LENDING A HELPING HAND

HAND SANITIZER
AVAILABLE HERE

APPLY  RUB  DRY

EPISODE 2: A Deeper Dive Into What Distilleries Should Know In Order To Legally and Responsibly Produce Hand Sanitizer
Richard M. Blau leads GrayRobinson’s Alcohol Industry Team, focusing on the laws that govern the manufacture, importation, distribution, marketing, sale and consumption of beer, wine, distilled spirits and other licensed beverages. Richard devotes a substantial portion of his practice to trade regulation, brand development and protection, M & A compliance guidance, litigation and mediation involving the members of the alcohol industry.

Elizabeth A. DeConti has spent more than 20 years focusing her law practice on the unique area of alcohol beverage and food regulation. She is a shareholder in the Tampa office and is one of the original members of the firm’s Alcohol Beverage and Food Team. She concentrates on litigation, compliance, and promotions matters related to the rules, regulations and business practices governing the marketing, sale and consumption of malt beverages, wine, distilled spirits and other regulated products in the alcohol and food industry.

Anna M. Wiand is a shareholder in GrayRobinson’s Tampa office and a member of the firm’s Nationwide Alcohol Beverage & Food Law Department. She focuses her practice on matters relating to regulated products, including laws governing the alcohol beverage, food, cosmetics, cannabis, and tobacco industries.

David Bateman has over 40 years of federal alcohol regulatory service, experience and contacts. He joined the U.S. Bureau of Alcohol, Tobacco and Firearms (ATF) in 1973 in Milwaukee, WI where he became familiar with operations at Schlitz, Pabst, and Miller Brewing Company.

John J. Harris has knowledge in alcohol beverage and tobacco regulations; government processes; government decision makers; alcohol beverage dealer training; and liquor and business licensing. Today, John has over 51 years of experience in government and consulting.

Charlie Tull served as the Beer Industry Analyst for the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) until his retirement from the agency in May of 2014. During an illustrious 40-year career with TTB and its successor, the U.S. Bureau of Alcohol, Tobacco and Firearms (ATF), Charlie maintained contact with all phases of activity within the beer industry.
WHERE THINGS STAND NOW

• (A) DISCUS COVID-19 Resources--Accessible to members at: https://www.distilledspirits.org/distillers-responding-to-covid-19/

• (B) Confirmed positives: 395,011

• (C) Reported deaths: 12,754


• (E) List of distillers already participating in the sanitizer initiative https://www.distilledspirits.org/distillers-responding-to-covid-19/distilleries-producing-hand-sanitizer/
The CARES Act and What It Provides

The Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law on March 27, 2020. The 854-page bill provides approximately $2 trillion in relief and assistance to individuals, businesses, state governments, health providers and others affected by the COVID-19 outbreak.

The following are a couple of the relief measures created or expanded by the new law that are relevant to distilleries making hand sanitizer:

Charitable contributions. The limit for corporate charitable deductions has been raised from 10% to 25% for 2020. The deduction for food inventory contributions has been raised from 15% to 25% for 2020.

Alcohol excise tax changes. Hand sanitizer produced and distributed in 2020 in response to the pandemic and pursuant to FDA regulations will be exempt from the federal excise tax on distilled spirits. Hand sanitizer produced under these conditions also will be exempt from federal bulk sales and labeling requirements.
Clarifying Guidance and Removing Roadblocks

LATEST TTB POSITION (3/31/2020):

TTB revised its public guidance on “Production of Hand Sanitizer to Address the COVID-19 Pandemic” on March 26th to reflect changes in FDA policy and to allow for additional flexibility. This guidance now acknowledges that FDA requires hand sanitizer products to be manufactured with denatured alcohol and points DSPs to FDA’s allowable denaturing formulas.

TTB now formally exempts DSPs from the requirements to request approval to receive denatured distilled spirits in-bond from another DSP.

TTB’s new guidance also provides some helpful clarity to further exempt some undenatured alcohol used to produce hand sanitizer:

- It provides certain exemptions for alcohol, whether or not denatured, to be delivered tax-free to state and local governments for non-beverage purposes.
- Additionally, it provides that the FET will not apply to undenatured alcohol provided for use by hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions, if not for resale or use in the manufacture of any product for sale.

