

DATA SUPPLEMENT

Acacia senegal

Butoxyethanol

Centaurea cyanus flower

Fatty Amphocarboxylates

2-Nitro-*p*-Phenylenediamine

Sodium Borate

EXPERT PANEL MEETING

JUNE 15-16, 2026

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Monice Fiume, M.B.A.,
Senior Director, CIR
Date: June 5, 2026
Subject: Wave 2 - Draft Final Amended Report on the Safety Assessment of Acacia Senegal Gum and Acacia Senegal Gum Extract as Used in Cosmetics

Enclosed please find comments submitted by PCPC on the Draft Final Amended Report on the Safety Assessment of Acacia Senegal Gum and Acacia Senegal Gum Extract as Used in Cosmetics (*PCPCcomments_AcaciaSenegal_Wave2_062026*). This editorial change will be made in the final document.



Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Jaap Venema, Ph.D.
EVP and Chief Scientist – Personal Care Products Council
Industry Liaison to the CIR Expert Panel

DATE: June 1, 2026

SUBJECT: Draft Final Amended Report: Amended Safety Assessment of Acacia Senegal Gum and Acacia Senegal Gum Extract as Used in Cosmetics (June 2026 meeting draft)

The Personal Care Products Council respectfully submits the following comment on the draft final amended report, Amended Safety Assessment of Acacia Senegal Gum and Acacia Senegal Gum Extract as Used in Cosmetics.

Summary – The Summary incorrectly states: “According to the RLD submitted to CIR in 2025, Acacia Senegal Gum is not used...”. The use section and Table 3 report 2938 uses for Acacia Senegal Gum in the RLD.



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, MSES, Senior Scientific Analyst/Writer, CIR
Date: June 5, 2026
Subject: Wave 2 – Amended Safety Assessment of Butoxyethanol as Used in Cosmetics

Please find attached the comments provided by the Personal Care Products Council on the Draft Final Amended Report on Butoxyethanol. The comments are all editorial.



Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Jaap Venema, Ph.D.
EVP and Chief Scientist – Personal Care Products Council
Industry Liaison to the CIR Expert Panel

DATE: June 1, 2026

SUBJECT: Draft Final Amended Report: Amended Safety Assessment of Butoxyethanol as Used in Cosmetics (June 2026 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the draft final amended report, Amended Safety Assessment of Butoxyethanol as Used in Cosmetics.

Developmental and Reproductive Toxicity – What doses were used in the dermal studies? What exposure concentrations (or doses) were used in the inhalation studies?

Developmental and Reproductive Toxicity – Based on the summary of the DART information from the original CIR report, it is not possible to link the NOAELs used by the SCCS to a specific study summarized in the original CIR report. If possible, please provide the primary reference for the source of the NOAELs used by the SCCP.

Carcinogenicity, Mechanism – Please revise the following sentence: “However, neither Butoxyethanol nor butoxyacetic acid (a metabolite) did not directly activate macrophages, as evidenced by a lack of TNF- α production from macrophages.” (it would be clearer if “did not” was deleted, and “activate” was changed to “activated”)

Summary – Please revise: “In a 90-d inhalation study in rats, the NOAEC was less than 50 ppm exposed to Butoxyethanol 7 h/d for 5 d/wk.” (it would be clearer if “in rats” was moved before exposed)



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Litta Paulson, M.P.H., Scientific Analyst/Writer, CIR
Date: June 5, 2026
Subject: Wave 2 - Safety Assessment of *Centaurea cyanus* Flower-Derived Ingredients as Used in Cosmetics

Summary data (*data_CentaureaCyanus_Wave2_062026*) was provided on Centaurea Cyanus Flower Extract. This data includes the following:

- Chemical properties and method of manufacturing
- Composition and impurities



Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: May 22, 2026

SUBJECT: Centaurea Cyanus Flower Extract

Anonymous. 2026. Summary: Method of manufacture and composition information Centaurea Cyanus Flower Extract.

Chemical properties and method of manufacturing data

Add 1,3-butylene glycol solution to the inflorescence of *Centaurea cyanus* L. (Compositae), extract, purify, allow it to stand in a cold place, and filter after quality standardization to obtain the final product.

No synthetic reagents, preservatives, or chemical modifications are used.

Composition and Impurities

As sold to the cosmetics industry, this ingredient is a mixture, which is composed of Butylene Glycol : Water : Centaurea Cyanus Flower Extract (49.725 : 49.725 : 0.550). Centaurea Cyanus Flower Extract contains flavonoids and tannins.

Heavy metals and pesticide residues comply with cosmetic ingredient standards (Heavy metals <20 ppm, Arsenic <2 ppm). (JSQI)

No synthetic additives or preservatives are present.



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Priya Ferguson, M.S., Senior Scientific Analyst/Writer, CIR
Date: June 5, 2026
Subject: Wave 2 – Safety Assessment of Fatty Amphocarboxylates Used in Cosmetics

Please find attached the comments provided by the Personal Care Products Council (Council) on the Draft Final Report on the Safety Assessment of Fatty Amphocarboxylates as Used in Cosmetics (*PCPCcomments_FattyAmphocarboxylates_Wave2_062026*). If the Panel is in agreement with the comments, these will be addressed following the June Panel meeting.



Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Jaap Venema, Ph.D.
EVP and Chief Scientist – Personal Care Products Council
Industry Liaison to the CIR Expert Panel

DATE: June 1, 2026

SUBJECT: Draft Final Report: Safety Assessment of Fatty Amphocarboxylates as Used in Cosmetics (June 2026 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the draft final report, Safety Assessment of Fatty Amphocarboxylates as Used in Cosmetics.

Non-Cosmetic Use – 21CFR178.1010 provides a list of ingredients that FDA says “may be safely used” as sanitizing agents for food-processing equipment and utensils. It does not provide proof that the ingredients are used for this purpose.

Dermal Irritation and Sensitization – In the text, rather than giving a range of the number of subjects used in the HRIPTs, please indicate the number of subjects with the concentration tested in each study.

Reference 4 (HRIPT of Sodium Lauroamphoacetate 0.15% solids tested at 0.5% in 99 subjects) is described twice (once at the end of the fifth paragraph, and in the last paragraph). One description should be deleted.

Ocular Irritation – Rather than “in assays performed in humans”, please describe the study in which subjects used a cleanser containing Disodium Cocoamphoacetate as a use study.



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, MSES, Senior Scientific Analyst/Writer, CIR
Date: June 5, 2026
Subject: Wave 2 – Amended Safety Assessment of 2-Nitro-*p*-Phenylenediamine as Used in Cosmetics

Please find attached the comment provided by the Personal Care Products Council on the Draft Final Amended Report on 2-Nitro-*p*-Phenylenediamine. The comment is a suggested editorial revision in the original report summaries.



Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Jaap Venema, Ph.D.
EVP and Chief Scientist – Personal Care Products Council
Industry Liaison to the CIR Expert Panel

DATE: June 1, 2026

SUBJECT: Draft Final Amended Report: Amended Safety Assessment of 2-Nitro-p-Phenylenediamine as Used in Cosmetics (June 2026 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the draft final amended report, Amended Safety Assessment of 2-Nitro-p-Phenylenediamine as Used in Cosmetics.

ADME, Animal, Dermal and Human, Dermal, old report summary – Both subsections say: “under direct conditions”. A reader not familiar with different hair dye types may not understand what this means as there is no explanation in the CIR report until Hair Dye Epidemiology section. Perhaps, this should be revised to “under conditions representing direct hair dye use”.

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Jinqiu Zhu, PhD, DABT, ERT, DCST, CIR Toxicologist
Temima Nguyen, M.S., Scientific Analyst/Writer, CIR
Date: June 5, 2026
Subject: Wave 2 – WVHJ’s comments on the Tentative Amended Safety Assessment of Sodium Borate and Boric Acid as Used in Cosmetics

Attached are comments dated June 4, 2026 from Weaving Voices for Health & Justice (WVHJ) on the draft Tentative Amended Safety Assessment of Sodium Borate and Boric Acid as Used in Cosmetics (identified as *WVHJcomments_SodiumBorate_Wave 2_062026*), along with an accompanying FDA Adverse Event Monitoring System (AEMS) database search for Summer’s Eve and Monistat products from January 2024 through April 2026 (identified as *WVHJ_AEMS_database_Wave 2_062026*). WVHJ’s comments focus on four main points: 1) Boric Acid vaginal suppositories are not discussed in the assessment; 2) the margin of exposure (MOE) calculation is not protective of health; 3) FDA AEMS reports should be considered; and 4) additional Boric Acid-containing intimate washes and douches may not be reflected in the 2025 RLD.

Response to WVHJ Comments

1. Potential product-classification issue

Some of the examples provided by WVHJ, particularly Boric Acid vaginal suppositories and certain products marketed for intravaginal use, may raise product-classification questions that depend on the specific product claims, labeling, intended use, and directions for use. Products marketed with therapeutic claims, or intended for treatment, mitigation, or prevention of infection or other vaginal conditions, may be regulated as drug or over-the-counter (OTC) drug products rather than as cosmetics. Evaluation of drug or OTC drug uses is outside the purview of the Expert Panel. Therefore, these examples should not be used to expand the scope of the cosmetic ingredient safety assessment beyond reported cosmetic uses of Boric Acid and Sodium Borate, unless further clarification from the US FDA indicates that these products fall within cosmetic exposure scenarios. For instance, WVHJ states that some Boric Acid vaginal suppositories are marketed for odor control or vaginal freshness and may contain 600 mg Boric Acid per suppository, which WVHJ estimates as approximately 20% Boric Acid in a 3-g suppository. These products represent a materially different exposure scenario from the low-concentration rinse-off cosmetic uses for which concentration-of-use data were submitted to CIR.

2. Risk assessment and data insufficiency

The current MOE calculation in the draft report is based on the maximum reported cosmetic concentration of 0.00016% Boric Acid in rinse-off body wash products. For the Boric Acid MOE, CIR staff used the PCPC daily product amount for body wash (25,500 mg/d, 90th percentile),¹ a retention factor of 0.01, and a conservative assumption of 100% mucosal absorption of the retained amount. This calculation was intended to provide a conservative estimate for a rinse-off wash scenario with potential genital-area exposure. It is specific to the assessed rinse-off exposure scenario and should not be extrapolated to other intimate-care products or to retained intravaginal use.

CIR Staff also considered additional exposure models for douches and intimate hygiene wipes. The 2025 RLD reported 1 use of Boric Acid in douches and 7 uses in disposable wipes; these product categories may also be associated with intimate-area exposure. However, concentration-of-use data were not available for these specific categories; therefore, quantitative Systemic Exposure Dose (SED) and MOE calculations for douches and disposable wipes were not included in the report. Based on National Institute for Public Health and the Environment (RIVM) of the Netherlands models,² the intimate hygiene wipe (leave-on) use scenario assumes a default use frequency of 463 uses/yr and an amount of product available for exposure of 0.75 g/use, resulting in an estimated daily product amount of 0.95 g/d (with a retention factor of 1.0 applied). The douche use scenario assumes a product

amount of 133 g/use, a use frequency of 71 uses/yr, and a retention factor of 0.1, resulting in an estimated daily applied product amount of 25.9 g/d and an estimated daily retained amount of 2.59 g/d.

Thus, exposure inputs for intimate hygiene (disposable) wipes and douches are available; the limiting data gap is the absence of category-specific concentration-of-use data. The available maximum concentration of 0.00016% from the Council survey was reported for rinse-off body wash/shampoo-type products and should not be assumed to apply to douches or disposable wipes without category-specific concentration data. If such concentration data become available, additional MOE calculations could be performed. For those calculations, CIR staff might conservatively assume 100% absorption of the amount available for exposure for leave-on wipes, or 100% absorption of the retained amount for douches.

It should also be noted that, at the September 2025 meeting, the Panel issued an Insufficient Data Announcement (IDA) requesting data relevant to mucosal and vaginal exposure assessment; however, since the IDA was issued, CIR has not received the requested data. The data needs included:

- MOE calculations for cosmetic uses that result in mucosal and vaginal exposures.
- Mucosal absorption data
- Vaginal absorption and total application surface area data
- Maximum concentration for Sodium Borate in products applied near the eye area, that result in mucous membrane exposure, and in douches
- Maximum concentration for Boric Acid when used in products applied near the eye

NOAEL selection

WVHJ questioned the use of an oral developmental and reproductive toxicity point of departure (POD) for a scenario involving potential vaginal or mucosal exposure. WVHJ also stated that some vaginally-applied chemicals may be preferentially distributed to the uterus with limited systemic circulation. While route-to-route extrapolation introduces uncertainty, it should be noted that product-specific concentration of use data and exposure data for retained intravaginal cosmetic use remain insufficient. In addition, vaginally-administered pharmaceuticals are designed for drug delivery and may involve different formulations, doses, retention times, pharmacological targets, and exposure conditions than cosmetic intimate care products, such as rinse-off douches or leave-on intimate wipes.

The MOE calculation included in the draft Tentative Amended Report is intended to assess potential systemic exposure relative to the reproductive and developmental toxicity POD for Boric Acid. The calculation uses a conservative assumption of 100% absorption of the retained amount from the rinse-off body wash use scenario. This approach is intended to evaluate potential systemic exposure and should not be interpreted as an assessment of local vaginal irritation, local tissue effects, or retained intravaginal use.

