

Production of Ethanol-Based Hand Sanitizer in Breweries During the COVID-19 Crisis

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ABSTRACT

The outbreak of SARS-CoV-2 has overwhelmed health systems, created economic turmoil, and disrupted supply chains around the world. One of the earliest and most severe supply chain disruptions occurred in alcohol-based hand sanitizer, a critical resource in combating the spread of coronaviruses. Many breweries and distilleries quickly arrived at the same conclusion: their facilities could produce hand sanitizer to help mitigate viral transmission in their communities while sustaining revenues through the crisis. With bureaucracies at all levels of government

caught off guard, they were not able to give clear direction to businesses to make this pivot, leaving businesses to find their own way through various regulatory mazes. This manuscript describes the means taken by the brewing and distilling community in Alberta, Canada, that facilities can replicate to get high-quality hand sanitizers to market safely and efficiently.

Keywords: hand sanitizer, COVID-19, brewery, distillery, alcohol-based, ethanol-based, safety

Introduction

While many formulations exist for hand sanitizers, which are a critical resource in combating the spread of coronaviruses (1), this document will focus on the one most relevant to breweries and distilleries: ethanol-based sanitizer that follows the World Health Organization (WHO)-recommended formula. Where “alcohol-based” is used in place of “ethanol-based,” it indicates commonalities with alternative formulations that use isopropanol or *n*-propanol. Given that regulatory changes are occurring weekly, it is important for readers to check the latest information from governments; this document is current only to mid-April 2020. Because safety is the top priority before diving into regulatory and process considerations, the discussion will begin there.

Safety Considerations

Each level of government has its own regulations around transporting ethanol and packaged hand sanitizer that govern volumes, means of containment, duty to respond, and other areas, so producers should ensure that they are licensed for any planned transportation activities. Many logistics companies are equipped to deliver ethanol in large volumes and dispense it into totes or other means of storage. Finished product should be contained as outlined in your transportation plan according to local regulations, and volumes should be kept within building code stipulations.

Local building inspectors should be consulted on appropriate means of storage and containment, and as outlined in Site, Product, and Alcohol Licensing, producers must ensure they carry

the appropriate licenses to warehouse and blend spirits. In most cases, building code exceptions may be required to accommodate the production of hand sanitizer: prepare for negotiation, compromise, and delay. Reach out to insurance providers at this point as well to determine if additional coverage can be provided in case of building damage. Several facilities have reported positive interactions with insurance providers who have quickly extended coverage to assist with these community efforts.

The main safety consideration is fire and explosion hazard, which in this case requires three factors: alcohol, oxygen, and an ignition source. Flashpoint refers to the minimum temperature at which a liquid can form vapor at a high enough pressure to ignite, and it varies with both humidity and atmospheric pressure—be sure to investigate how these numbers vary for your region. The flashpoint for pure ethanol is 13°C (55°F), and the flashpoint for 80% v/v ethanol is 16°C (61°F) (2). The lower explosion limit is the minimum vapor concentration that will propagate a flame if ignited. For ethanol at 80% v/v in air, the lower explosion limit is 3.3% v/v (3). Minimizing oxygen concentration around ethanol will reduce its flammability. Commonplace ignition sources are flames and static discharge.

To prepare the site for product blending, it is critical that all sources of ignition, such as fan motors and furnaces, are identified and mitigated. Fire departments are trained for this and can assist with procedural development. Stainless steel vessels dedicated to product blending should be grounded and bonded (where nearby electrical conductors are joined to reduce the risk of arcing) by a licensed electrician to reduce risk of static discharge, and prior to introduction of ethanol, vessels should be purged of oxygen twice with CO₂. Transfer of liquids between vessels or to the filling system is best done by CO₂ pressure—electric pumps should not be used anywhere near sanitizer solution. Vessels should be chilled to <10°C (50°F) to stay below the flashpoint.

Product packaging is, unfortunately, made even more complex by the fact that bottling and canning lines designed for

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breweries generate sparks within their electronic panels during operation. Because the vapor density is higher than air, ethanol vapors collect on the floor (4). To make matters worse, ethanol flames are difficult to spot in daylight because of their low luminosity (5). Therefore, it is critical to ensure that ethanol vapors are being actively removed from the packaging area during operation to keep them well below the lower explosion limit. Distillery bottling lines, on the other hand, are typically built to run safely with higher ethanol vapor concentrations; the drawbacks of these systems versus typical brewery equipment are largely in throughput, cost of bottles, and in some cases impractical unit volumes.

