SENATE THIRD READING
SB 39 (Weber Pierson)
As Amended June 12, 2025
2/3 vote. Urgency

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).

Major Provisions

1) Makes several findings and declarations.

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 a warning statement, as specified.

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.

COMMENTS

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. Candidate chemicals have known hazard traits and/or environmental or toxicological risks, and DTSC uses its 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.* 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. 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.

Federal regulation of cosmetics versus drugs: At the federal level, the federal Food, Drug, and Cosmetic Act (FD&C Act) 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. 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.

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 (Health and Safety Code (HSC) Section 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 Section 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 Cosmetics 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 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." 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. Section 355] is in effect for this product…
>
> 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]."

Multi-year drug development and review process under the FDA: At the time of the writing of this analysis, some manufacturers are in the process of pursuing FDA drug approval for their BAS products. 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.

This bill: Current state law bans the manufacture and sale of cosmetic products containing intentionally added boric acid, beginning on January 1, 2027. Because BAS represents one of the few options available to treat recurrent vaginal infections caused by drug resistant microbes, SB 39 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. 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. 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. Overall, SB 39 takes a targeted approach to preserving people'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.

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."

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.

FISCAL COMMENTS

This bill is keyed non-fiscal by Legislative Counsel.

VOTES

SENATE FLOOR: 34-0-6
YES: Allen, Archuleta, Arreguín, Ashby, Blakespear, Cabaldon, Caballero, Cervantes, Choi, Cortese, Dahle, Durazo, Gonzalez, Grayson, Grove, Laird, Limón, McGuire, McNerney, Menjivar, Niello, Ochoa Bogh, Padilla, Pérez, Richardson, Rubio, Seyarto, Smallwood-Cuevas, Stern, Strickland, Umberg, Valladares, Wahab, Wiener
ABS, ABST OR NV: Alvarado-Gil, Becker, Hurtado, Jones, Reyes, Weber Pierson

ASM ENVIRONMENTAL SAFETY AND TOXIC MATERIALS: 7-0-0
YES: Connolly, Ellis, Bauer-Kahan, Castillo, Lee, McKinnor, Papan

ASSEMBLY FLOOR: 75-0-4
YES: Addis, Aguiar-Curry, Ahrens, Alanis, Alvarez, Arambula, Ávila Farías, Bains, Bennett, Berman, Boerner, Bonta, Bryan, Calderon, Caloza, Carrillo, Castillo, Chen, Connolly, Davies, DeMaio, Dixon, Elhawary, Ellis, Fong, Gabriel, Gallagher, Garcia, Gipson, Jeff Gonzalez, Mark González, Hadwick, Haney, Harabedian, Hart, Hoover, Irwin, Jackson, Kalra, Krell, Lackey, Lee, Lowenthal, Macedo, McKinnor, Muratsuchi, Nguyen, Ortega, Pacheco, Papan, Patel, Patterson, Petrie-Norris, Quirk-Silva, Ramos, Ransom, Celeste Rodriguez, Michelle Rodriguez, Rogers, Sanchez, Schiavo, Schultz, Sharp-Collins, Solache, Soria, Stefani, Ta, Tangipa, Valencia, Wallis, Ward, Wicks, Wilson, Zbur, Rivas
ABS, ABST OR NV: Bauer-Kahan, Flora, Pellerin, Blanca Rubio

UPDATED

VERSION: June 12, 2025

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