The European Commission Scientific Committee on Consumer Safety (SCCS) applied the same developmental toxicity NOAEL of 55 mg Boric Acid/kg bw/d (equivalent to 9.6 mg boron/kg bw/d)³ in their MOE calculation for boron compounds in cosmetic bath products. In their calculation, a dermal absorption rate of 0.5% was used.⁴

The oral developmental and reproductive toxicity POD used in the CIR assessment is consistent with values used by other authoritative risk assessments for boron compounds. European Food Safety Authority (EFSA) identified the Price et al. (1996)³ rat developmental toxicity study as the pivotal study and selected an NOAEL of 55 mg Boric Acid/kg bw/d, equivalent to 9.6 mg boron/kg bw/d, based on decreased fetal body weight. EFSA applied an uncertainty factor of 60 and established a group Acceptable Daily Intake (ADI) of 0.16 mg boron/kg bw/d for Boric Acid and Sodium Tetraborate. Similarly, the US Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS) assessment identified decreased fetal body weight in rats as the critical effect for boron compounds and derived an oral Reference Dose (RfD) of 0.2 mg boron/kg/d based on a BMDL₀₅ of 10.3 mg boron/kg/d from the developmental toxicity data of Heindel et al. (1992)⁵ and Price et al. (1996)³ studies, with a uncertainty factor of 66 applied.⁶

Importantly, both the EFSA ADI and the US EPA RfD are health-based guidance values intended to represent daily lifetime exposures that are not expected to present an appreciable risk to human health, including sensitive populations, after application of uncertainty factors. It should also be noted that an MOE greater than 100 has traditionally been considered acceptable in CIR safety assessments when the POD is derived from animal data and the endpoint is systemic toxicity. This default value reflects the conventional 10-fold factor for interspecies differences and 10-fold factor for intraspecies variability, including toxicokinetic and toxicodynamic considerations.

3. FDA AEMS reports

WVHJ submitted an AEMS summary identifying 119 report entries for selected products from January 2024 through April 2026, including 47 reports for products identified as containing Boric Acid, 44 reports for products possibly containing Boric Acid, and 28 reports for products identified as not containing Boric Acid. The AEMS table lists reported adverse event terms under the column “Event MedDRA PT(s)” (Medical Dictionary for Regulatory Activities), including urinary tract infection, fungal infection, bacterial vaginosis, burning sensation, chemical burn, vulvovaginal burning, vulvovaginal pain, vulvovaginal swelling, and related infection or irritation terms. One entry involving a Boric Acid-containing intimate-care product was reported with hospitalization

and life-threatening outcomes. These reports identify the types of adverse events captured in AEMS, but do not establish that Boric Acid caused the reported events.

These data may be useful as post-market safety information, but they should be interpreted cautiously. AEMS is a post-market adverse-event reporting system that relies on submitted reports, including reports from industry, healthcare providers, and consumers. As with passive adverse-event reporting systems, AEMS data are useful for identifying potential safety signals, but they cannot establish incidence, causality, or comparative risk without reliable information on the number of exposed consumers, frequency of product use, product-specific exposure conditions, and clinical confirmation of the reported events. For example, many reported events, including bacterial vaginosis, fungal infection, and urinary tract infection, may also represent underlying conditions for which consumers used the product or conditions that occurred independently of product use. In addition, similar adverse event terms were reported for products identified as “containing,” “possibly containing,” and “not containing” Boric Acid, which further limits any ingredient-specific causal interpretation. Concomitant drug treatments, co-reported products, incomplete product identification, and uncertainty regarding whether the reported product was a cosmetic, drug, or both further limit the ability to determine whether the reported events were caused by Boric Acid. Therefore, the AEMS reports may be described as safety-signal or post-market complaint information, but they do not by themselves demonstrate that Boric Acid caused the reported events or that all listed products are appropriately classified as cosmetics.

4. Additional market examples and RLD

WVHJ provided examples of marketed Boric Acid-containing intimate washes and douches and stated that these products may not all be reflected in the 2025 RLD. These examples are useful in showing that Boric Acid-containing intimate-care products are present in the marketplace and may include product types or use patterns that are not fully captured in the available use and concentration-of-use datasets. They also raise a reasonable question as to whether certain intimate-care product categories may involve Boric Acid concentrations or exposure conditions that differ significantly from those currently reflected in the CIR report.

However, website screenshots and ingredient listings generally do not provide verified quantitative concentration data, and product listings may change over time. CIR’s exposure and risk assessment are based on the maximum use concentrations reported in the Council’s survey. Concentrations reported for one product category should not be assumed to apply to other product categories, particularly products involving direct vaginal or mucosal exposure, without category-specific concentration-of-use data.

Accordingly, marketplace examples may be useful for identifying potential data gaps, but they do not provide an adequate basis for quantitative MOE calculations unless verified concentration data are available. Manufacturers seeking to ensure that such use patterns are reflected in CIR safety assessments should submit updated, product category-specific concentration-of-use information through the Council survey process.

The Panel is asked to review WVHJ’s comments, the accompanying AEMS summary, and the staff response, and to provide guidance on whether any additional considerations should be reflected in the safety assessment.

Reference:

1. Loretz L, Api AM, BarraJ L, et al. Exposure data for personal care products: hairspray, spray perfume, liquid foundation, shampoo, body wash, and solid antiperspirant. *Food Chem Toxicol*. 2006;44(12):2008–2018.
2. National Institute for Public Health and the Environment (RIVM) of the Netherlands. Cosmetics Fact Sheet Default parameters for estimating consumer exposure - updated version 2025. <https://www.rivm.nl/bibliotheek/rapporten/2025-0099.pdf>. 2025.
3. Price CJ, Strong PL, Marr MC, Myers CB, Murray FJ. Developmental toxicity NOAEL and postnatal recovery in rats fed boric acid during gestation. *Fundam Appl Toxicol*. 1996;32(2):179–193.
4. Scientific Committee on Consumer Safety. 2010. Opinion on Boron compounds. https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_027.pdf.
5. Heindel JJ, Price CJ, Field EA, et al. Developmental toxicity of boric acid in mice and rats. *Fundam Appl Toxicol*. 1992;18(2):266–277.
6. U.S. Environmental Protection Agency (EPA). Boron and Compounds; CASRN 7440-42-8. https://iris.epa.gov/static/pdfs/0410_summary.pdf. 2004.



WeavingVoices

FOR HEALTH & JUSTICE

June 4, 2026

To the CIR:

I am writing on behalf of Women's Voices for the Earth to offer comments on the Re-Review of the Safety Assessment of Boric Acid and Sodium Borate as Used in Cosmetics.

Our comments include the following points:

1. This safety assessment currently omits any mention of boric acid suppositories.
2. The method of calculation of the MOE in this assessment is not protective of health.
3. The safety assessment should consider adverse event reports collected by FDA.
4. There are additional examples of boric acid cosmetics that may not be reflected in the RLD data.

1) This safety assessment currently omits any mention of boric acid suppositories.

Boric acid suppositories are leave on cosmetic products, marketed to control odor and support “vaginal freshness”. These products usually contain 600 mg of boric acid, which in a 3 g suppository would roughly translate to at least a 20% concentration of boric acid in this leave on product (about 100,000 times higher than the maximum concentration of boric acid mentioned in the safety assessment.)

