Office of Senate Floor Analyses
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UNFINISHED BUSINESS

Bill No: SB 39
Author: Weber Pierson (D)
Amended: 9/2/25
Vote: 27 - Urgency

SENATE ENVIRONMENTAL QUALITY COMMITTEE: 8-0, 3/19/25
AYES: Blakespear, Valladares, Dahle, Gonzalez, Hurtado, Menjivar, Padilla, Pérez

SENATE FLOOR: 34-0, 3/28/25 (Consent)
AYES: 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
NO VOTE RECORDED: Alvarado-Gil, Becker, Hurtado, Jones, Reyes, Weber Pierson

ASSEMBLY FLOOR: 78-0, 9/8/25 - See last page for vote

SUBJECT: Cosmetic safety: vaginal suppositories

SOURCE: Author

DIGEST: This bill exempts boric acid vaginal suppositories (BAS) from a prohibition on boric acid, and requires BAS to include a product label commencing January 1, 2027, and bans BAS commencing January 1, 2035, unless the BAS product becomes regulated by the federal Food and Drug Administration.

Assembly Amendments require boric acid vaginal suppositories (BAS) to include a product label commencing January 1, 2027, and ban BAS commencing January 1, 2035, unless the BAS product becomes regulated as a drug by the United States Food and Drug Administration, and address a chaptering conflict to restrict and prohibit the manufacture, sale, delivery, hold, or offering for sale cosmetic

products that contain any of the specified musk-related ingredients, beginning January 1, 2027.

ANALYSIS:

Existing federal law requires, pursuant to the federal Food, Drug & Cosmetic Act (FD&C Act), cosmetics produced or distributed for retail sale to consumers for their personal care to bear an ingredient declaration. (21 Code of Federal Regulations 701.3)

Existing state law:

1) Defines, pursuant to the Sherman Act, "cosmetic" as any article, or its components, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part of the human body, for cleansing, beautifying, promoting attractiveness, or altering the appearance. Further, the law makes it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any cosmetic that is adulterated or for any person to adulterate any cosmetic. (Health & Safety Code (HSC) § 109900)

2) Requires, pursuant to the Safe Consumer Cosmetic Act (Cosmetics Act), a manufacturer of a cosmetic that is subject to regulation by the federal Food and Drug Administration (FDA) to submit to the California Department of Public Health (CDPH) a list of its cosmetic products sold in California that contain any ingredient that is a chemical identified as causing cancer or reproductive toxicity. (HSC § 111792)

3) Requires the Department of Toxic Substances Control (DTSC), under the state's Green Chemistry regulations, to establish a process to identify and prioritize chemicals or chemical ingredients in consumer products that may be considered a chemical of concern. (HSC § 25252)

4) Requires DTSC to develop and maintain a list of Candidate Chemicals that exhibit a hazard trait and/or an environmental or toxicological endpoint and is either 1) found on one or more of the statutorily specified authoritative lists or 2) is listed by DTSC using specified criteria. (California Code of Regulations § 69502.2 (b))

5) Prohibits a person or entity from manufacturing, selling, delivering, holding, or offering for sale in commerce any cosmetic product that contains 24 specified

intentionally added chemical ingredients commencing January 1, 2025. Further, prohibits a person or entity from manufacturing, selling, delivering, holding, or offering for sale in commerce any cosmetic product that contains 41 specified intentionally added chemical ingredients commencing January 1, 2027. (HSC § 108980)

This bill:

1) Exempts a BAS product from the prohibitions of manufacturing, selling, delivering, holding, or offering for sale in commerce any cosmetic product containing the intentionally added ingredients specified in subparagraph (B) of paragraph (19) of subdivision (b) of Section 108980 of the Health and Safety Code (boric acid) under specified conditions.

2) Requires a person or entity that manufactures, sells, delivers, holds, or offers for sale in commerce a BAS product that is not regulated as a drug by the FDA to include a warning statement on the product label commencing January 1, 2027.

3) Prohibits the manufacture, sale, delivery, hold, or offering for sale in commerce of a BAS product that is not regulated as a drug by the FDA commencing January 1, 2035.

4) Makes related findings and declarations.

