



May 14, 2020

The Honorable Stephen M. Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Via email

Dear Commissioner Hahn:

As you know, demand for alcohol-based hand sanitizer products has sharply increased in recent months, as American businesses and households attempt to mitigate the spread of COVID-19. In turn, the supply of alcohol suitable for use in hand sanitizer has not been able to keep pace with surging demand, resulting in hand sanitizer shortages across the country. Where hand sanitizer products are available, they are often being offered at prices that are unaffordable for many Americans, especially low-income households that already have the highest risk for contracting COVID-19. Hand sanitizer shortages are expected to grow more acute in the weeks ahead, as states are easing stay-at-home orders and Americans return to public spaces like retail stores, restaurants, churches, and other shared venues.

To prepare for further increases in demand for alcohol-based hand sanitizer and to ensure sufficient and affordable supplies are available to help protect American citizens, we respectfully request that the U.S. Food and Drug Administration immediately adopt a transparent and unambiguous temporary standard for the manufacture of alcohol for incorporation into alcohol-based hand sanitizer products. Doing so would give manufacturers who typically make alcohol for other purposes (e.g., industrial, technical, fuel) the certainty and clarity they need to repurpose their operations and increase production of high-purity alcohol suitable for use in hand sanitizer products. A reasonable temporary standard would ensure sufficient and affordable volumes of alcohol for hand sanitizer are available during the COVID-19 crisis, helping to protect American citizens.

We note that Health Canada has already taken such action, concluding that the public health benefits of slightly easing restrictions on alcohol for hand sanitizer far outweigh the risks to Canadian citizens. We urge FDA to follow Health Canada's lead.

Attached please find a brief white paper and our recommendation for a temporary standard that establishes provisional impurity limits, some of which are slightly less restrictive than those implied by FDA's current guidance.

We would appreciate the opportunity to further discuss this request with appropriate FDA staff. Thank you for your consideration of this important matter. The U.S. ethanol industry is eager to help our nation combat the spread of COVID-19 and protect our communities as public spaces begin to reopen.

Sincerely,

A handwritten signature in black ink that reads "Geoff Cooper". The signature is written in a cursive, slightly slanted style.

Geoff Cooper
President & CEO

Cc:

Amy Abernethy, MD, PhD
Principal Deputy Commissioner

Keagan Lenihan
Chief of Staff

Janet Woodcock, MD
Director, Center for Drug Evaluation & Research

Anna Abram
Deputy Commissioner, Office of Policy, Legislation, & International Affairs

TEMPORARY STANDARD FOR THE MANUFACTURE OF ALCOHOL FOR INCORPORATION INTO ALCOHOL-BASED HAND SANITIZER PRODUCTS

May 14, 2020

BACKGROUND

Demand for alcohol-based hand sanitizer products has sharply increased in recent months, as American businesses and households attempt to mitigate the spread of COVID-19. In turn, the supply of alcohol suitable for use in hand sanitizer has not been able to keep pace with surging demand, resulting in hand sanitizer shortages across the country. Where hand sanitizer products are available, they are often being offered at prices that are unaffordable for many American households (especially low-income households that already have the highest risk for contracting COVID-19). Hand sanitizer shortages are expected to grow more acute in the weeks ahead, as states ease stay-at-home orders and Americans return to public spaces like retail stores, restaurants, churches, and other shared venues.

THE NEED FOR A TEMPORARY STANDARD

To prepare for further increases in demand for alcohol-based hand sanitizer and to ensure sufficient and affordable supplies are available to help protect American citizens, the U.S. Food and Drug Administration (FDA) should immediately adopt a transparent and temporary standard for the manufacture of alcohol for incorporation into alcohol-based hand sanitizer products. Doing so would allow manufacturers who typically make alcohol for other purposes (e.g., industrial, technical, fuel) to repurpose their operations to increase high-purity alcohol suitable for use in hand sanitizer products.

A reasonable temporary standard would ensure sufficient and affordable volumes of alcohol for hand sanitizer are available during the COVID-19 crisis, helping to protect the health of American citizens. Notably, Health Canada has already taken such action, concluding that the public health benefits of slightly easing restrictions on alcohol for hand sanitizer far outweigh the risks to Canadian citizens.¹

FDA ACTIONS TO DATE HAVE CREATED MARKET CONFUSION AND UNCERTAINTY

Since the onset of the COVID-19 pandemic in the United States, FDA has issued multiple guidance documents regarding the manufacture of alcohol for incorporation into alcohol-based hand sanitizers.² FDA has clarified that its guidance “contains nonbinding recommendations” and “is not binding on FDA or the public.”

¹ <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/covid19-technical-grade-ethanol-hand-sanitizer/risk-assessment-summary-report.html>

² <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/hand-sanitizers-covid-19>

March 27 Guidance

On March 27, FDA issued guidance clarifying that non-synthetic (i.e., biogenically-derived) alcohol used for hand sanitizer production does not need to meet United States Pharmacopoeia (USP) and Food Chemical Codex (FCC) grade requirements for purity, as long as other quality conditions outlined in the guidance were met (e.g., not less than 94.9% ethanol by volume, any water used must be sterile, etc.).

Many ethanol producers who typically produce alcohol for other purposes (e.g., fuel, industrial) welcomed the March 27 guidance and responded by investing in the process modifications necessary to supply high-purity alcohol for incorporation into hand sanitizers.