Annex Ale Project in Calgary, AB, provides a useful example for how to create a safe packaging environment, summarized in Figure 1. This facility remodeled its HVAC system to carry vapors along the floor to an outlet that expels them outside of the building. The canning line was grounded and bonded, ethanol sensors were installed at strategic locations around the packaging area, and a fire suppression company with trained firefighters, thermal cameras, and a supply of alcohol-resistant aqueous film-forming foam (AR-AFFF) was hired to remain onsite throughout every blending and packaging run. An evacuation plan was practiced, and a pre-run checklist was built to ensure lockdown of potential ignition sources.

Raw Materials, Blending, and Testing

The WHO formulation for ethanol-based hand sanitizer is, by volume, 80% ethanol, 1.45% glycerol, and 0.125% hydrogen peroxide, with the remainder made up of distilled, sterile fil-

tered, or boiled and cooled water (6). Most regulatory authorities require pharmaceutical grade ingredients for these products, so care should be taken when sourcing these to affirm that the grade fits within the appropriate regulatory framework. The WHO guidelines describe production of 10 L of sanitizer owing to safety concerns around handling large volumes of ethanol; because most breweries will be blending much larger volumes, it is imperative that measures are taken as outlined in Safety Considerations.

Ethanol is the medicinally active ingredient in the formulation. The WHO insists that its final concentration by volume should be between 75 and 85%, with a target of 80%. It is also recommended by the WHO to avoid denatured spirits (more on this under Supply Chain Management), but the U.S. Food and Drug Administration (FDA) (7) and Health Canada (8) require denaturants to be added to formulations. Suitable denaturants in the United States include denatonium benzoate, sucrose octaacetate, and isopropanol (7). In the United Kingdom, trade-specific denatured alcohol is made with a wide variety of denaturants (9). Note that denaturing alcohol requires a special permit in many jurisdictions.

Of considerable relevance to our current situation, a study was published in 2017 documenting the impacts of different strengths of the WHO formulation on a range of enveloped viruses, including MERS-CoV and SARS-CoV, causative agents of the Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). This study demonstrated high susceptibility of these virus types to hand-rub formulations as low as 40% ethanol by volume in suspension tests, which do not typically reveal surface porosity impacts (10). A compre-

