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# Technical-grade ethanol for the manufacture of hand sanitizers during the COVID-19 pandemic: Risk assessment summary report

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## Context

The unprecedented demand for hand sanitizer products during the COVID-19 pandemic has created global shortages of pharmaceutical and food-grade ethanol. In response, Health Canada published a Notice to Industry on April 15, 2020 about the time-limited approval of specific sources of technical-grade ethanol to be used in the manufacture of hand sanitizers. Other countries are also experiencing similar shortages and are providing similar flexibilities to suppliers and manufacturers. Risk assessment approaches have been established in the United States for ethanol in hand sanitizers (April 15, 2020 updated temporary\_policy), and in the United Kingdom for isopropyl alcohol-based handrubs. In support of our transparency objectives, this report provides a summary of our risk assessment, including recommendations and risk mitigation measures.

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. Industry and their associations were consulted and advised of this time-limited approval, and we will continue to engage implicated stakeholders in the transition plan as the shortage situation evolves.

## **What Health Canada approved**

We approved the temporary supply of technical-grade ethanol for use in hand sanitizers for a short period, subject to the conditions outlined below and as per the April 15, 2020 Notice to Industry.

## **Why it was approved**

Recent data released by Statistics Canada shows that there has been a seven-fold increase in sales of hand sanitizer in mid-March compared to sales during the same one-week period last year. This high demand has resulted in shortages of raw materials, such as ethanol, which has led to searches for substitute ingredients. Hand sanitizers are normally made with pharmaceutical or food-grade ethanol. We have received a number of submissions from proponents interested in temporarily supplying technical-grade ethanol for use in hand sanitizers.

On April 13, 2020, we completed a thorough risk assessment of the benefits and risks of the use of technical-grade ethanol in hand sanitizers. To help alleviate current shortages of hand sanitizers, and without compromising product safety and efficacy, we are temporarily approving the use of specific sources of technical-grade ethanol in hand sanitizer products.

## **Scientific rationale and process for Health Canada's decision and recommendations**

Numerous Canadian entities and industries not currently regulated by Health Canada have recently expressed interest in providing additional and/or alternate sources of ethanol (also known as anhydrous alcohol, ethyl alcohol, or grain alcohol) for use in the production of hand sanitizers to help alleviate supply shortages during the COVID-19 pandemic.

On April 3, 2020, we published an [interim guide on the use of ethanol](#) as an ingredient in alcohol-based hand sanitizers sold in Canada. The guide outlines quality requirements for ethanol to be used in the production of alcohol-based hand sanitizers. It also explains that in situations where the ethanol does not meet the established quality standards, a risk assessment is undertaken on a case-by-case basis to determine if the ethanol is safe for use in alcohol-based hand sanitizers in the context of the COVID-19 pandemic, with particular attention given to the types and level of impurities. We received submissions from various producers to allow the temporary supply of technical-grade ethanol for use in alcohol-based hand sanitizers.

On April 13, 2020, a task force of government experts in toxicology, emergency medicine, dermal absorption, and food assessment completed the risk assessment and provided final recommendations on the use of technical-grade ethanol in alcohol-based hand sanitizers in Canada.

The primary impurity of concern in technical-grade ethanol is acetaldehyde, which can be found in concentrations of 800 - 1000 ppm. In contrast, acetaldehyde limits established in the pharmacopoeia (including the United States Pharmacopeia (USP), the British Pharmacopoeia, and the European Pharmacopoeia), which are internationally accepted as the quality standards

applicable to drug or medicinal use, have been set at 10 ppm. Acetaldehyde is considered to be possibly carcinogenic to humans according to the International Agency for Research on Cancer (IARC). Evidence on carcinogenicity of this substance is mainly via inhalation, leading this substance to be considered “toxic” to human health as defined under section 64(c) of the *Canadian Environmental Protection Act, 1999*. Acetaldehyde is naturally found in many foods, and is present in cosmetics which are expected to be safe when applied to the skin.

The risk assessment concluded that acetaldehyde exposure from ethanol-based hand sanitizers is not expected to result in acute toxicity, high irritation or sensitization. However, concerns remain about potential carcinogenicity due to an increase in acetaldehyde exposure, particularly if the hand sanitizer is used for a longer duration. The risk is considered a Type II health hazard, which means that the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

The task force compared the relative risk of unavailability of alcohol-based hand sanitizers in situations where individuals may be unable to routinely access soap and water. It was determined that the public health benefit to limit the spread of COVID-19 outweighs the risk associated with exposure to technical-grade ethanol impurities (acetaldehyde) at higher levels than those typically found in these products.