Example:

SHOP ▾ LEARN ▾ SYMPTOM CHECKER

AZO

Home > Shop > Vaginal Health > AZO® Boric Acid Suppositories

VAGINAL

AZO® Boric Acid Suppositories

★★★★☆ 4.3 (175) REVIEWS [Write a review](#)

Vaginal suppositories to support odor control and intimate health

- Your vagina is usually a no-go area for smelly bacteria, but sometimes bacteria and yeast can move in. AZO® Boric Acid Suppositories are your go-to for maintaining the vaginal environment when yeast and odor causing bacteria linked to menstruation, intimacy, menopause & more, cause you to feel less fresh.

PACK SIZE

14 Suppositories \$0.71/ea	30 Suppositories \$0.70/ea
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Larger count size may ship as two separate product containers.

<https://azoproducts.com/products/azo-boric-acid?>

The CIR definition of a cosmetic product is:

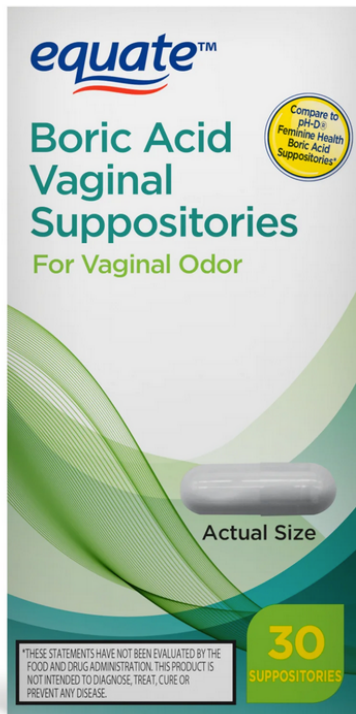
“Cosmetic” means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that it shall not include soap.

The vaginal suppository shown above is a product introduced into the body for promoting attractiveness (ie a “fresh scent”). Another quote from the Azo website about their product says:

“Your vagina is self-cleaning. Most of the time. But sometimes, bacteria and yeast can move in and raise a stink – completely normal but can leave you feeling uncomfortable. AZO® Boric Acid Suppositories help maintain the vaginal environment so you can feel confident and experience the freshness you deserve.”

While certainly boric acid suppositories are sometimes used “off-label” in hopes of having a therapeutic effect, possibly even recommended by doctors, these products have never been registered as drugs with the FDA. In fact, they are not allowed to make any “drug-like” claims in their marketing. **The safety of these leave-on cosmetic products, commonly used by women, should be addressed by the CIR Expert Panel in this assessment.**

Other examples of boric acid suppository cosmetic products, marketed to affect odor include:



2) The method of calculation of the MOE in this assessment is highly controversial, is unprecedented in the scientific literature and is not protective of health.

- The MOE is attempting to assess exposure only for rinse-off products, and omits consideration of leave on products.

The RLD data clearly states that there are seven leave-on feminine deodorant products reported containing boric acid. But there is no information available on the concentration of boric acid in these leave on products, so no MOE for leave-on products was calculated. Nevertheless the draft discussion is overly broad in applying the utility of the rinse-off product MOE calculation by stating

“However, CIR staff calculated an MOE for products that result in vaginal mucosal exposure.”

It should be made very clear that an MOE has NOT been calculated for ALL products that result in vaginal mucosal exposure. In fact, the current MOE vastly underestimates exposure from some vaginal products (such as douches and suppositories).

- The retention factor used in the MOE is inexplicably “.01”. Previous MOE calculations done by the CIR have used a retention factor of “.1” for rinse-off products. It is unclear why an intimate wash would be considered to have 10 times less retention than other cleansing products.

Example: https://cir-safety.org/sites/default/files/ADMIN_CIRSSCRisk_Exposure.pdf

- The MOE uses a NOAEL which comes from an oral developmental exposure study, not a vaginal exposure study.

When the exposure route is oral, the substance of interest is ingested, digested, enters the circulatory system and eventually reaches for example, the reproductive system, where it can cause harm. In the case of vaginal exposure, the harmful substance does not need to be absorbed systemically to do harm. Research shows that some chemicals applied vaginally are preferentially distributed to the uterus, with almost no systemic circulatory distribution. (This is why vaginal contraceptives, like the vaginal ring, are so effective at much lower doses than oral pills, and why there are fewer side effects, because serum levels of the contraceptive hormones are virtually negligible, when administered vaginally.) Basically, oral exposure and vaginal exposure are like apples and oranges when it comes to measuring dose or impact, because the relevant doses to cause an effect are vastly different. The concerning studies on vaginally applied boric acid in humans have demonstrated reproductive harm, and likely have done so without increasing systemic levels of boric acid. There is significantly greater concern for harm from exposure at much lower doses when chemicals are applied vaginally. I have never seen an MOE calculation for vaginal exposure which is based on a NOAEL from an oral exposure study. The CIR Expert panel should not set a precedent for this scientifically unsupported method of MOE calculation.

3) The safety assessment should take into account adverse event reports collected by FDA:

Since the passage of MoCRA, serious adverse event reports are now required to be reported by manufacturers to the FDA. These reports are publicly available on the FDA AEMS dashboard website. Attached you will find a spreadsheet of all the adverse event reports for two brands of intimate washes, Summer’s Eve and Monistat. Monistat’s sole intimate wash contains boric acid. Summer’s Eve has one

intimate wash (Ultimate Odor Protection) which contains boric acid, as well as a handful of other washes which do not. The AEMS data show that there have been an extraordinary number of adverse event reports associated with just these two products in the past two years. Specifically, there were 47 adverse events reported for just the two boric acid-containing products. There were an additional 44 adverse events for non-specified Summer's Eve washes (meaning these reports possibly could include the boric acid containing wash.) There were just 28 adverse events for specific Summer's Eve washes known not to contain boric acid. By way of comparison, I also downloaded all of the adverse event reports for Dove brand body washes (none of which contain boric acid). Dove is a considerably more popular brand than Summer's Eve or Monistat, with much higher sales, and many more types/scents of body washes. In the past two years there were only 28 adverse events reported for all Dove body washes, and no more than 4 reports for any individual Dove body wash. The extent of adverse events reported for the boric acid washes is highly disproportionate and should be taken into account when assessing the safety of these products.

4) There are examples of boric acid intimate washes that may not all be reflected in the RLD data.

Boric acid washes have proliferated in recent years. Below I have included photos and website links to 12 rinse-off intimate wash products and 3 douches that contain boric acid. This is considerably more than reflected in the RLD data which only lists 3 rinse-off feminine deodorant products. Some of these products may be too new to be in the RLD, and some may be manufactured by companies small enough not to be required to report to the RLD. I think it is important for the CIR Expert Panel to have a better sense of the extent of the market for this type of product.

