Date of Hearing: June 17, 2025

ASSEMBLY COMMITTEE ON ENVIRONMENTAL SAFETY AND TOXIC MATERIALS
Damon Connolly, Chair
SB 39 (Weber Pierson) – As Amended June 12, 2025

SENATE VOTE: 34-0

SUBJECT: Cosmetic safety: Vaginal suppositories

SUMMARY: Requires, commencing on January 1, 2027, a person or entity that manufactures or sells a vaginal boric acid suppository (BAS) product to include specified language on the product label; prohibits, beginning on January 1, 2035, a person or entity from manufacturing or selling a BAS product; provides that neither of these provisions apply if a BAS product becomes regulated as a drug under the United States Food and Drug Administration (FDA). Specifically, **this bill**:

1) Makes several findings and declarations, including that:

    a) Intravaginal boric acid represents one of the few available options for addressing recurrent vaginal infections, and is included in multiple national guidelines, including guidelines issued by the American College of Obstetricians and Gynecologists;

    b) Existing state law bans, beginning January 1, 2027, the manufacture and sale of cosmetic products containing intentionally added boric acid; and,

    c) Because intravaginal boric acid represents one of the few available options for addressing recurrent vaginal infections, additional time for BAS is warranted, to allow these products time to become regulated as a drug under the FDA.

2) Requires, commencing on January 1, 2027, a person or entity that manufactures, sells, delivers, holds, or offers for sale in commerce a vaginal suppository product containing intentionally added boric acid to include on the product label the following statement:

    "WARNING: IT IS RECOMMENDED TO CONSULT WITH A DOCTOR BEFORE USE, particularly if you have sensitivity in your lower pelvis or abdomen, a sexually transmitted disease (STD), pelvic inflammatory disease (PID), vaginal bleeding, sores, ulcerations, nausea, fever, or chills. Do not use on broken or irritated skin. Stop use and contact a doctor if symptoms persist or worsen, or if you experience irritation, burning, bleeding, or cramping. NOT FOR ORAL CONSUMPTION. FOR VAGINAL USE ONLY. DO NOT USE IF PREGNANT, TRYING TO CONCEIVE, OR NURSING. IF YOU BECOME PREGNANT WHILE USING THIS PRODUCT, DISCONTINUE USE IMMEDIATELY. If swallowed, get medical help or contact Poison Control Center immediately. Some boric acid suppository products may break down a condom—ensure product has completely dissolved before having sex."

3) Prohibits, commencing on January 1, 2035, a person or entity from manufacturing, selling, delivering, holding, or offering for sale in commerce a vaginal suppository product containing intentionally added boric acid.

4) Provides that the above labeling requirement and prohibition do not apply to a vaginal suppository product containing intentionally added boric acid, if the product becomes regulated as a drug by the FDA.

5) Defines "product label" to mean a display of written, printed, or graphic matter upon a cosmetic product or upon its immediate container.

6) Provides that this bill is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of the California Constitution and shall go into immediate effect, in order for women in this state to have necessary medical and hygiene materials available to them in a timely manner.

EXISTING LAW:

1) Prohibits, commencing January 1, 2025, a person or entity from manufacturing, selling, delivering, holding, or offering for sale in commerce any cosmetic product that contains any of 24 specified chemicals as intentionally added ingredients. (Health and Safety Code (HSC) § 108980(a))

2) Prohibits, commencing January 1, 2027, a person or entity from manufacturing, selling, delivering, holding, or offering for sale in commerce any cosmetic product that contains any of 41 specified chemicals as intentionally added ingredients, including boric acid. (HSC § 108980(b))

3) Provides that trace quantities of a chemical prohibited under HSC § 108980 shall not cause a cosmetic product to be in violation, if the trace quantity is technically unavoidable and stems from ingredient impurities, the manufacturing process, storage, or migration from packaging. (HSC § 108980(c))

4) Defines, for the purposes of the federal Food, Drug, and Cosmetic Act (FD&C Act), "cosmetic" to mean:

    a) 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,

    b) Articles intended for use as a component of any such articles. (21 United States Code (USC) § 321(i))