The task force estimated acetaldehyde exposure through the skin (dermally) and by inhalation resulting from hand sanitizer use. Exposure scenarios were based on a variety of **factors** including:

- the number of applications per day in a healthcare setting, which could be as high as 109 exposures per day for nurses in the Intensive Care Unit (ICU)
- an absorption rate of acetaldehyde of 2% inferred from the Kramer *et al.* (2007) study
  - as the Kramer *et al.* study provided variable absorption rates of ethanol following exposure and did not directly measure the absorption rate of acetaldehyde, this value remains an uncertainty factor in the calculations
- based on its vapour pressure, acetaldehyde would be expected to evaporate much more rapidly than ethanol
- ethanol could also be expected to act as a skin penetration enhancer, thereby increasing the absorption of constituents such as acetaldehyde (Lachenmeier 2008)

Based on these factors, and using a worst case scenario of an acetaldehyde concentration of 1000 ppm (v/v), the increase in cancer risk resulting from both dermal and inhalation exposures when applying hand sanitizers would not be considered negligible. However, this risk is considered to be tolerable for the short-term, under the current COVID-19 circumstances. Should the level of acetaldehyde decrease, the risk of cancer would decrease as well.

The task force considered product use settings, including general-purpose personal care hand sanitizers (where the frequency of use is expected to be lower) and settings such as hospitals, clinics, commercial settings and other facilities where essential workers are present (where the frequency of use is expected to be higher as compared to general personal-care use). The task force determined that, based on the factors outlined above, the risk related to higher frequency of use and exposure, although not negligible, would be tolerable as a short-term solution, given the current shortage of ethanol and given the amplified need for alcohol-based hand sanitizers within these settings. Therefore, no restrictions would need to be imposed on suppliers of technical grade ethanol or their clients with respect to the distribution of hand sanitizer containing technical grade ethanol.

As concluded by the task force, there is no duration of use of products containing acetaldehyde levels higher than the USP limit of 10 ppm that would result in a negligible risk. Risk is a function of hazard and exposure. Thus, the greater the exposure to acetaldehyde in the alcohol-based hand sanitizers (i.e., in terms of concentration, quantity of hand sanitizer used in each application, frequency of applications per day, and duration of use), the greater the risk. This risk is expected to decrease with decreasing exposure (e.g., limiting the time to which one is exposed and/or reducing the number of applications within any given period), as well as with decreasing concentrations of acetaldehyde present in the technical-grade ethanol.

The task force further recommended that appropriate risk mitigation was to establish additional product labelling requirements, i.e., **adults only, do not use on broken or damaged skin**, a **contraindication for pregnant and lactating women** (typically considered a vulnerable subpopulation), and a **do not inhale** warning to mitigate concerns associated with dermal and inhalation exposure to acetaldehyde. In addition, the task force recommended reinforcing the requirement to report adverse reactions to us.

The task force compared the relative risk associated with the unavailability of alcohol-based hand sanitizers in situations where individuals may be unable to routinely access soap and water. We support the task force conclusion that the public health benefit to limit the spread of COVID-19 outweighs the risk associated with exposure to technical-grade ethanol impurities (acetaldehyde) at higher levels than those typically found in these products.

The advice from the task force supports the steps taken by Health Canada to address product supply chain shortages while encouraging opportunities for higher quality ethanol-based hand sanitizers to re-enter the market at sufficient levels to meet the demand as soon as feasible. We will continue to monitor and re-evaluate the ethanol supply chain as the COVID-19 crisis evolves and take appropriate actions as necessary.

## Implementation

To provide full transparency to the Canadian public on approved sources of technical grade ethanol and support appropriate monitoring of suppliers and users of technical grade ethanol for the production of hand sanitizers, we are taking the following steps:

- maintaining and publicly releasing a List of companies approved to supply technical grade ethanol for the production of hand sanitizers in Canada
- providing a notification form for manufacturers to inform us of various aspects of the supply chain associated with these products and enable prompt follow-up action as necessary

Should the shortages in higher quality ethanol persist beyond the time-limited approval period, we will consider whether any additional risk mitigation strategies are required.

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