5) Addresses a chaptering conflict by joining in AB 60 (Papan), which restricts and prohibits the manufacture, sale, delivery, hold, or offering for sale cosmetic products that contain any of the specified musk-related ingredients, beginning January 1, 2027.

Background

1) *Regulatory requirements for California's cosmetics.* Prior to 2020, California had two laws governing the safety of cosmetics: The Sherman Act and the Cosmetics Act. These laws focused on the identification and notification of hazardous chemicals in cosmetics and outlawing the tampering of products. The Sherman Act prohibits the manufacture, sale, delivery, hold, or offer for sale of any cosmetic that is adulterated and makes it unlawful for any person to adulterate any cosmetic. The Cosmetic Act, established by SB 484 (Migden, Chapter 729, Statutes of 2005), requires the manufacturer, packer, and/or distributor of cosmetic products to provide the CDPH a list of all cosmetic

products that contain any ingredient known or suspected to cause cancer, birth defects, or other reproductive harm. CDPH does not have any enforcement authority over the manufacturers that are covered, so compliance may be lacking.

2) *Chemical bans for cosmetics*. Over the past several years, California has shifted its approach to the regulation of cosmetics. Section 108980 of the Health and Safety Code, as established by AB 496 (Friedman, Chapter 441, Statutes of 2023) and AB 2762 (Muratsuchi, Chapter 314, Statutes of 2020), prohibits the manufacture, sale, delivery, holding, or offering for sale in commerce any cosmetic product that contains any of 65 intentionally added ingredients. This approach is meant to reflect the hazard-based, regulatory framework of the European Union (EU) and leads to the banning of hazardous chemicals in cosmetics. On September 15, 2022, the European Commission published Regulation (EU) 2022/1531 to amend Cosmetics Regulation (EC) No. 1223/2009 for the use of certain ingredients classified as carcinogenic, mutagenic, or toxic for reproduction (CMR substances) in cosmetic products. These regulations require EU member states to prohibit the marketing of cosmetic products containing these ingredients. The scope of products covered under the EU's definition of cosmetics is broader than the scope of products covered under California's definition of cosmetics.

3) *The use of boric acid in suppositories.* Boric acid is a naturally occurring chemical that is associated with antifungal activity and can quickly kill 50-90% of certain fungi.[1] Boric acid suppositories (BAS) are gelatin capsules of boric acid applied intravaginally and said to address vaginal odor and infections, such as yeast infections and bacterial vaginosis. BAS are marketed as a natural remedy and an alternative to pharmaceuticals. They are sometimes encouraged for use when other viable treatment options have been exhausted and for stubborn and recurrent infections.[2] Boric acid is recommended for use against atypical species of fungi and more severe infections.[3] Only 5-10% of yeast infections are caused by atypical species.[3] The Centers for Disease Control and Prevention (CDC) and the American College of Obstetricians and Gynecologists (ACOG) recommend the use of boric acid in a gelatin capsule only after recurrence of a yeast infection caused by atypical fungi species and

[1] Prutting, S. M., & Cerveny, J. D. (1998). Boric acid vaginal suppositories: a brief review. Infectious diseases in obstetrics and gynecology, 6(4), 191.
[2] Iavazzo, C., Gkegkes, I. D., Zarkada, I. M., & Falagas, M. E. (2011). Boric acid for recurrent vulvovaginal candidiasis: the clinical evidence. Journal of women's health, 20(8), 1245-1255.
[3] Paavonen, J. A., & Brunham, R. C. (2020). Vaginitis in nonpregnant patients: ACOG practice bulletin number 215. Obstetrics & Gynecology, 135(5), 1229-1230.

after longer periods of treatment via other methods.[3,4] BAS are considered to be effective as experimental results have demonstrated that these products can lead to relief from symptoms of vaginal infections within 48 hours.[5]

Though useful in suppositories, boric acid has been considered reproductively toxic over the last 50 years.[6] Boric acid was added to the List of Substances Prohibited in Cosmetic Products (Annex II) in the EU in 2022. There, it is classified as a reproductive toxicant and BAS is currently not available for purchase in the EU. Boric acid is also identified as a Candidate Chemical for the California Department of Toxic Substances Control (DTSC). The Expert Panel for Cosmetic Ingredient Safety concluded that boric acid in concentrations less than or equal to 5% is safe.[5] The capsules of BAS typically contain 0.6 grams of boric acid and are considered safe for use as 15 grams of boric acid can have toxic effects.[7,8] Because BAS are administered intravaginally, the risk of introducing the toxic chemical to other parts of the body is lower, however, there is a risk of introducing the toxic chemical into the bloodstream if there is damage to the vaginal wall.[1,5] There are side effects of BAS including increased irritation, burning, and vaginal discharge.