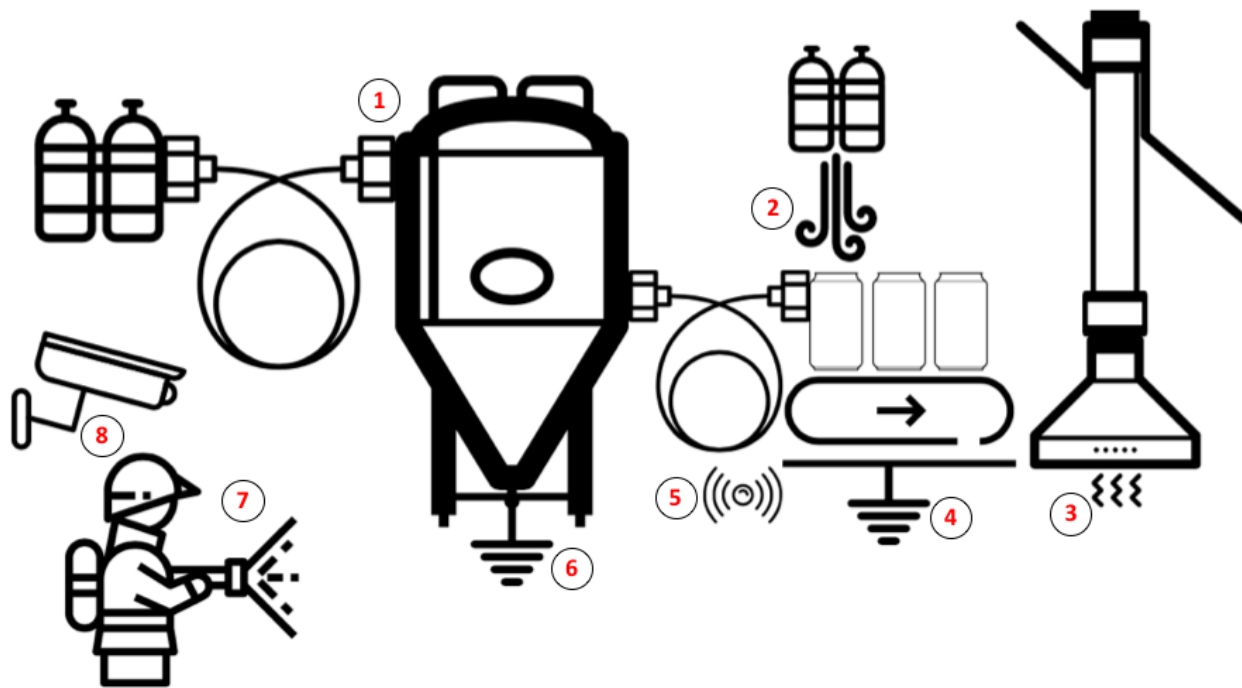


Figure 1. Measures taken to safeguard packaging runs at Annex Ale Project against fire hazard: 1 = CO₂ pressure, rather than a pump, is used to drive sanitizer liquid to packaging line; 2 = CO₂ purging of cans prior to filling reduces oxygen contact with liquid; 3 = HVAC modifications draw ethanol vapors from floor near packaging line to exterior of building; 4 = grounding and bonding of packaging line reduces risk of static discharge; 5 = ethanol vapor sensors are placed at high vapor zones with alarms set below the 3.3% v/v lower explosion limit; 6 = grounding and bonding of blending tank reduces risk of static discharge; 7 = fire suppression team equipped with AR-AFFF foam; and 8 = infrared camera detects near-invisible ethanol fires.

hensive review of studies published in March 2020 showed moderate virucidal activity for formulations as low as 62% ethanol by volume in carrier tests, which provide more information related to surface effects, with 1 min exposure time (11). With additional applied research and where regulations allow it, these studies may eventually support the argument for reduced strength of the standard formulation during the crisis to help stretch ethanol supplies, but for now the simplest route to market is to follow the 80% formula.

Glycerol is included in the formulation as a humectant or moisturizer—not as an agent to help prolong contact time of ethanol on skin, as is commonly assumed. Glycerol is extremely viscous in its pure form, and vigorous mixing is required to ensure it blends fully into the solution. This can be validated by measuring specific gravity until an endpoint is reached; a distillers' hydrometer will be required, or else samples can be diluted in a standard solution that will provide enough density to allow for measurement with a brewer's hydrometer. There is evidence that glycerol mildly inhibits the bactericidal effect of alcohol in hand sanitizers (12,13), although these studies did not address antiviral properties. An alternative humectant formulation showed no decrease in bactericidal activity (13), but the ingredients are not readily available for the average brewery or distillery. It has also been observed that skin damage resulting from use of hand sanitizers can actually result in increased viable bacterial counts (14); this may indicate that the role of humectants in sustaining skin health may offset their inhibitory effects on alcohols. In a study conducted in São Paulo, it was found that 0.5% v/v glycerol provided better skin care than the standard 1.45% v/v formulation, leading the authors to suggest that this could encourage improved usage compliance among healthcare workers (15).

Hydrogen peroxide is included in the blend to destroy hardy microbes that might be introduced from the other ingredients (6). It is not intended to serve as an active disinfectant in the finished hand sanitizer, because ethanol alone serves that purpose. For rapid testing, a variety of test strips are available for hydrogen peroxide. Our lab has validated WaterWorks peroxide strips (Industrial Test Systems, Rock Hill, SC) in dilution series of hand sanitizer in water and obtained adequate accuracy and resolution across the tested range. For more precise analysis, there are traditional spectrophotometric tests (16,17).

Addition of odorants or dyes should be avoided because these can trigger allergic reactions for some consumers (6).

Blending must be carried out with nonsparking equipment, such as a pneumatic pump. Final alcohol measurement is most easily obtained using a digital density meter such as a DMA 35 (Anton Paar, Graz, Switzerland); without dilution or omission of any ingredients, our lab obtained accurate results for bench-scale and production-scale measurements using this device. For facilities lacking such equipment, we advise consulting your nearest distillery for alcohol testing. In some cases, it may be best to leave glycerol out of the blend until alcohol concentration is verified.

Supply Chain Management

For cost effectiveness, it is recommended that breweries carrying appropriate alcohol blending licenses find a supply of neutral grain spirit or fuel ethanol, ensuring that federal regulatory requirements on methanol concentration (e.g., <200 ppm) and ethanol purity (e.g., >94.9% v/v) are met (18). As described in Raw Materials, Blending, and Testing, denaturants may be required to mitigate the risk of consumption by infants and

small children. Shortages have been reported for denaturants in some jurisdictions.