5) Defines, for the purposes of the FD&C Act, "drug" to mean:

    a) Articles recognized in any of several specified lists;

    b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

    c) Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and,

    d) Articles intended for use as a component of any such articles. (21 USC § 321(g)(1))

6) Requires the label of a cosmetic product to bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product. (21 Code of Federal Regulations § 740.1(a))

7) Requires a cosmetic to be deemed misbranded under specified circumstances, including if its labeling is false or misleading. (21 USC § 362)

8) Prohibits the introduction or delivery for introduction into interstate commerce any drug or cosmetic that is adulterated or misbranded. (21 USC § 331(a))

FISCAL EFFECT: Unknown.

COMMENTS:

Need for the bill: According to the author:

> "There is robust safety and efficacy data on the use of boric acid in vaginal products, so much so that they have been standard of care in women's health for many years. For example, the Centers for Disease Control and Prevention (CDC) recommends the use of boric acid suppositories (BAS) in their current [sexually transmitted disease] guidelines (published 2015). Likewise, the American College of Obstetricians and Gynecologists (ACOG) recommends the use of BAS in vaginal health applications. Additionally, BAS are on the treatment protocols of many major academic and medical centers and/or are recommended for their patients (e.g., Kaiser Permanente, UCLA, Harvard, Columbia, Tufts, and American Association of Family Physicians).
>
> Boric acid products are readily available at every major retailer in the US and are also available on Amazon. Healthcare providers guide their patients to purchase boric acid products at these retailers. Unless SB 39 is enacted, the ban on boric acid will prohibit women from accessing boric acid products and eliminate a woman's right to choose how to manage her feminine health (especially in disadvantaged populations), eliminating a safe, effective, and accessible non-antibiotic treatment for conditions such as vaginal odor and yeast infections."

Boric acid, BAS, and vaginal infections: Boric acid is a naturally-occurring compound with antimicrobial properties. Due to its potential to cause reproductive harm, the European Union bans the use of boric acid in cosmetic products, and California's Department of Toxic Substances Control (DTSC) lists boric acid as a "candidate chemical" under its Safer Consumer Products program, which aims to advance the design, development, and use of products that are chemically safer for people and the environment. DTSC uses the Candidate Chemicals list to identify potential product-chemical combinations for future regulation.

Despite its potential for toxicity, boric acid is sometimes used in healthcare applications due to its antimicrobial properties. BAS are gelatin capsules containing boric acid, applied intravaginally to treat vaginal infections caused by yeast or bacteria, or to address vaginal odor (although some medical organizations, such as the Cleveland Clinic, state that vaginal odor is common and generally does not require treatment, except when the odor is strong and unfamiliar or unpleasant, which can signal a potential infection and is often accompanied by other symptoms).

BAS are easily available over-the-counter and, although they are often used to address vaginal infections, they are not currently regulated as drugs under the FDA. In 2021, researchers from the Johns Hopkins School of Medicine published the study, "Data on safety of intravaginal boric acid use in pregnant and non-pregnant women: A narrative review," in the journal *Sexually Transmitted Diseases.* In the study, the authors note that safety data specific to intravaginal boric acid use are sparse; however, the authors also note that intravaginal boric acid represents one of the only options available to treat recurrent vaginal infections caused by certain strains of drug resistant fungal and bacterial microbes. Intravaginal boric acid has been used for decades to treat vaginal infections. In addition, use of over-the-counter or clinician-recommended intravaginal boric acid is widespread, and may increase if microbial resistance to other treatment options rises.

In their review of studies examining the safety of intravaginal boric acid, the authors state the following:

- Available evidence suggests intravaginal use at dosages commonly described in the literature is likely safe for women, at least those with normal kidney function. However, the authors state that they "feel [intravaginal boric acid] should be prescribed by a provider" and that, given uncertainties, they cannot recommend unregulated use of over-the-counter products.