<https://www.summerseve.com/>



<https://www.cvs.com/shop/cvs-health-boric-acid-instant-vaginal-odor-rinse-6-oz-prodid-631944>

CVS Health Boric Acid Instant Vaginal Odor Rinse, 6 OZ

★★★★★ 4.8 (60 reviews)

Share

FSA / HSA

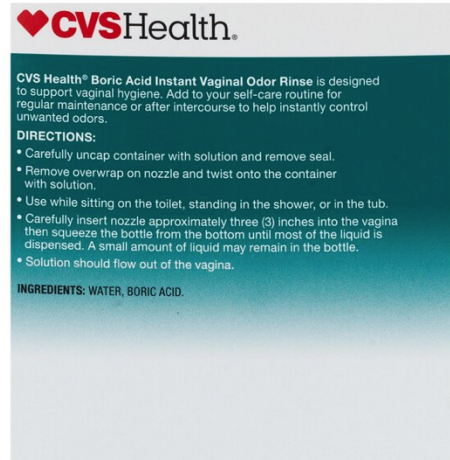


CVS Health Boric Acid Instant Vaginal Odor Rinse, 6 OZ

★★★★★ 4.8 (60 reviews)

Share

FSA / HSA



Note: This cosmetic douche has only two ingredients, water and boric acid. It seems highly unlikely that this product contains water with just .00016% of a second ingredient.



<https://www.phdfemininehealth.com/>



<https://yonipeachcare.com/products/boric-fresh%E2%84%A2-ph-balancing-daily-feminine-wash>

[feminine-wash](https://yonipeachcare.com/products/boric-fresh%E2%84%A2-ph-balancing-daily-feminine-wash)



<https://www.walmart.com/ip/NutraBlast-So-Fresh-Clean-pH-Balance-Feminine-Wash-with-Boric-Acid-10-fl-oz/1405947783>



<https://poisedorganics.com/products/my-fresh-nani-yoni-wash-with-boric-acid>



<https://www.monistat.com/maintain-boric-acid/feminine-cleanser>



<https://www.amazon.com/Her-Fantasy-Box-Sensitive-Feminine/dp/B0CSKT4XK5>



<https://madaninaturals.com/products/boric-revive-with-boric-acid-advanced-odor-control-itch-relief-pleasure-boosting-erotica-body-wash-libido-enhancing-ph-balancing-odor-fighting-formula?>



<https://loyalbody.com/products/phresh-clean?>



<https://femigist.com/products/vagelly?>



<https://parishouseofbeauty.com/products/boricacidprobiotics?>



<https://veenourish.com/products/boric-acid-feminine-wash-fragrance-free?>

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads 'Alexandra Scranton'. The signature is written in a cursive, flowing style.

Alexandra Scranton
Director of Science and Research

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U.S. FDA Adverse events (AEMS) Database search for Summer's Eve and Monistat cosmetic products January 2024 - April 2026

