

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

(PROPOSITION 65)

**NOTICE OF INTENT TO LIST BY THE AUTHORITATIVE BODIES MECHANISM:
PERFLUOROBUTANOIC ACID (PFBA) AND RELATED SALTS**

OCTOBER 30, 2026

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) intends to list *perfluorobutanoic acid (PFBA) and related salts* as known to the state to cause reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986, codified in Health & Safety Code section 25249.5 *et seq.*, otherwise known as Proposition 65.

As stated in US EPA (2022), *related salts* include "salts (including alkali metal salts) of PFBA that would be expected to fully dissociate in aqueous solutions of pH ranging from 4–9 (e.g., in the human body) ... it does apply to PFBA salts including ammonium perfluorobutanoate (CASRN 10495-86-0), sodium perfluorobutanoate (CASRN 2218-54-4), potassium heptafluorobutanoate [2966-54-3], and other non-metal or alkali metal salts of PFBA." (Executive Summary, Pg. xi)

This action is being proposed under the "Authoritative Bodies" listing mechanism (Health & Safety Code section 25249.8(b)) described below. OEHHA has determined that *PFBA and related salts* meet the criteria for listing for reproductive toxicity, based on the developmental, male reproductive, and female reproductive endpoints, by this mechanism. *PFBA and related salts* are members of a large group of chemicals known as per- and polyfluoroalkyl substances (PFAS), which have widespread use in consumer products and industrial applications due to their heat-, oil-, stain-, and water-resistant properties (US EPA, 2022). PFBA and related salts have been used in consumer products and PFBA is a breakdown product of other PFAS.

Background on listing via the Authoritative Bodies mechanism: A chemical must be listed under the Proposition 65 regulations when two conditions are met:

- 1) An authoritative body formally identifies the chemical as causing reproductive toxicity pursuant to Cal. Code of Regs., tit. 27, section 25306(d).
- 2) The evidence considered by the authoritative body meets the sufficiency criteria contained in Cal. Code of Regs., tit. 27, section 25306(g).

However, the chemical is not listed if scientifically valid data which were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met (Cal. Code Regs., tit. 27, section 25306(h)).

The US Environmental Protection Agency (US EPA) is one of several institutions designated as authoritative for the identification of chemicals as causing reproductive toxicity (Cal. Code of Regs., tit. 27, section 25306(l)).

OEHHA is the lead agency for Proposition 65 implementation. After an authoritative body has made a determination about a chemical, OEHHA evaluates whether listing under Proposition 65 is required using the criteria contained in Cal. Code Regs., tit. 27, section 25306.

OEHHA's determination: *PFBA and related salts* meet the criteria for listing as known to the state to cause reproductive toxicity under Proposition 65, based on findings by the US EPA (2022), as outlined below.

Formal identification and sufficiency of evidence:

OEHHA is relying on:

- The statement in the US EPA's Toxicological Review of Perfluorobutanoic Acid [PFBA, CASRN 375-22-4] and Related Salts (US EPA, 2022) that "This assessment applies to PFBA as well as salts (including alkali metal salts) of PFBA that would be expected to fully dissociate in aqueous solutions of pH ranging from 4–9 (e.g., in the human body) ... it does apply to PFBA salts including ammonium perfluorobutanoate (CASRN 10495-86-0), sodium perfluorobutanoate (CASRN 2218-54-4), potassium heptafluorobutanoate [2966-54-3], and other non-metal or alkali metal salts of PFBA." (Executive Summary, Pg. xi)
- US EPA's conclusion that "PFBA exposure is likely to cause developmental effects in humans".
- US EPA's conclusion that PFBA causes male and female reproductive toxicity, i.e., "evidence for delayed development of the reproductive system (i.e., delayed vaginal opening and preputial separation) following gestational PFBA exposure (Das et al., 2008)."
- US EPA's establishment of a subchronic oral reference dose (RfD) for PFBA based on developmental toxicity (delayed time to vaginal opening, i.e., delayed development of the female reproductive system).

The findings and actions in this document satisfy the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations for listing.

