine wash
2-Bromo-2-Nitropropane-1, 3-Diol	Preservative	Releases formaldehyde, allergic rash, cancer	Wipes

- 1 Examples on [www.summerseve.com](http://www.summerseve.com), [www.tampax.com](http://www.tampax.com), [www.fds.info](http://www.fds.info), [www.vagisil.com](http://www.vagisil.com).
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 **WOMEN'S VOICES FOR THE EARTH**

is a national organization that works to eliminate toxic chemicals that harm women's health by changing consumer behaviors, corporate practices and government policies.



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