- Though limited, oral toxicity studies suggest that the amount of intravaginal boric acid required to induce significant toxicity in women would likely be more than the intravaginal doses commonly prescribed by clinicians to healthy adults.

- Guidelines from several medical professional and public health organizations, including the American College of Obstetricians and Gynecologists, advise that intravaginal boric acid use should be avoided in pregnancy.

- Although studies of the potential for intravaginal boric acid to cause birth defects in humans is "sparse and flawed," the authors state that high levels of oral consumption has been associated with birth defects in animals. As a result, the authors conclude that it is not possible to recommend, based on existing data, changes to guidelines advising against intravaginal boric acid use in pregnancy.

Federal regulation of cosmetics: Cosmetics are sold to consumers across California, including to young people in sensitive periods of development and women of childbearing age. These products are also often used on or in the body's most sensitive areas. As a result, thoughtful consideration of the ingredients used in cosmetics is important for ensuring that mothers, fetuses, nursing children, and adolescents are not exposed to chemicals that can cause cancer or reproductive toxicity.

At the federal level, the FD&C authorizes the FDA to oversee and regulate the production, sale, and distribution of food, drugs, medical devices, and cosmetics. Under the FD&C, a cosmetic is defined as an article "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," as well as any substance intended for use as a component in a cosmetic product. One of the FDA's primary tools for regulating cosmetics is the ability to prohibit the marketing of adulterated or misbranded cosmetics in interstate commerce. Adulteration refers to violations involving product composition, whether they result

from ingredients, contaminants, processing, packaging, or shipping and handling. For example, a cosmetic is adulterated under the FD&C if "it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under conditions of use as are customary and usual." "Misbranding" refers to violations involving improperly labeled or deceptively packaged products. For example, a cosmetic may be deemed misbranded due to failure to provide material facts, including any directions for safe use and warning statements needed to ensure a product's safe use.

Federal regulation of cosmetics versus drugs: Products intended for a therapeutic use, such as treating or preventing disease, or to affect the structure or function of the body, are considered drugs under the FD&C. In some ways, the FDA's authority to regulate cosmetics is more limited than its authority to regulate drugs. Unlike drugs, cosmetic products and ingredients do not need FDA premarket approval, with the exception of color additives. In addition, for the most part, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that the ingredient and the finished cosmetic are "safe under labeled or customary conditions of use"; the product is properly labeled; and use of the ingredient does not cause the cosmetic to be adulterated or misbranded under the FD&C. Neither the law nor regulations require specific tests to demonstrate the safety of individual cosmetic products or ingredients. In addition, the law also does not require cosmetic companies to register their cosmetic establishments, file their product formulations, or share their safety information with the FDA. The FD&C also does not authorize the FDA to compel companies to recall cosmetics.

State regulation of cosmetics: Before January 2021, California's primary law for governing the safety of cosmetics was the state's Sherman Food, Drug, and Cosmetic Law (Sherman Law). The Sherman Law (HSC § 109875, *et seq.*) is administered by the California Department of Public Health (CDPH) and serves as California's state level, implementing legislation for the federal FD&C. Under the Sherman Law, selling misbranded cosmetics can lead to civil and administrative penalties, embargoes, and even bans on products.

In addition, the California Safe Cosmetics Act of 2005 (Cosmetics Act; HSC § 111791, *et seq.*), housed under Sherman Law, requires manufacturers of any cosmetic product, sold into California and subject to regulation by the FDA, to provide CDPH with a complete and accurate list of cosmetic products that contain any ingredient that is a carcinogen or reproductive toxicant. The Cosmetics Act further requires CDPH to maintain a consumer-friendly, searchable online database that contains product information collected by CDPH pursuant to the Act.