AER#	FDA Initial VER#	Received Date	FDA Latest Received Date	Report Type	Event Dat	Suspect Reported Product Name	Concomitant I	Patient Age	Patient Age Unit	Sex	Serious	Event MedDRA PT(s)	MedDRV	Case Outcomes(s)	Product Contains Boric acid?
24506980	1	17-JAN-2024	17-JAN-2024	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Not Specified	Y	Infection	28.1	Other Serious or Important Medical Even	Yes
23630426	1	13-MAR-2024	13-MAR-2024	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Not Specified	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Yes
23630484	1	13-MAR-2024	13-MAR-2024	Expedited (15-Day)	-	Monistat 1 Ovule Complete Therapy Kit;Monistat Maintain F	-	Not Specified	Not Specified	Female	Y	Fungal Infection;Product Use In Unaj	28.1	Other Serious or Important Medical Even	Yes
23630583	1	13-MAR-2024	13-MAR-2024	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Yes
23753110	1	03-APR-2024	03-APR-2024	Expedited (15-Day)	-	Summer'S Eve Complete Clean Odor Reduction Douche	-	Not Specified	Not Specified	Female	N	Urinary Tract Infection	28.1	Non-Serious	Yes
23858343	1	13-MAY-2024	13-MAY-2024	Expedited (15-Day)	-	Summer'S Eve Complete Clean Odor Reduction Douche	-	Not Specified	Not Specified	Female	Y	Bacterial Vaginosis	28.1	Other Serious or Important Medical Even	Yes
23913723	1	28-MAY-2024	28-MAY-2024	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection	-	35	YR	Female	Y	Bacterial Vaginosis	28.1	Other Serious or Important Medical Even	Yes
23940757	1	04-JUN-2024	04-JUN-2024	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Not Specified	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Yes
23973748	1	13-JUN-2024	13-JUN-2024	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection Wash	-	Not Specified	Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Yes
24095531	1	11-JUL-2024	11-JUL-2024	Expedited (15-Day)	-	Summer'S Eve Complete Clean Odor Reduction Douche	-	Not Specified	Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Yes
24170830	1	31-JUL-2024	31-JUL-2024	Expedited (15-Day)	-	Summers Eve Ultimate Odor Protection;Summers Eve Ulti	Cephalexin;L	Not Specified	Not Specified	Female	Y	Burning Sensation;Chemical Burn Of	28.1	Other Serious or Important Medical Even	Yes
24170981	1	31-JUL-2024	31-JUL-2024	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	Lasix;Levothrc	56	YR	Female	Y	Burning Sensation;Cellulitis;Pruritus)	28.1	Other Serious or Important Medical Even	Yes
24174411	1	02-AUG-2024	02-AUG-2024	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection Spray (Summers Ev	-	Not Specified	Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Yes
24194679	1	06-AUG-2024	06-AUG-2024	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Yes
24195296	1	08-AUG-2024	08-AUG-2024	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection Wash (Summers Ev	-	Not Specified	Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Yes
24230003	1	20-AUG-2024	20-AUG-2024	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Perineal Ulceration	28.1	Other Serious or Important Medical Even	Yes
24307930	1	09-SEP-2024	09-SEP-2024	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser (Monistat Maintain Fe	-	Not Specified	Not Specified	Not Specified	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Yes
24418637	1	07-OCT-2024	07-OCT-2024	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Chemical Burn Of Genitalia	28.1	Other Serious or Important Medical Even	Yes
24557865	1	24-OCT-2024	24-OCT-2024	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Not Specified	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Yes
24695609	1	03-DEC-2024	03-DEC-2024	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection Wash (Summers Eve	Hydrocortison	Not Specified	Not Specified	Female	Y	Chemical Burn Of Genitalia	28.1	Other Serious or Important Medical Even	Yes
24770312	1	19-DEC-2024	19-DEC-2024	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Bacterial Vaginosis	28.1	Other Serious or Important Medical Even	Yes
24852903	1	13-JAN-2025	13-JAN-2025	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Not Specified	Y	Bacterial Vaginosis	28.1	Other Serious or Important Medical Even	Yes
24966234	1	11-FEB-2025	11-FEB-2025	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection Wash	-	Not Specified	Not Specified	Female	Y	Dysuria;Rash Erythematous;Vulvovag	28.1	Other Serious or Important Medical Even	Yes
25017268	1	25-FEB-2025	25-FEB-2025	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Bacterial Vaginosis	28.1	Other Serious or Important Medical Even	Yes
25015443	1	25-FEB-2025	25-FEB-2025	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Bacterial Vaginosis;Chemical Burn;Fu	28.1	Other Serious or Important Medical Even	Yes
25017230	1	25-FEB-2025	25-FEB-2025	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Bacterial Vaginosis;Chemical Burn;Fu	28.1	Other Serious or Important Medical Even	Yes
25207888	1	15-APR-2025	15-APR-2025	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection Wash (Summers Ev	-	Not Specified	Not Specified	Female	Y	Infection	28.1	Other Serious or Important Medical Even	Yes
25282177	1	07-MAY-2025	07-MAY-2025	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection Wash	-	Not Specified	Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Yes
25351975	1	21-MAY-2025	21-MAY-2025	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser With Boric Acid (Moni	-	Not Specified	Not Specified	Female	Y	Fungal Infection;Vulvovaginal Burnin	28.1	Other Serious or Important Medical Even	Yes
25389046	1	02-JUN-2025	02-JUN-2025	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Fungal Infection;Pain;Skin Burning Se	28.1	Other Serious or Important Medical Even	Yes
25548535	1	09-JUL-2025	09-JUL-2025	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection Wash (Summers Ev	-	Not Specified	Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Yes
25651436	2	04-AUG-2025	22-AUG-2025	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection	-	Not Specified	Not Specified	Female	Y	Dysuria;Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Yes
25766641	1	03-SEP-2025	03-SEP-2025	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Vulvovaginal Mycotic Infection	28.1	Other Serious or Important Medical Even	Yes
25833101	1	22-SEP-2025	22-SEP-2025	Expedited (15-Day)	-	Summer'S Eve Complete Clean Odor Reduction Douche	-	Not Specified	Not Specified	Female	Y	Fungal Infection;Vaginal Haemorrhag	28.1	Other Serious or Important Medical Even	Yes
25833075	1	22-SEP-2025	22-SEP-2025	Expedited (15-Day)	-	Metronidazole;Monistat Maintain Feminine Cleanser With B	-	39	YR	Female	Y	Bacterial Vaginosis	28.1	Other Serious or Important Medical Even	Yes