Boric acid use is not recommended for pregnant women, as there is limited data on its harmful effects. Experts recommend that affected individuals consult their healthcare provider before using BAS to treat infections. Researchers claim that BAS should not be considered for the first-line treatment of uncomplicated vaginal infections because of insufficient data, controversy surrounding safety, and the availability of safer and effective treatments.[1] Because of its potential ability to impair fertility, researchers also suggest boric acid be considered a last option in exceptional cases for non-pregnant women.[9,10] The alternatives to BAS include prescribed antifungal and antibacterial medication, probiotics, and diets incorporating fermented food.

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[4] Centers for Disease Control and Prevention. (2021). Vulvovaginal Candidiasis. www.cdc.gov/std/treatment-guidelines/candidiasis.htm#print

[5] Writer, C. I. R. (2024). Safety Assessment of Boric Acid and Sodium Borate as Used in Cosmetics.

[6] Chapin, R. E., & Ku, W. W. (1994). The reproductive toxicity of boric acid. Environmental health perspectives, 102(suppl 7), 87-91.

[7] Farfán-García, E. D., Castillo-Mendieta, N. T., Ciprés-Flores, F. J., Padilla-Martínez, I. I., Trujillo-Ferrara, J. G., & Soriano-Ursúa, M. A. (2016). Current data regarding the structure-toxicity relationship of boron-containing compounds. Toxicology letters, 258, 115-125.

[8] Sevim, Ç., & Kara, M. (2022). Boron and boron-containing compounds toxicity. In The Toxicity of Environmental Pollutants. IntechOpen.

[9] Donders, G., Sziller, I. O., Paavonen, J., Hay, P., de Seta, F., Bohbot, J. M., ... & Mendling, W. (2022). Management of recurrent vulvovaginal candidosis: Narrative review of the literature and European expert panel opinion. Frontiers in Cellular and Infection Microbiology, 12, 934353.

[10] Farr, A., Effendy, I., Frey Tirri, B., Hof, H., Mayser, P., Petricevic, L., ... & Mendling, W. (2021). Guideline: vulvovaginal candidosis (AWMF 015/072, level S2k). Mycoses, 64(6), 583-602.

4) *A controversial capsule.* BAS are currently not approved by the U.S. Food and Drug Administration (FDA) and have not been rigorously tested to ensure that they are safe and effective for use. Their status with the FDA classifies BAS as homeopathic products, which are not required to be reviewed by the FDA. Homeopathic products tend to pose higher risks to public health because they may contain unsafe ingredients, undergo improper and unregulated manufacturing, have contamination, and lack labels that inform consumers of risks and side effects. BAS also tend to be marketed to treat and prevent infections, which could qualify these products as drugs. Under the Federal Food, Drug, and Cosmetic Act, products marketed in this manner and without FDA approval would violate federal law. In 2018, the FDA issued a warning to a manufacturer of a BAS product sold by the sponsor of this bill (pH-D Feminine Health) claiming that the online marketing of their product characterized their product as a drug. This was based on the manner in which the product is administered and the ailments it addresses. The manufacturer argued that the product has long been considered a cosmetic and should be regulated as such. The sponsor also alleges that they were advised incorrectly on acceptable marketing. As a result, the FDA required the product to undergo clinical trials and the manufacturer began to market the product as a cosmetic that solely addresses vaginal odor.

   In 2024, a class action lawsuit was filed against manufacturers for illegally selling BAS marketed to treat and prevent infections without FDA approval. Additionally in 2024, Women's Voices for the Earth, on behalf of several health and advocacy organizations, issued a letter of concern to a healthcare manufacturer to remove boric acid from their intimate care products over concerns of reproductive safety and to stop the spread of misinformation. This class action lawsuit is still pending.