In 2020, AB 2762 (Muratsuchi, Chapter 314) was signed into law, establishing a new body of statute that, independent of the state's Sherman Law, prohibits the manufacture or sale of cosmetic products containing any one of 24 chemicals as intentionally added ingredients. In 2023, AB 496 (Friedman, Chapter 441) added another 41 chemicals, including boric acid, to the list. For both bills, the aim was to prohibit chemicals in California that had already been banned from cosmetics in the European Union, due to their classification as substances with carcinogenic, mutagenic (i.e., capable of causing genetic mutations), or reproductive toxicity properties. This bill would provide manufacturers of BAS, which contain intentionally added boric acid, with an additional eight years before the prohibition takes effect, to allow them time to undergo the FDA's drug development and review process (described further below) and become regulated as drugs under the FD&C.

FDA action on BAS: When the FDA identifies what it believes are significant violations of federal requirements, it notifies the appropriate party, often through a "warning letter." Warning letters identify the concern (such as poor manufacturing practices, problems with claims for what a product can do, or incorrect directions for use). In August 2018, the FDA issued a warning letter to Vireo Resources regarding its product, pH-D Feminine Health Support Boric Acid Vaginal Suppositories. In the letter, in a section entitled "Unapproved New Drug and Misbranded Drug," the FDA states:

> "Statements on your website…establish that pH-D Feminine Health Support Boric Acid Vaginal Suppositories is a drug as defined [under the FD&C], because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or to affect the structure or function of the body…New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA…No approved application pursuant to section 505 of the Act [21 U.S.C. § 355] is in effect for this product…
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> Your pH-D Feminine Health Support Boric Acid Vaginal Suppositories is intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, adequate directions for use cannot be written so that a layperson can use your product safely for its intended purposes. Accordingly, pH-D Feminine Health Support Boric Acid Vaginal Suppositories fails to bear adequate directions for its intended uses and, therefore, the product is misbranded under [the FD&C]."

At the time of the writing of this analysis, some manufacturers are in the process of pursuing FDA drug approval for their BAS products.

Multi-year drug development and review process under the FDA: Current state law bans the manufacture and sale of cosmetic products containing intentionally added boric acid, beginning on January 1, 2027. This bill provides manufacturers of BAS products with an additional eight years before they are banned under state law, to provide them with time to undergo the FDA's drug development and review process and pursue status and regulation as an FDA-approved drug. As stated in the bill's findings and declarations, this extension is based on research showing that intravaginal boric acid represents one of the few available options for addressing recurrent vaginal infections, as well as recommendations—issued by professional medical associations such as the American College of Obstetricians and Gynecologists—for the use of BAS products. To provide a layer of consumer protection while manufacturers pursue regulation of their BAS products as drugs under the FDA, this bill further requires that manufacturers label their products with information pertaining to the safe use of BAS, including that these products should not be used during pregnancy, or while nursing or trying to conceive.

The FDA's drug development and review process can take a number of years to complete and includes numerous steps. According to the FDA, the clinical trials stage often takes the longest time, usually multiple years. If a drug receives FDA approval, it then becomes subject to FDA regulatory oversight, in which the FDA monitors real-time data from patients, drug manufacturers, and healthcare professionals, including reports of adverse reactions. Based on these data, the FDA can take various actions, including updating drug labeling requirements to ensure safe use and issuing drug recalls.

Potential drugs must typically undergo the following steps before federal approval:

1) Preclinical (animal) testing: Before testing a potential drug in people, researchers use animal or in vitro (e.g., cell-based) models to determine dosing levels and whether a potential drug may cause serious harm, or toxicity, in humans.

2) Submission of an Investigational New Drug application (IND): The IND outlines what the sponsor (company, research institution, or other organization) of a new drug proposes for human testing in clinical trials. Sponsors must show the FDA results of preclinical testing in laboratory animals; the FDA then decides whether it is reasonably safe for the company to move forward with testing the drug in humans via clinical trials.

