

08 August 2024

Ron Lombardi President & CEO Prestige Consumer Healthcare, Inc. 660 White Plains Road Tarrytown, NY 10591

Dear Mr. Lombardi,

We are writing to you on behalf of Women's Voices for the Earth and 18 of concerned organizations across the country to express our concerns about your Summer's Eve Ultimate Odor Protection products, as well as your Monistat Maintain Boric Acid Wash. We are organizations that work to improve public health by reducing and eliminating consumers' exposure to toxic chemicals. We are especially concerned about toxic chemical exposure from the use of intimate care products, and the impact they have on reproductive health.

After reviewing publicly available information about your products, we have found:

- 1. These intimate care products contain boric acid, a potent reproductive toxicant. Boric acid is prohibited from use in cosmetics in the European Union due to its classification as a reproductive toxicant.
- 2. These products do not include any warning against use during pregnancy or prepregnancy.
- 3. The marketing of these products is deceptive, leading your customers to misunderstand the purpose/impact of the products and their ingredients, leading to unhealthy use in the following ways:
- a. The marketing incorrectly implies that daily vaginal exposure to boric acid is a preventative measure, when boric acid is only recommended by healthcare providers for vaginal use as a drug of last resort for chronic infections.
- b. The marketing of these products as "ph-balanced" incorrectly implies that these products will help fix or maintain a healthy vaginal pH to prevent infections or other conditions.
- c. The marketing of these products incorrectly implies that boric acid controls vaginal odor.

To protect the health of your customers and prevent unnecessary confusion about the potential uses of your products, we ask for you to eliminate the use of toxic chemicals, like boric acid, from all of your personal care products including your Summer's Eve Ultimate Odor Protection products and Monistat Maintain Boric Acid Wash.

We also ask that you stop spreading the misinformation that boric acid controls vaginal odor and that vaginal application of boric acid is safe and healthy for daily use. This marketing leads users to be more likely to use these washes internally, as they seek to get at the perceived source of the odor.

See the attached addendum for further information about our concerns.

We would like to meet with you by phone or Zoom to further discuss these issues. Please respond by August 30th to Alexandra Scranton, WVE's Director of Science and Research, at alexs@womensvoices.org or by phone at 720-667-8778 to set up a time.

Thank you for your attention to this matter.

Alexandra Scranton

Director of Science and Research

Women's Voices for the Earth

On behalf of



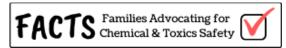




























Form, LLC Los Jardines Institute Moms for a Nontoxic New York

ADDENDUM Summary of Concerns

1. These intimate care products contain boric acid, a potent reproductive toxicant.

We believe that no responsible company should manufacture an intimate care product which intentionally includes a known reproductive toxicant as an ingredient. The Safety Data Sheets (SDS) for these products are clear that boric acid is a Category 1B Reproductive Toxicant, requiring the hazard statements "May damage fertility or the unborn child." Studies have shown that use of boric acid vaginal suppositories during pregnancy leads to significantly increased risk of birth defects.¹ There are no available studies to show that a potentially smaller exposure to vaginal boric acid during pregnancy (such as exposure from daily use of an intimate wash) would be any less harmful.

2. <u>Boric acid is prohibited from use in cosmetics in the European Union due to its classification as a reproductive toxicant.</u>

In 2019 the European Union amended Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products to add boric acid to Annex II, the List of Substances Prohibited in Cosmetic Products.² Boric acid has been classified as "Repr 1B" reproductive toxicant in the European Union.

3. <u>Product packaging does not include any language warning against use during pregnancy or pre-pregnancy.</u>

Unlike Monistat Maintain Boric Acid Suppositories (an OTC drug product) none of the Summer's Eve Ultimate Odor Protection products nor the Monistat Maintain Boric Acid Wash contain any language warning against use during pregnancy. As stated previously, there is no available evidence that exposure to vaginal boric acid during pregnancy from daily use of an intimate wash is safe during pregnancy. There is no known "no-effect level" for vaginal boric acid during pregnancy which poses no increased risk of birth defects.

And it is clear that pregnant women do use these products. For example, this product review found on Amazon for Summer's Eve Ultimate Odor Protection wipes states:

"Stacey

5.0 out of 5 stars <u>Great for on the go</u> Reviewed in the United States on February 18, 2024

Size: 12 Count (Pack of 1

These fenine wipes are perfect to throw in my purse or the glove box of my car. Whenever you need a refresh you can easily use and dispose of a wipe. This is such a nice smart idea coming individually wrapped. I will never leave home without having a few of these with me. Especially being 7 months pregnant I need an occasional refresh."

Source: https://www.amazon.com/Summers-Eve-Ultimate-Control-Feminine/dp/B0CLWTMBBC?th=1

It is a serious disservice to your customers (who may be pregnant or intending to become pregnant) to not warn them about the potential significant harm of boric acid exposure to their child.