25833102	1	22-SEP-2025	22-SEP-2025	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Infection;Pain	28.1	Other Serious or Important Medical Even	Yes
25944249	1	14-OCT-2025	14-OCT-2025	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Fungal Infection;Vulvovaginal Drynes	28.1	Other Serious or Important Medical Even	Yes
25953139	1	23-OCT-2025	23-OCT-2025	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Yes
26012715	1	07-NOV-2025	07-NOV-2025	Expedited (15-Day)	-	Diffucan (Fluconazole);Summer'S Eve Ultimate Odorprotecti	-	Not Specified	Not Specified	Female	Y	Fungal Infection;Vulvovaginal Discort	28.1	Other Serious or Important Medical Even	Yes
26123449	1	04-DEC-2025	04-DEC-2025	Expedited (15-Day)	-	Monistat Maintain Feminine Cleanser	-	Not Specified	Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Yes
26226066	1	02-JAN-2026	02-JAN-2026	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection Wash	-	Not Specified	Not Specified	Female	Y	Bacterial Vaginosis;Vaginal Discharge	28.1	Other Serious or Important Medical Even	Yes
26324286	1	27-JAN-2026	27-JAN-2026	Expedited (15-Day)	-	Metronidazole;Summer'S Eve Ultimate Odor Protection Was	-	40	YR	Female	Y	Bacterial Vaginosis;Vulvovaginal Disc	28.1	Other Serious or Important Medical Even	Yes
26368055	1	09-FEB-2026	09-FEB-2026	Direct	24-Jan-20	Monistat Maintain Feminine Cleanser With Boric Acid	-	25	YR	Female	Y	Infection;Subcutaneous Abscess;Vuh	28.1	Hospitalization;Life Threatening	Yes
26405767	1	17-FEB-2026	17-FEB-2026	Expedited (15-Day)	-	Summer'S Eve Ultimate Odor Protection	-	Not Specified	Not Specified	Female	Y	Bacterial Vaginosis	28.1	Other Serious or Important Medical Even	Yes
26423916	1	19-FEB-2026	19-FEB-2026	Expedited (15-Day)	-	Summer'S Eve Complete Clean Odor Reduction Douche	-	Not Specified	Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Yes
26424011	1	19-FEB-2026	19-FEB-2026	Expedited (15-Day)	-	Monistat Maintain Boric Acid Cleanser	-	Not Specified	Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Yes
26464111	1	03-MAR-2026	03-MAR-2026	Expedited (15-Day)	-	Monistat Maintain Boric Acid Cleanser	-	Not Specified	Not Specified	Female	Y	Subcutaneous Abscess;Vaginal Cyst;\	28.1	Other Serious or Important Medical Even	Yes
47 reports															
24506986	1	17-JAN-2024	17-JAN-2024	Expedited (15-Day)	-	Summers Eve Cleansing Cloths	-	Not Specified	Not Specified	Not Specified	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
23512585	1	09-FEB-2024	09-FEB-2024	Expedited (15-Day)	-	Summer'S Eve Feminine Wash	-	Not Specified	Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
23544033	1	20-FEB-2024	20-FEB-2024	Expedited (15-Day)	-	Summers Eve Cleansing Wash, Delicate Con	-	Not Specified	Not Specified	Female	Y	Vulvovaginal Mycotic Infection	28.1	Other Serious or Important Medical Even	Possibly
23630700	1	13-MAR-2024	13-MAR-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	Not Specified	Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Possibly
23681303	1	27-MAR-2024	27-MAR-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	Not Specified	Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Possibly
23753509	1	09-APR-2024	09-APR-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	Not Specified	Not Specified	Female	N	Haemorrhage;Rash	28.1	Non-Serious	Possibly
23790967	1	24-APR-2024	24-APR-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	Not Specified	Not Specified	Female	Y	Chemical Burn Of Genitalia	28.1	Other Serious or Important Medical Even	Possibly
23858355	1	13-MAY-2024	13-MAY-2024	Expedited (15-Day)	-	Rocephin (Ceftriaxone) (Drug Used To Treat Ae);Summer'S	-	Not Specified	Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
23888101	1	22-MAY-2024	22-MAY-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	Not Specified	Not Specified	Not Specified	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
24171413	1	31-JUL-2024	31-JUL-2024	Expedited (15-Day)	-	Isummer'S Eve Cleansing Wash	-	Not Specified	Not Specified	Female	Y	Pain;Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
24194685	1	06-AUG-2024	06-AUG-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	Not Specified	Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Possibly
24226585	1	19-AUG-2024	19-AUG-2024	Expedited (15-Day)	-	Summer'S Eve Feminine Wash	-	29	YR	Female	Y	Application Site Infection;Fungal Infe	28.1	Other Serious or Important Medical Even	Possibly
24260781	1	28-AUG-2024	28-AUG-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Cloths	-	Not Specified	Not Specified	Not Specified	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
24343895	1	19-SEP-2024	19-SEP-2024	Expedited (15-Day)	-	Summer'S Eve Feminine Cloth - Iwc	-	Not Specified	Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
24376200	1	27-SEP-2024	27-SEP-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Cloths (Summers Eve Cleansing Clot	-	Not Specified	Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
24557913	1	24-OCT-2024	24-OCT-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	52	YR	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
24825893	1	07-JAN-2025	07-JAN-2025	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	Not Specified	Not Specified	Not Specified	Y	Abdominal Pain;Chills;Discomfort;Fla	28.1	Other Serious or Important Medical Even	Possibly
24902254	1	24-JAN-2025	24-JAN-2025	Expedited (15-Day)	-	Summer'S Eve Cleansing Cloths	-	Not Specified	Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Possibly
24902255	1	24-JAN-2025	24-JAN-2025	Expedited (15-Day)	-	Summer'S Eve Feminine Fragrance Douche	-	Not Specified	Not Specified	Female	Y	Kidney Infection;Urinary Tract Infecti	28.1	Other Serious or Important Medical Even	Possibly
24902396	1	24-JAN-2025	24-JAN-2025	Expedited (15-Day)	-	Summer'S Eve Feminine Wash	-	Not Specified	Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
24918898	1	30-JAN-2025	30-JAN-2025	Expedited (15-Day)	-	Summer'S Eve Feminine Fragrance Douche	-	Not Specified	Not Specified	Female	Y	Fungal Infection;Vulvovaginal Burnin	28.1	Other Serious or Important Medical Even	Possibly
24966239	1	11-FEB-2025	11-FEB-2025	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	Not Specified	Not Specified	Female	Y	Fungal Infection;Rash;Vulvovaginal P	28.1	Other Serious or Important Medical Even	Possibly
25282190	1	07-MAY-2025	07-MAY-2025	Expedited (15-Day)	-	Summer'S Eve Feminine Fragrance Douche	-	Not Specified	Not Specified	Not Specified	Y	Infection	28.1	Other Serious or Important Medical Even	Possibly
25472298	1	17-JUN-2025	17-JUN-2025	Expedited (15-Day)	-	Summer'S Eve Cleansino Wash	-	80	YR	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
25526167	1	30-JUN-2025	30-JUN-2025	Expedited (15-Day)	-	Summers Eve Feminine Wash	-	Not Specified	Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Possibly