3) Clinical trials: Clinical studies are conducted in humans and can begin only after an IND is reviewed by the FDA and a local institutional review board (a panel of scientists and non-scientists in hospitals and research institutions that oversee clinical research). This stage consists of three phases:

   - Phase 1: These studies usually involve 20-80 healthy volunteers and are aimed at identifying common side effects, as well as how the human body processes a drug;

   - Phase 2: These studies begin if Phase 1 does not reveal unacceptable toxicity. While the emphasis in Phase 1 is on safety, the emphasis in Phase 2 is on effectiveness. This phase aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition. Patients receiving the drug are compared with similar patients receiving a different treatment, usually a placebo. Typically, the number of subjects in Phase 2 studies ranges from a few dozen to about 300. At the end of Phase 2, the FDA and sponsors try to come to an agreement on how large-scale studies in Phase 3 should be done.

   - Phase 3: Phase 3 studies begin if Phase 2 produces evidence of effectiveness. These studies gather more information about safety and effectiveness, studying different populations and different dosages and using the drug in combination with other drugs. The number of subjects usually ranges from several hundred to 3,000 people.

4) Submission of an NDA and FDA review: This is the formal step a drug sponsor takes to ask that the FDA consider approving a new drug for marketing in the United States. A drug developer must include everything about a drug—from preclinical data to Phase 3 clinical trial data—in an NDA. Developers must also include reports on all studies, data, and analyses; proposed labeling; and directions for use, among other things.

5) Post-market drug safety monitoring: After the FDA has approved a product for marketing, post-market monitoring and studies are required of or agreed to by a sponsor. The FDA uses post-market monitoring and studies to gather additional information about a product's safety, efficacy, or optimal use.

This bill: Because BAS represents one of the few options available to treat recurrent vaginal infections caused by drug resistant microbes, SB 39 allots additional time for manufacturers of BAS products to undergo the FDA's drug development and review process, before these products are banned under existing law that prohibits the manufacture or sale of cosmetics containing intentionally added boric acid. Further, the bill provides that BAS products that become regulated under the FDA as a drug would not be subject to the ban on cosmetics containing

intentionally added boric acid. Finally, this bill provides a layer of consumer protection while manufacturers work towards FDA drug approval, by requiring these products to bear a label containing information about the safe use of BAS. Overall, SB 39 takes a targeted approach to preserving women's ability to access BAS products, without weakening state laws aimed at protecting consumers from cosmetics containing chemicals with known carcinogenic, mutagenic, and reproductive toxicity traits.

Arguments in support: According to the California Pan-Ethnic Health Network:

> "Boric acid suppositories are a long-standing, evidence-based, effective and affordable treatment option for managing yeast infections and bacterial vaginosis—conditions that disproportionately affect low-income women of color who face systemic barriers to health care. Current regulations on cosmetic products as created by AB 2762 (Muratsuchi, Chapter 314, Statutes of 2020) and amended by AB 496 (Friedman, Chapter 441, Statutes of 2023) exclude boric acid, forcing many individuals to choose between unregulated markets or untreated infections which can lead to severe reproductive complications. SB 39 would add a necessary and thoughtful update to California's regulations for cosmetic products and ensure access to boric acid in gynecological care."

Arguments in opposition: None on file.

Related legislation:

1) AB 60 (Papan). Prohibits, commencing January 1, 2027, a person or entity from manufacturing, selling, delivering, holding, or offering for sale in commerce any cosmetic product that contains any of five specified ingredients. This bill is pending in the Senate Environmental Quality Committee.

2) AB 496 (Friedman, Chapter 441, Statutes of 2023). Prohibits, beginning January 1, 2027, the manufacture, sale, delivery, holding, or offering for sale in commerce of any cosmetic product containing 41 specified intentionally added ingredients.

3) AB 2771 (Friedman, Chapter 804, Statutes of 2022). Prohibits any person or entity from manufacturing, selling, delivering, holding, or offering for sale in commerce any cosmetic product that contains any per- or polyfluoroalkyl substance.

4) AB 2762 (Muratsuchi, Chapter 314, Statutes of 2020). Prohibits, beginning January 1, 2025, the manufacture, sale, delivery, holding, or offering for sale in commerce of any cosmetic product containing 24 specified intentionally added ingredients.

REGISTERED SUPPORT / OPPOSITION:

Support

California Pan - Ethnic Health Network

Opposition

None on file

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