April 15 Guidance

However, FDA issued revised guidance on April 15, which confused ethanol producers, compounders, and other parties in the supply chain. The April 15 guidance stated “...fuel or technical grade ethanol should only be used if it meets USP or FCC grade requirements and the ethanol has been screened for any other potentially harmful impurities not specified in the USP or FCC requirements.” Many in the marketplace interpreted this statement as meaning alcohol produced at facilities that typically manufacture fuel grade ethanol must meet USP or FCC requirements in order to be used in hand sanitizer. FDA further confused the issue by stating in the same guidance that “Ethanol produced in facilities normally producing fuel or technical grade may be considered for use [in hand sanitizer] if the ethanol is produced from fermentation and distillation as would be typically used for consumable goods, and no other additives or other chemicals have been added to the ethanol.”

The April 15 guidance also stated that firms wishing to supply ethanol that does not meet USP or FCC requirements should “...submit information on the ethanol with regard to the levels of impurities listed in the USP monograph as well as any other potentially harmful impurities that may be present given the manufacturing environment.”

April 16 Conference Call

On a conference call with stakeholders on April 16, FDA officials stated again that ethanol used for hand sanitizer does not need to meet USP or FCC requirements. FDA also suggested that ethanol producers who wished to supply alcohol for hand sanitizer “should” submit data regarding impurity levels to FDA, but officials on the call did not specify how the submitted data would be used. Officials stated that they were most concerned about the possibility of contaminants like gasoline, benzene, and heptane being present in alcohol destined for hand sanitizer production. These compounds are not present in alcohol produced from biogenic feedstocks (e.g., corn starch) at typical ethanol plants.

Following the April 15 guidance and April 16 conference call, some ethanol producers voluntarily submitted data regarding impurities to FDA, as suggested, without knowing how FDA would use the data or whether they should expect a response from FDA.

FDA Responses to Data Submittals

In recent weeks, FDA has begun to reply via email to many ethanol producers who submitted data. In many of these replies, FDA has suggested ethanol produced by the business submitting the data is not appropriate for use in hand sanitizer (e.g., “FDA has determined that your proposed ethanol is not suitable as an API [active pharmaceutical ingredient] for use in hand sanitizer under the Agency’s temporary enforcement discretion policy.”)

In many of these replies, FDA says its conclusion that the ethanol is “not suitable” is based on “high levels” of naturally occurring acetaldehyde, acetal, and/or “all-other impurities.” However, FDA has failed to clarify to ethanol producers, compounders, or the general public what levels of these impurities are deemed suitable or acceptable. Thus, ethanol producers and hand sanitizer manufacturers have no idea what standards regarding certain impurities (e.g., acetaldehyde, methanol, acetal) are being used by FDA to “pass” or “fail” submitted samples. FDA has also failed to explain to these parties what chemicals are considered as part of the “all-other impurities” category and what levels of “all-other impurities” is deemed acceptable.

PROPOSED TEMPORARY STANDARD

To eliminate rampant marketplace confusion and uncertainty, and to bring needed clarity to this issue, we recommend that U.S. FDA adopt and make available to the public a temporary standard with specific limits for the same impurities that are identified in Table 2 of USP Monograph. This would enable alcohol manufacturers to know exactly what levels of these impurities are acceptable without having to guess or await a reply from FDA.

We recommend that FDA adopt the attached standard through at least December 31, 2020 (at which time a determination could be made on whether an extension is necessary).

DRAFT – PROPOSED STANDARD SUBMITTED TO FDA FOR CONSIDERATION

**TEMPORARY STANDARD FOR THE MANUFACTURE OF ALCOHOL FOR
INCORPORATION INTO ALCOHOL-BASED HAND SANITIZER PRODUCTS**

This standard establishes temporary impurity limits, some of which are slightly less restrictive than those found in Table 2 of the United States Pharmacopoeia (USP) Monograph. The public health benefits of temporarily adopting this standard for alcohol incorporated into hand sanitizer far outweigh the risks to American citizens. This standard applies to biogenically-derived alcohol (i.e., non-synthetic) produced using current good manufacturing practices (CGMPs). This standard prohibits the addition of other additives or other chemicals to the ethanol prior to denaturing, and special caution must be taken to ensure any other chemicals on site are not introduced into the ethanol either intentionally or via cross contamination.

PRODUCT DATA SHEET
CHEMICAL AND PHYSICAL PROPERTIES
Acceptable Criteria

Ethanol, % volume @ 60 °F, min ¹	94.9	Proofing Hydrometer
Acetaldehyde + Acetal ² , ppm	1,000	Gas Chromatography
Methanol ³ , ppm	650	Gas Chromatography
Benzene ⁴ , ppm	2	Gas Chromatography
Sum of all other impurities ⁵ , ppm	3,000	Gas Chromatography

Product denatured under these formulas:

- a. Formula 40A or 40B with or without the tert-butyl alcohol
- b. Formula 3C (isopropyl alcohol)

¹ Consistent with existing FDA Guidance.

² Based on Health Canada. *Technical-grade ethanol for the manufacture of hand sanitizers during the COVID-19 pandemic: Risk assessment summary report*. April 18, 2020. (“We engaged a broad range of technical and scientific experts in the assessment of the potential risks to health posed by hand sanitizers containing technical-grade ethanol with concentrations of up to 1000 ppm of acetaldehyde. Based on the results of this assessment, we have determined that, when used as directed and for a limited period of time, the public health benefits of using hand sanitizer containing specific sources of technical-grade ethanol outweigh the risk.”)

³ FDA responses to individual ethanol producers who have submitted sample data indicate that methanol levels of up to 650 ppm are not of concern.

⁴ Consistent with Table 2 of USP Monograph.

⁵ Referenced here as the “sum of other impurities” are the common congeners from a grain fermentation found in distilled ethanol: ethyl acetate, iso-butanol, n-propanol, active amyl alcohol and iso-amyl alcohol. There is no scientific reason to believe there are any other “harmful” impurities that would be present in ethyl alcohol manufactured via grain fermentation using cGMPs.