



WOMEN'S VOICES FOR THE EARTH

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**Biomonitoring California
Scientific Guidance Panel
March 8, 2021.**

Women's Voices for the Earth submits the following comments for the agenda item "Evaluating the Safety of Quaternary Ammonium Compounds (QACs)".

U.S. Food and Drug Administration Review of ADBAC

It is worth noting that the Food and Drug Administration is also currently assessing the safety of ADBAC for its OTC monograph on topical antiseptic drug products (ie. hand sanitizers). In 2016 they proposed a final rule for this OTC monograph (which had begun in 1994) and categorized ADBAC (benzalkonium chloride) as a Category III ingredient **because of a lack of adequate safety data**. While information may be presented at this meeting that there is robust scientific literature on the safety of quats, it must be understood that the FDA found this body of literature to be lacking, and has required the industry to conduct additional studies to fill the data gaps. This research has begun and is still on-going. Specifically, the FDA noted:

"In summary, our administrative record for the safety of benzalkonium chloride is incomplete with respect to the following:

- *Human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), including documentation of validation of the methods used to measure benzalkonium chloride and its metabolites;*
- *Animal dermal ADME;*
- *Dermal carcinogenicity; and*
- *Data from laboratory studies that assess the potential for the development of resistance to benzalkonium chloride and cross-resistance to antibiotics as discussed in section VIII.C."*

Sources:

<https://www.federalregister.gov/documents/2016/06/30/2016-15410/safety-and-effectiveness-of-consumer-antiseptics-topical-antimicrobial-drug-products-for>

<https://www.regulations.gov/docket/FDA-2015-N-0101>

<https://www.regulations.gov/document/FDA-2015-N-0101-1495>