Regardless of access to large-scale ethanol supply, it is recommended that breweries attempt to make use of local distilleries for a portion of the blend to help sustain local economic activity and reduce the risk of supply chain disruption if the larger producers fail to supply required volumes, which has been a consistent trend in Western Canada. When partnering with a distillery, indicate that heads cuts are not appropriate for blending because of methanol content. If the brewery is aiming to supply a distillery with wash (or “mash,” high-alcohol beer used as feedstock for spirits distillation), brewers should ask whether the distiller is able to ferment on grain, which eliminates the need for lautering. Exogenous enzymes can help achieve full attenuation, and many distillers will have a supply of such enzymes. Many facilities are opting to cut costs by using sucrose as a sugar source, which comes with two primary considerations: (1) ensure the yeast has enough nutrients, and (2) mitigate pH drop below ~4.0. Both of these can be accomplished by including a portion of barley malt (20% was cited on Episode 167 of the Master Brewers Podcast [19]), but if this is cost-prohibitive, a combination of yeast nutrients and baking soda targeting pH >4.0 have been reported as sufficient to achieve high-alcohol wash (20).

Regardless of substrate selection, aeration should be maximized on knockout to ensure adequate yeast growth. Yeast strain should be discussed with your supplier or local distiller, because they are well versed in producing high-alcohol wash, but be sure to indicate that flavor is not a priority.

Packaging materials create a dilemma for many facilities, particularly given the recent shift to canning. The traditional plastic pump dispensers, squeeze bottles, and spray bottles are in short supply, and most facilities are not equipped to carry out mass filling of these in any case. Can manufacturers insist that can liners are not appropriate to contain 80% alcohol by volume, or hydrogen peroxide for that matter. Our preliminary results appear to indicate a difference between traditional epoxy liners and the newer BPA-free liners; an upcoming study in the *Journal of the ASBC* will elaborate on these findings. Many breweries still equipped with bottling capacity are finding glass to be the more attractive format, although serious risks remain and are discussed in Safety Considerations. Kegging for large-scale dispensing is a final option being employed in some facilities, and it may represent the safest option for breweries able to find buyers such as pharmacies that can repackage it into smaller containers for general consumption.

Prior to reaching full scale, prospective producers should approach local retailers or procurement entities to determine required volumes. Most retailers will require a safety data sheet; a draft document is described in Additional Information.

Packaging

Questions have been raised about the resilience of can liners against highly alcoholic solutions such as hand sanitizer and are discussed under Supply Chain Management. For facilities that move forward with canning, it is recommended that regardless of liner composition, cans clearly state that the product is to be transferred to a plastic or glass container within four to six weeks of packaging date (or use a best before date with a similar instruction).

Samples should be retained from every run both to verify product stability periodically and to accommodate federal law;

for example, Canadian Natural Health Product regulations require samples to be held for a full year after packaging. If canning, open one unit at least every week and inspect the interior liner: if failing, the liner will appear pitted, lifted, or as if bubbles are forming (Fig. 2). Check on all retained samples every few days, looking for signs of corrosion: small liquid droplets forming on the outside of cans indicates complete package failure. This has been observed in early high-temperature incubation experiments, although as yet no room-temperature-stored packages have shown similar failures. Batch identifiers are critical to allow for effective product recalls; in most jurisdictions, best-before or packaged-on dates are sufficient, although batch or lot numbers may also be required.

Bottling may not present any unique technical challenges, but crowning should be closely monitored for spark formation, and the steps described in Safety Considerations should be applied. Kegging could allow operators to maintain a closed atmosphere between source and package, but applicable measures such as grounding and bonding of equipment, positioning of ethanol detectors, and a clear site evacuation plan are still recommended in the packaging area.

Labeling requirements are clearly outlined by federal governments, and, for Canada and the European Union, are provided as producers move through the product licensing process. A label template was created by Annex Ale Project for free use by craft brewers, and a link is provided under Additional Information. Note that wording will need adjustment to satisfy local federal law, and Product License information is required in some jurisdictions.