The marketing of these products is deceptive, leading your customers to misunderstand the purpose/impact of the products, leading to unhealthy misuse in the following ways:

4. The marketing incorrectly implies that daily vaginal exposure to boric acid is a preventative measure, when boric acid is only recommended for vaginal use as a drug of last resort for chronic infections.

The Monistat brand is clearly associated with the long-marketed Monistat yeast infection OTC treatments. Marketing an intimate wash under this brand name is clearly misleading customers into thinking that the intimate wash will have either the same effects or will help with preventing yeast infections. Furthermore, by marketing a Summer's Eve wash highlighting the inclusion of boric acid, you are also misleading customers who already associate boric acid suppositories as treatments for yeast infections and chronic bacterial vaginosis. Even without direct language the connection to preventing yeast infections is entirely implied.

Your company is aware of this confusion among your customers. The product reviews speak for themselves, making clear what many of your customers misunderstand your products.

These reviews of Monistat Maintain feminine wash indicate the users are using the product to treat and/or prevent vaginal conditions such as yeast infections.

5 out of 5 stars review

Verified Purchase

9/23/2023

This is working very well to heal up some sores on body. Make sure to rinse well.

Source: https://www.walmart.com/reviews/product/1875799075

miss wood nc

5.0 out of 5 stars Great feminine wash

Reviewed in the United States on January 1, 2024

<u>Scent: UnscentedSize: 10 Fl Oz (Pack of 1)Verified Purchase</u>

I'm on jardiance and ozempic which causes you to urinate sugar out leading to yeast infections and uti, this has been a great wash for this.

4 people found this helpful

Source: https://www.amazon.com/gp/customerreviews/R2ONT1T2H9F3FI/ref=cm_cr_getr_d_rvw_ttl?ie=UTF8&ASIN=B08QPQ1P7G

adrian

4.0 out of 5 stars Not sure it's working

Reviewed in the United States on July 23, 2023

Scent: UnscentedSize: 10 Fl Oz (Pack of 1)Verified Purchase

I can tell it cleanses, I feel clean after using it. I'm not sure it works super great in preventing yeast infections, I still experience some symptoms, I know it's not a treatment but I thought it would help more than it is. Not 100% satisfied. Think I will try something else next time.

This review indicates that the user believes the boric acid in Summer's Eve Ultimate Odor Protection Wipes will help promote good bacteria and get rid of bad, connecting her use to helping with the chronic bacterial vaginosis she has experienced.

Life changing!

5 out of 5 stars leahg31 - 2 months ago originally posted on influenster.com

The Summer's Eve Ultimate Odor Protection Wipes are seriously life-changing! I have been plagued with bacterial vaginosis my whole life. I have to be very careful about anything I use from my underwear to my toilet paper. I was initially worried about using these wipes but when I sen they had boric acid in them I was relieved. I had never heard of using boric acid for intimate health until a few months ago and now I will never be without it. These wipes are thick and durable. They feel cloth-like and are a great size. I love that they come in this little sachet so you can throw a couple into your purse or even into your pocket for on-the-go. They help cut down on odor and leave me smelling and feeling fresh and clean. The boric acid helps promote good bacteria and helps get rid of the bad stuff. I will continue to purchase them because they are the only wipes that work for me and Summer's Eve is a brand I trust with my intimate health. Source: https://www.target.com/p/summer-39-s-eve-odor-relief-with-boric-acid-wipes-12ct/-/A-89568645?ref=tgt_adv_xsf&AFID=google&CPNG=Health&adgroup=245-3

The misunderstanding that these intimate care products can help prevent or treat infections, also means that users are applying these intimate care products intravaginally in order to have an effect. The instructions indicating "for external use only" are clearly being ignored, a situation which your company has long understood to be a reality.

5. The marketing of these products as "pH-balanced" incorrectly implies that these products will help fix or maintain a healthy vaginal pH to prevent infections or other conditions.

There is a general understanding that maintaining an appropriately acidic vaginal pH (i.e. 3- 4.5) is beneficial to vaginal health. People associate the idea of having a disturbed vaginal pH with the increased risk of vaginal infections such as bacterial vaginosis (BV) and yeast infections. However, the term "pH-balanced" on your products actually refers to a pH that is

more appropriate for vulvar skin (i.e. pH of 5) than your average soap product which may have a pH of 6 or more. The pH of your wash products are in fact quite high for vaginal contact and could create an imbalance of vaginal pH. Your customers, however, are commonly confused by your marketing language — and thus likely to be using your wash products internally, in an attempt to improve or balance their vaginal pH.

The Summer's Eve website states that the Ultimate Odor Protection wash contains: "a boric acid complex for a pH-balanced wash that matches the body's natural chemistry".

The Monistat Maintain Feminine Cleanser label states:

"Unique pH balanced complex match a healthy pH"

While we understand this means the product is formulated to match the pH of external vulvar skin, this language is easily misinterpreted to mean that the boric acid is included in the product to help balance vaginal pH, and thus will help prevent or treat infections. Again, we can look to the reviews of these products, to see the common misinterpretation which occurs with your customers.