Pertinent statements and information in US EPA (2022) documenting the Agency's conclusions about reproductive toxicity (developmental, male reproductive, and female reproductive endpoints) include the following:

Developmental endpoint:

- “The hazard identification judgment that the **evidence indicates** PFBA exposure is likely to cause developmental effects in humans (given relevant exposure circumstances), including increased prenatal effects (full-litter resorptions) and delays in developmental milestones (days to eye opening, vaginal opening, and preputial separation) without effects on fetal (pup) growth is based on a single study in mice exposed gestationally to PFBA.” [emphasis in original] (Pg. 4-2)
- “There is evidence for delayed development of the reproductive system (i.e., delayed vaginal opening and preputial separation) following gestational PFBA exposure (Das et al., 2008). These latter results are synthesized and integrated in the developmental effects section (see Section 3.2.3) where the human relevance of delayed development of the reproductive system observed in mice are outlined and not discussed further in this section.” (Pg. 3-57)
- “From these subchronic osRfDs, an **overall subchronic RfD of 6×10^{-3} mg/kg-day PFBA based on developmental delays** is selected (the corresponding overall subchronic RfD is 7×10^{-3} mg/kg-day for the ammonium salt).” [emphasis in original] (Pg. 5-26)

Male and female reproductive endpoints:

- “The hazard identification judgment that the **evidence indicates** PFBA exposure is likely to cause developmental effects in humans (given relevant exposure circumstances), including....delays in developmental milestones (...vaginal opening, and preputial separation)....is based on a single study in mice exposed gestationally to PFBA.” [emphasis in original] (Pg. 4-2)
- “The male and female reproductive developmental landmarks (preputial separation and vaginal opening, respectively) were delayed. Preputial separation was delayed by 2.3 days at 350 mg/kg-day although vaginal opening was delayed 3.3 and 3.6 days (175 and 350 mg/kg-day, respectively).” (Pg. 3-51)

- “Given the sparsity of evidence on potential reproductive effects, the relative insensitivity of the outcome measures (organ weights) in animals, and the largely null findings, there is ***inadequate evidence*** to determine whether PFBA exposure has the potential to cause reproductive effects in humans (other than the developmental delays discussed in Section 3.2.3; see Table 3[-]11).” [emphasis in original] (Pg. 3-57)
- “There was ***inadequate evidence*** to determine whether PFBA exposure has the potential to cause reproductive toxicity (in adults).” [emphasis in original] (Pg. 4-2)
- “As the EPA’s Reproductive Guidelines (U.S. EPA, 1996) state that both accelerations and delays in the timing of puberty should be considered adverse, it is reasonable to extend this conclusion to developmental milestones that are more broadly indicative of sexual and/or reproductive developmental *[sic]*, Further, the absence of effects on body weight in PFBA-exposed offspring or maternal toxicity strengthens the confidence that the observed developmental delays are biologically significant, adverse effects. Taken together, the available animal studies provided *moderate* evidence of potential developmental effects.” [emphasis in original] (Pg. 3-53 & 3-54)

OEHHA has reviewed the studies or study descriptions cited in US EPA (2022) as providing the basis for the Agency’s conclusions regarding reproductive toxicity (developmental, male reproductive, and female reproductive endpoints) relative to the criteria in Cal. Code Regs., tit. 27, section 25306(g). The criteria for listing *PFBA and related salts* through the authoritative bodies mechanism as causing reproductive toxicity (developmental, male reproductive, and female reproductive endpoints) have been met.

Opportunity for Comment: OEHHA is providing this opportunity to comment as to whether this chemical meets the criteria set forth in the Proposition 65 regulations for authoritative bodies listings.

Submission of Comments

All written comments must be submitted to OEHHA by electronic submission, mail, or hand-delivery, by **Monday, November 30, 2026**. OEHHA strongly recommends that comments be submitted electronically through our website at <https://oehha.ca.gov/comments>, rather than in paper form. Alternatively, comments can be submitted in paper form, either by mail or delivered in person.

Mailed submission via the United States Postal Service:

Attention: Kiana Vaghefi
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, California 95812-4010

In-person delivery submission:

Attention: Kiana Vaghefi
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, California 95814

OEHHA encourages all commenters to submit their comments in a format compliant with Section 508 of the federal Rehabilitation Act, Web Content Accessibility Guidelines 2.1 (<https://www.w3.org/WAI/standards-guidelines/wcag>) and California Government Code sections 7405 and 11135, so that they can be read using screen reader technology.

Comments received during the public comment period will be posted on the OEHHA website after the close of the comment period.

OEHHA is subject to the California Public Records Act and other laws that require the release of certain information upon request. If you provide comments, please be aware that your name, address, and e-mail may be available to third parties.

If you have any questions, please contact Kiana Vaghefi at Kiana.Vaghefi@oehha.ca.gov or at 916-322-1268.

Reference

US EPA (US Environmental Protection Agency). 2022. IRIS Toxicological Review of Perfluorobutanoic Acid [PFBA, CASRN 375-22-4] and Related Salts (EPA/635/R-22/277Fa) Washington, DC.
https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=CPHEA&dirEntryId=356425