Site, Product, and Alcohol Licensing

United States

On March 20 the U.S. FDA announced an exemption from future legal action for producers that follow WHO formulations (21), but on March 23 it announced the requirement for ethanol-based sanitizers to include denaturants (more on denaturants in Raw Materials, Blending, and Testing) to prevent their consumption by young children, who can be poisoned by small quantities of alcohol (7). On April 15, a set of final recommendations was issued by the FDA that outlined requirements for raw materials quality, materials handling, and package labeling (7). This governance covers supply of sanitizers for most uses including provision to medical facilities, and the Alcohol and Tobacco Tax and Trade Bureau (TTB) has temporarily waived its requirement for formula approval on the basis that the WHO formulation is followed (22).



Figure 2. Pitting and bubble formation in can liners predict can failure by corrosion. Scale: 5 × 10 cm.

The TTB clearly states that nonbeverage ethanol-based products are not subject to excise tax (22). It remains to be seen whether legislators will lift the requirement for denaturation of alcohol for use in hand sanitizers.

Canada

Starting March 18, Health Canada began issuing guideline documents for facilities looking to produce hand sanitizer. By mid-April, a comprehensive guide had been published that outlined the requirements and licensing process (8). For all producers, both a Site License and a Product License are required before donating or selling the product, and the current governance covers only personal domestic use rather than use by commercial or medical facilities. To circumvent site and product licensing, some facilities have instead opted to submit a Cosmetics Notification Form (23,24). The main distinction is that such products cannot be listed as hand sanitizers: other descriptors such as “cleanser” must be used.

Canadian regulation of ethanol, denatured alcohol, and specially denatured alcohol (SDA) falls under the Excise Act, 2001 (25), and requires licenses specific to the manufacture of alcohol-based products not intended for consumption, such as sanitizers. The Excise Department requires a User License for ethanol-based sanitizers and an SDA License for any denatured alcohol sanitizer production. In the case at Annex Ale Project in Calgary, AB, both licenses were required because both ethanol and SDA are in use. A Declaration of Recipe was also required by the Canadian Border Services Agency. Distilleries, and occasionally breweries, will possess spirit and warehousing licenses, but the User and SDA Licenses will permit a sanitizer facility to operate without having to pay excise duty.

European Union

Similar to Canada, a distinction is made between products intended for disinfection and for personal hygiene. On March 30, Cosmetics Europe provided guidance on the regulatory requirements, whereby products intended for disinfection must go through the biocidal regulatory framework specific to each member state. Products intended for personal hygiene, for which no overt claims of biocidal activity are made, are subject to Cosmetics Europe regulation (26). With appropriate labeling language, the latter approach may represent an expedited route to market similar to that described for the Canadian framework. The European Chemicals Agency summarized the regulatory requirements for each member state and provided contact information for the appropriate agency (27).

Different member states will apply their own tax levies based on local laws around denatured ethanol, and readers should consult their governing tax authority for more information.

United Kingdom

Under the Biocidal Products Regulation, facilities following WHO-recommended formulation for ethanol-based sanitizer do not require product authorization, while isopropanol-based sanitizer will continue to require authorization (28). On the surface at least, this stance appears similar to that taken by the U.S. FDA.

The key distinction was established on March 24, when Her Majesty’s Revenue & Customs (HMRC) issued guidance to the effect that excise tax will not be applied to industrial denatured alcohol, trade-specific denatured alcohol, or duty-free alcohol used in hand sanitizer production. The update provides for licensed distillers and gin manufacturers to distribute san-

itizer to hospitals and care homes, with the production of the WHO-recommended formula serving as the denaturing step for duty-free ethanol (29). Breweries looking to produce sanitizer must still apply to HMRC to stock, distribute, sell, or use denatured ethanol (30).

Summary

Blending, packaging, and transporting ethanol-based hand sanitizer should not be treated as another day at the brewery. There are serious safety risks to facility staff and end users, as well as legal implications and liabilities, all of which are tightly regulated under normal circumstances at all levels of government. While the production process may seem attractive to sustain revenue during the COVID-19 crisis, the potential ramifications should be considered from all angles before proceeding with licensing and manufacturing. By consulting local authorities, property owners, and insurance providers ahead of time, brewery operators can realistically assess the costs to safely produce hand sanitizer and avoid later surprises.

Additional Information

Link to free label design for use by breweries and distilleries (Adobe Illustrator File) <https://drive.google.com/file/d/1i6PjPUCMlnOt0SmTovrlxWNeQfalZhcY/view>

Visit www.raftbeerlabs.ca to request access to a draft Safety Data Sheet.

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