Reviews of Monistat Boric Acid Feminine Cleanser state:

Dayna Murphy

5.0 out of 5 stars It helped me restore balance and comfort where it mattered most.

Reviewed in the United States on October 24, 2023

Scent: UnscentedSize: 10 Fl Oz (Pack of 1)Verified Purchase

"The Monistat Boric Acid Feminine Cleanser has been a real game-changer for me. After several surgeries, my pH balance was completely thrown off, and I was struggling to get back to normal. This fragrance-free wash proved to be a crucial part of my recovery. It helped me restore balance and comfort where it mattered most. It's gentle, effective, and truly a relief in a bottle. I'm grateful for products like this that make the healing process more manageable. If you're in a similar situation, I highly recommend giving it a try."

https://www.amazon.com/Monistat-Maintain-Feminine-Boric-Fragrance/product-

 $reviews/B08QPQ1P7G/ref=cm_cr_arp_d_viewopt_kywd?ie=UTF8\&reviewerType=all_reviews\&pageNumber=1\&filterByKeyword=boric+acid$

Sasha

5.0 out of 5 stars Worth every scent!

Reviewed in the United States on January 15, 2022

Scent: UnscentedSize: 10 Fl Oz (Pack of 1)Verified Purchase

One of the best feminine washes in the game! Since being introduced this product over 6 months ago, it is all that I use. If you are aware of the benefits of using boric acid suppositories to combat BV and yeast infections, then you will find this feminine wash product to be very helpful. My intimate area is very sensitive and I find this wash has never caused any irritation. It does not have a scent, which I prefer because it thoroughly cleans and maintains my PH balance. This product is definitely worth a try. I highly recommend over other mainstream brands of feminine wash products.

5 people found this helpful

 $https://www.amazon.com/gp/customer-reviews/R1VYXX1B3QNQPV/ref=cm_cr_getr_d_rvw_ttl?ie=UTF8\&ASIN=B08QPQ1P7G$

Monistat Maintain Feminine Cleanser

Kay414

3 years ago

As a woman in my mid 30's, my own personal care has become more important than ever. I've tried other feminine washes in the past. None like Monistat's Feminine Cleanser with Boric Acid!... My hope in using this is to keep my p-H balanced, as well as try to prevent possible infections. There are different soaps for every age group! It's ok to use what you need. I'd highly recommend!

https://www.riteaid.com/shop/monistat-maintain-feminine-cleanser-with-boric-acid-10-fl-ozen and the complex of the complex o

Highland Lass

5.0 out of 5 stars Best Wash

Reviewed in the United States on September 17, 2022

When dealing when a yeast infection from hell this stuff works great and brings comfort. The boric acid kills the bacteria, itching and burning.

https://www.amazon.com/gp/customer-reviews/ROUMD9I97P2SV/ref=cm_cr_getr_d_rvw_ttl?ie=UTF8&ASIN=B08QPQ1P7G

Undoubtedly these users are using the wash internally in an effort to impact their vaginal pH, because they have understood from the marketing that this is what these products are intended to do.

6. The marketing of these products incorrectly implies that boric acid controls vaginal odor.

We are unaware of any research (or patents) which find that boric acid has any properties which control vaginal odor. However, marketing for both Monistat Maintain and Summer's Eve Ultimate Odor Protection strongly implies that the addition of boric acid does control vaginal odor.

The website for Summer's Eve Ultimate Odor Protection Daily Refreshing Wash states:

"Summer's Eve Ultimate Odor Protection was containing a patented odor-reducing ingredient and a boric acid complex for a ph-balanced wash that matches the body's natural chemistry."

The website frequently states the product is "formulated with Patented Odor Reducing Ingredient" without naming the ingredient.

The reviews of Summer's Eve Ultimate odor products clearly show the confusion among your customers – who incorrectly believe that the boric acid ingredient is patented to reduce odor.

Sarah

5.0 out of 5 stars Odor killer! Super refreshing, burns slightly

Reviewed in the United States on February 29, 2024

I love these little wipes when I need to refresh myself. I'm 42 and starting perimenopause... which means everything down there is changing. I have days where I'm self-conscious because of odor, and some days I just feel a little dry or need some moisture. These boric acid wipes are perfect!

I've sworn by boric acid suppositories for a while now. They seem to neutralize any funky odors within one or two uses. I don't think these wipes have enough to stop major odor, but they definitely work for small issues.

https://www.amazon.com/gp/customer-reviews/R11P9VAR7YX3QP/ref=cm_cr_getr_d_rvw_ttl?ie=UTF8&ASIN=B0CLWTMBBC

The misinformation that boric acid controls vaginal odor further promotes the inaccurate notion that vaginal boric acid is safe and healthy for regular application. It also leads users to be more likely to use these washes internally, to get to the perceived source of the odor.

Thank you in advance for considering our concerns.