
Ethyl Alcohol, FCC

Type of Posting: Notice of Intent to Revise

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Targeted Effective Date: To be Determined

In accordance with the Rules and Procedures of the Council of Experts, this is to provide notice that the Food Ingredients Expert Committee intends to revise the *Food Chemicals Codex (FCC)* Ethyl Alcohol monograph to address immediate concerns documented in a letter by the U.S. Food and Drug Administration (FDA) (Ref. 1). The intended revisions, which will be made using an accelerated revision process (*FCC Immediate Standard*) include:

1. Replacing the test for *Methanol* in the *Organic Impurities* section of the monograph with a test for *Methanol and Other Volatile Impurities*. This method is consistent with the test for *Organic Impurities* present in the *USP–NF* monograph for Alcohol and that recently was added to the Identification test section via a [Revision Bulletin](#);
2. Including a limit of NMT 200 µL/L for methanol;
3. Adding limits for other volatile impurities consistent with those included as *Ketones and Other Alcohols* in the monograph for Ethyl Alcohol developed by the 46th Session of the FAO-WHO Joint Expert Committee on Food Additives (JECFA, 2006), including a limit of NMT 1000 µL/L for any other single impurity and a limit of NMT 5000 µL/L as the sum of all impurities determined by the method; and
4. Adding an *Identification* section to the monograph including an *Infrared Spectra* test and comparison to a published spectrum as a new testing requirement.

Recently, FDA alerted the public to a sharp increase in hand sanitizer products that are labeled to contain ethanol (also known as ethyl alcohol) and that have tested positive for methanol (Ref. 2-4). These recent reported incidents of products labeled as ethanol testing positive for methanol could create risks to public health beyond hand sanitizers since ethanol is extensively used in many other products, including foods. FDA's letter to USP regarding this issue (Ref. 1) indicates that the Agency is concerned that this critical contamination risk is poised to have a broad impact. To address this public health issue, FDA requested that USP revise the USP Alcohol and Dehydrated Alcohol monographs, the USP Isopropyl Alcohol monographs, and any related *USP* and *FCC* monographs¹.

USP is publishing this Notice of Intent to Revise (NITR) to inform stakeholders about the proposed upcoming revisions to the *FCC* monograph for Ethyl Alcohol via an accelerated revision process (*FCC Immediate Standard*) and to prepare companies for the operational and compliance implications associated with a rapid implementation timeframe. USP is planning to follow this NITR with the posting of an Immediate Standard to become official on a specified date.

USP encourages stakeholders to provide feedback by **September 18, 2020** on any impact that may

result from this revision; please direct any such feedback to the email fcc@usp.org. Feedback specific to ethyl alcohol as a material in the food supply chain and related food products which may be impacted by this revision is specifically encouraged.

1 USP has identified additional related monographs in the *USP–NF* and *FCC*, namely the *USP* Isopropyl Alcohol and *USP* Azeotropic Isopropyl Alcohol monographs, and the *FCC* Isopropyl Alcohol monograph. USP will announce potential compendial revisions to these monographs at a later date.

References:

1. US Pharmacopeial Convention (USP) website, Letter from FDA to USP on July 30, 2020
https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-notices/fda-letter-alcohols-nitr-att.pdf
2. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-reiterates-warning-about-dangerous-alcohol-based-hand-sanitizers>
3.
<https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-consumers-not-use-hand-sanitizer-products-manufactured-eskbiochem>
4.
<https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use>