Comments

1) *Purpose of this bill.* According to the author, "SB 39 will allow boric acid to continue to be used in vaginal and vulvar products sold in the State of California, and ultimately nationwide, as national retailers do not sell state-specific products. These products are marketed as cosmetics and are used by healthcare providers to treat two of the most common issues affecting women: vaginal yeast infections and vaginal odor. There is robust safety and efficacy data on the use of boric acid products in vaginal and vulvar products. For example, the Centers for Disease Control and Prevention (CDC) recommends the use of boric acid suppositories (BAS) in their current STD guidelines

(published 2015). Likewise, The American College of Obstetrics and Gynecology (ACOG) recommends the use of boric acid suppositories (BAS) in vaginal health applications. Boric acid products are readily available at every major retailer in the US. Healthcare providers guide their patients to purchase boric acid products at these retailers. Data shows that in areas where healthcare deserts exist, the sales of boric acid products are significantly higher, as well as healthcare providers instructing their patients to purchase these affordable products. 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."

2) *Accessibility to over-the-counter medications.* Boric acid suppositories are sold over the counter and do not require a prescription from a healthcare provider. This leaves an option for affected individuals to receive treatment and relief without a visit to the doctor. This is an important consideration given that 8% of women in California do not have access to health insurance and would not be prescribed alternative treatment options.[11] If these products are unavailable to current consumers, there is also the potential for affected individuals to seek boric acid intended for other applications to make homemade suppositories, which could put these individuals at a higher risk. Some research has claimed that BAS could be a safe and economic option for women with recurrent and chronic symptoms of vaginitis when conventional treatment fails with atypical, resistant strains of fungi.[2,12] However, given that there are concerns surrounding the hazardous nature of boric acid, insufficient data on safety, and that it is listed as a reproductive toxicant on the EU's List of Substances Prohibited in Cosmetic Products and the Candidate Chemical list for DTSC, more transparency could protect consumers and allow them to make an informed choice regarding the substances they introduce into their bodies. The temporary warning labeling requirement will provide such transparency for those who will continue to use BAS products until they are regulated by the FDA.

[11] KFF (2023). California Women's Health Insurance Coverage Data
[12] Mittelstaedt, R., Kretz, A., Levine, M., Handa, V. L., Ghanem, K. G., Sobel, J. D., ... & Tuddenham, S. (2021). Data on safety of intravaginal boric acid use in pregnant and nonpregnant women: a narrative review. Sexually transmitted diseases, 48(12), e241-e247.

Related/Prior Legislation

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.

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 (PFAS).

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.

FISCAL EFFECT: Appropriation: No Fiscal Com.: No Local: No

SUPPORT: (Verified 9/8/25)

American Congress of Obstetricians & Gynecologists - District Ix
Nutrablast
Ph-d Feminine Health, LLC
The Flex Company

OPPOSITION: (Verified 9/8/25)

None received

ASSEMBLY FLOOR: 78-0, 9/8/25
AYES: Addis, Aguiar-Curry, Ahrens, Alanis, Alvarez, Arambula, Ávila Farías, Bains, Bauer-Kahan, Bennett, Berman, Boerner, Bonta, Bryan, Calderon, Caloza, Carrillo, Castillo, Chen, Connolly, Davies, DeMaio, Dixon, Elhawary, Ellis, Flora, Fong, Gabriel, Gallagher, Garcia, Gipson, Jeff Gonzalez, Mark González, Hadwick, Haney, Harabedian, Hart, Hoover, Irwin, Jackson, Johnson, Kalra, Krell, Lackey, Lee, Lowenthal, Macedo, McKinnor, Ortega, Pacheco, Papan, Patel, Patterson, Pellerin, Petrie-Norris, Quirk-Silva, Ramos, Ransom, Celeste Rodriguez, Michelle Rodriguez, Rogers, Blanca Rubio, Sanchez, Schiavo, Schultz, Sharp-Collins, Solache, Soria, Stefani, Ta, Tangipa, Valencia, Wallis, Ward, Wicks, Wilson, Zbur, Rivas
NO VOTE RECORDED: Muratsuchi, Nguyen

ASSEMBLY FLOOR: 75-0, 6/27/25
AYES: 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

NO VOTE RECORDED: Bauer-Kahan, Flora, Pellerin, Blanca Rubio

Prepared by: Taylor McKie / E.Q. / (916) 651-4108
9/8/25 19:32:05

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