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25651277	2	01-AUG-2025	03-SEP-2025	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	Bacitracin;Dox 60	YR	Female	Y	Abscess;Chemical Burn Of Skin;Lymp	28.1	Other Serious or Important Medical Even	Possibly
25651904	1	04-AUG-2025	04-AUG-2025	Expedited (15-Day)	-	Cephalexin;Doxycycline;Ketorolac;Metronidazole;Ondansetr	Dicyclomine H Not Specified	Not Specified	Female	Y	Bacterial Vaginosis;Ovarian Cyst;Pelv	28.1	Other Serious or Important Medical Even	Possibly
25651902	1	04-AUG-2025	04-AUG-2025	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	Dexamethaso 36	YR	Female	Y	Contusion;Dermatitis;Haemorrhage;I	28.1	Other Serious or Important Medical Even	Possibly
25705008	1	19-AUG-2025	19-AUG-2025	Expedited (15-Day)	-	Monistat 7 Cream 7-Day Treatment Disposable Applicators;-	77	YR	Female	Y	Vulvovaginal Mycotic Infection	28.1	Other Serious or Important Medical Even	Possibly
25945930	1	20-OCT-2025	20-OCT-2025	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	Not Specified Not Specified	Female	Y	Bacterial Vaginosis	28.1	Other Serious or Important Medical Even	Possibly
25953130	1	22-OCT-2025	22-OCT-2025	Expedited (15-Day)	-	Summers Eve Extra Cleansing Douche, V Cont..	-	Not Specified Not Specified	Female	Y	Vaginal Disorder	28.1	Hospitalization	Possibly
26037481	1	12-NOV-2025	12-NOV-2025	Expedited (15-Day)	-	Summer'S Eve Cleansing Waash	-	Not Specified Not Specified	Female	Y	Fungal Infection;Vulvovaginal Discor	28.1	Other Serious or Important Medical Even	Possibly
26072178	1	19-NOV-2025	19-NOV-2025	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	Not Specified Not Specified	Not Specified	Y	Infection	28.1	Other Serious or Important Medical Even	Possibly
26119507	1	03-DEC-2025	03-DEC-2025	Expedited (15-Day)	-	Summer'S Eve Feminine Cloth - Softpac	-	Not Specified Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Possibly
26123425	1	04-DEC-2025	04-DEC-2025	Expedited (15-Day)	-	Summer'S Eve Cleansing Cloths	-	Not Specified Not Specified	Female	Y	Infection	28.1	Other Serious or Important Medical Even	Possibly
26162937	1	11-DEC-2025	11-DEC-2025	Expedited (15-Day)	-	Summer'S Eve Cleansing Cloths	-	Not Specified Not Specified	Female	Y	Hypersensitivity;Infection	28.1	Other Serious or Important Medical Even	Possibly
26198522	1	23-DEC-2025	23-DEC-2025	Expedited (15-Day)	-	Summer'S Eve Cleansing Cloths	-	Not Specified Not Specified	Female	Y	Infection	28.1	Other Serious or Important Medical Even	Possibly
26304079	1	16-JAN-2026	16-JAN-2026	Expedited (15-Day)	-	Summer'S Eve Feminine Wash	Tylenol	Not Specified Not Specified	Female	Y	Bacterial Vaginosis	28.1	Other Serious or Important Medical Even	Possibly
26304090	1	20-JAN-2026	20-JAN-2026	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	-	Not Specified Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	Possibly
26304088	2	20-JAN-2026	06-FEB-2026	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash	56	YR	Female	Y	Vaginal Infection	28.1	Other Serious or Important Medical Even	Possibly
26361937	1	05-FEB-2026	05-FEB-2026	Expedited (15-Day)	-	Summer'S Eve Cleansing Cloths	-	Not Specified Not Specified	Female	Y	Infection	28.1	Other Serious or Important Medical Even	Possibly
26361938	1	05-FEB-2026	05-FEB-2026	Expedited (15-Day)	-	Summer'S Eve Cleansing Cloths	-	Not Specified Not Specified	Not Specified	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
26464139	1	03-MAR-2026	03-MAR-2026	Expedited (15-Day)	-	Summer'S Eve Cleansing Cloths	Amiodarone;h 79	YR	Female	Y	Cystitis	28.1	Other Serious or Important Medical Even	Possibly
26458816	1	04-MAR-2026	04-MAR-2026	Expedited (15-Day)	-	Summer'S Eve Feminine Wash	-	Not Specified Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	Possibly
44 reports														
23481830	1	01-FEB-2024	01-FEB-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash (Summers Eve Simply Sensitiv	-	Not Specified Not Specified	Female	Y	Bacterial Vaginosis;Urinary Tract Infe	28.1	Other Serious or Important Medical Even	No
23512562	2	09-FEB-2024	03-APR-2024	Expedited (15-Day)	-	Summer'S Eve Feminine Deodorant Spray	-	Not Specified Not Specified	Not Specified	N	Infection	28.1	Non-Serious	No
23522446	1	14-FEB-2024	14-FEB-2024	Expedited (15-Day)	-	Summer'S Eve Active Cooling Wash	55	YR	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	No
23667427	1	22-MAR-2024	22-MAR-2024	Expedited (15-Day)	-	Summer'S Eve Active Cooling Wash	-	Not Specified Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	No
23753105	1	03-APR-2024	03-APR-2024	Expedited (15-Day)	-	Summer'S Eve Feminine Wash (Summer'S Eve Cleansing Was	-	Not Specified Not Specified	Not Specified	N	Fungal Infection	28.1	Non-Serious	No
23791030	1	25-APR-2024	25-APR-2024	Expedited (15-Day)	-	Summers Eve Douche, Island Splash	-	Not Specified Not Specified	Not Specified	Y	Burning Sensation;Infection;Pruritus	28.1	Other Serious or Important Medical Even	No
23936114	1	03-JUN-2024	03-JUN-2024	Expedited (15-Day)	-	Monistat Care Stay Fresh Gel	-	Not Specified Not Specified	Not Specified	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	No
23998416	1	20-JUN-2024	20-JUN-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash (Summers Eve Cleansing Was	-	Not Specified Not Specified	Female	Y	Bacterial Vaginosis;Urinary Tract Infe	28.1	Other Serious or Important Medical Even	No
23998410	1	20-JUN-2024	20-JUN-2024	Expedited (15-Day)	-	Monistat (Miconazole Nitrate);Summer'S Eve Freshening Spr	-	Not Specified Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	No
23998410	1	20-JUN-2024	20-JUN-2024	Expedited (15-Day)	-	Monistat (Miconazole Nitrate);Summer'S Eve Freshening Spr	-	Not Specified Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	No
24013760	1	25-JUN-2024	25-JUN-2024	Expedited (15-Day)	-	Macrobid (Clarithromycin) (Nitrofurantoin) (Drug Used To Tr	-	Not Specified Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	No
24278448	1	30-AUG-2024	30-AUG-2024	Expedited (15-Day)	-	Summer'S Eve Feminine Fragrance Douche (Summers Eve De	-	Not Specified Not Specified	Female	Y	Bacterial Vaginosis;Fungal Infection	28.1	Other Serious or Important Medical Even	No
24427614	2	10-OCT-2024	09-DEC-2024	Expedited (15-Day)	-	Summer'S Eve Essential Botanicals Daily Gentle Wash	29	YR	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	No
24651497	1	13-NOV-2024	13-NOV-2024	Expedited (15-Day)	-	Metronidazole (. Metronidazole);Summer'S Eve Freshening S	-	Not Specified Not Specified	Female	Y	Bacterial Vaginosis;Vulvovaginal Myc	28.1	Other Serious or Important Medical Even	No
24714698	1	05-DEC-2024	05-DEC-2024	Expedited (15-Day)	-	Summer'S Eve Cleansing Wash;Summers Eve Cleansing Wash	64	YR	Female	Y	Cystitis;Pyelonephritis;Urinary Tract I	28.1	Other Serious or Important Medical Even	No
24770300	1	19-DEC-2024	19-DEC-2024	Expedited (15-Day)	-	Summer'S Eve Essential Botanicals Daily Gentle Wash (Summ	-	Not Specified Not Specified	Female	Y	Nodule;Vaginal Discharge;Vaginal Inf	28.1	Other Serious or Important Medical Even	No
24793630	1	19-DEC-2024	19-DEC-2024	Expedited (15-Day)	-	Summer'S Eve Essential Botanicals Daily Gentle Wash (Summ	29	YR	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	No
25207870	1	15-APR-2025	15-APR-2025	Expedited (15-Day)	-	Summer'S Eve Feminine Deodorant Spray;Summers Eve Deo	-	Not Specified Not Specified	Female	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	No
25203777	1	16-APR-2025	16-APR-2025	Direct	15-Apr-20	Summers Eve Ultra Spray	Biotin;Cranbe; 49	YR	Female	Y	Chemical Burn Of Genitalia	28.1	Other Serious or Important Medical Even	No
25270606	1	29-APR-2025	29-APR-2025	Expedited (15-Day)	-	Summer'S Eve Freshening Spray	-	Not Specified Not Specified	Female	Y	Chemical Burn Of Skin	28.1	Other Serious or Important Medical Even	No
25270462	1	01-MAY-2025	01-MAY-2025	Expedited (15-Day)	-	Summers Eve Cleansing Wash, Blissful Escape	-	Not Specified Not Specified	Female	Y	Abdominal Pain;Pollakiuria;Urinary T	28.1	Other Serious or Important Medical Even	No
25282261	2	07-MAY-2025	28-MAY-2025	Expedited (15-Day)	-	Summer'S Eve Feminine Deodorant Spray (Summers Eve Dex	Bactrim;Ibupr 32	YR	Female	Y	Abscess;Hypersensitivity;Pain;Vulvov	28.1	Other Serious or Important Medical Even	No
25526549	1	02-JUL-2025	02-JUL-2025	Expedited (15-Day)	-	Summer'S Eve Frzeshening Spray	-	Not Specified Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	No
25716873	1	22-AUG-2025	22-AUG-2025	Expedited (15-Day)	-	Summers Eve Cleansing Wash, Lavender	-	Not Specified Not Specified	Female	Y	Fungal Infection	28.1	Other Serious or Important Medical Even	No
25766553	1	03-SEP-2025	03-SEP-2025	Expedited (15-Day)	-	Summer'S Eve Spa Luxurious Wash	-	Not Specified Not Specified	Not Specified	Y	Urinary Tract Infection	28.1	Other Serious or Important Medical Even	No
26198499	1	23-DEC-2025	23-DEC-2025	Expedited (15-Day)	-	Summer'S Eve Feminine Deodorant Spray	-	Not Specified Not Specified	Female	Y	Fungal Infection;Rash	28.1	Other Serious or Important Medical Even	No
26409010	2	18-FEB-2026	02-MAR-2026	Expedited (15-Day)	-	Summer'S Eve Whole Body Deodorant	-	Not Specified Not Specified	Female	Y	Fungal Skin Infection	28.1	Other Serious or Important Medical Even	No
26537234	1	20-MAR-2026	20-MAR-2026	Expedited (15-Day)	-	Summers Eve Deodorant Spray, Ultra	-	Not Specified Not Specified	Female	Y	Bacterial Vaginosis;Vaginal Ph Abnor	28.1	Other Serious or Important Medical Even	No
28 reports														

Total reports for Summer's Eve/Monistat products	119	
Boric acid-containing	47	39%
Possibly containing boric acid	44	37%
Not containing boric acid	28	24%