TTB also postponed several filing and payment due dates for 90 days where the original due date falls on or after March 1, 2020, through July 1, 2020.
TTB COVID-19 RELAXED DEADLINES

TTB is postponing the following filing and payment due dates for 90 days where the original due date falls on or after March 1, 2020, through July 1, 2020:

1. Postponing tax payment due dates for wine, beer, distilled spirits, tobacco products, cigarette papers and tubes, firearms, and ammunition excise taxes.
2. Postponing filing due dates for excise tax returns.
3. Postponing filing due dates for submission of operational reports.
4. Postponing filing due dates for claims for credit or refund by producers.
5. Postponing filing due dates for claims by manufacturers of nonbeverage products.
6. Postponing due dates for submission of export documentation.
7. Considering emergency variations from regulatory requirements for affected businesses on a case-by-case basis.
8. Reviewing requests for relief from penalties based on reasonable cause.

See TTB Industry Circular 2020-2 for additional details; accessible online at: https://www.ttb.gov/industry-circulars/ttb-industry-circulars-2020-2
TTB COVID-19 GUIDANCE

• Tax-free ethanol may be used by DSPs and AFPs to produce hand sanitizer if it is denatured according to TTB regulations and FDA guidance. Alcohol MUST be denatured.

• Alcohol, whether or not denatured, may be delivered tax-free to state and local governments for non-beverage purposes. The same is true for hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions, if not for resale or use in the manufacture of any product for sale.

• TTB is temporarily waiving certain formula approvals for the manufacture of hand sanitizer and expediting certain permit requirements.

• Distilled spirits permittees who wish to produce ethanol-based hand sanitizers to address the demand for such products during the COVID-19 emergency can immediately commence production of hand sanitizer or distilled spirits (ethanol) for use in hand sanitizer, without having to first obtain authorization. USE AN EXISTING APPROVED FORMULA, OR A WORLD HEALTH ORGANIZATION (WHO) FORMULA CONSISTENT WITH FDA GUIDANCE.

• Any existing DSP also may remove undenatured or denatured ethanol from bonded premises free of tax for use by any state or local government to produce hand sanitizer.

• In addition, any existing DSP may remove undenatured or denatured ethanol from bonded premises free of tax for use by hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions seeking to use it to manufacture hand sanitizer, and not for resale or use in the manufacture of any product for sale.
TTB COVID-19 GUIDANCE

Permit guidance for alcohol fuel plants (AFPs) and beverage DSPs:

• TTB is exempting AFPs and beverage DSPs from the requirement to obtain additional permits or bonds to manufacture hand sanitizer or to supply ethanol for use in the manufacture of hand sanitizer to other TTB permittees who are authorized to receive such distilled spirits.

• Beverage DSPs must continue to keep records of their operations, including any undertaken as authorized under this exemption.
Tax guidance for the manufacture of hand sanitizer:
Nonbeverage products made with ethanol, including hand sanitizer, are not subject to federal excise tax, **SO LONG AS** the manufacturer complies the FDA guidance regarding the use of denaturants when compounding hand sanitizer.

Formula guidance for the manufacture of hand sanitizer:
TTB is authorizing the manufacture of hand sanitizer products by DSPs using a WHO formulation consistent with the FDA’s COVID-19 guidance, without first obtaining formula approval from TTB.
TTB COVID-19 GUIDANCE

Guidance for industrial alcohol users:

TTB is also exempting industrial alcohol user permittees from the requirement to request approval from TTB to increase the quantities of denatured ethanol that they may procure.

Guidance regarding transfers in bond.

Under current TTB regulations, when DSPs want to receive either denatured or undenatured ethanol from another domestic DSP, the receiving DSP must submit an application to TTB for authorization prior to the first transfer and ensure appropriate bond coverage. During the period covered by TTB’S COVID-19 guidance, for transfers of either denatured or undenatured distilled spirits between domestic DSPs, TTB is exempting DSPs from the requirements to request approval from TTB to receive denatured or undenatured distilled spirits from another DSP and to obtain additional bond coverage.

Rather than submit such requests to TTB for approval using TTB F 5100.16, DSPs must maintain records of such receipts, which would include records of the information currently required on TTB F 5100.16.
TTB COVID-19 GUIDANCE

Guidance for state and local governments:

Consistent with 27 CFR Part 22, both denatured and undenatured alcohol may be removed free of tax for the use of a state, any political subdivision of a state, or the District of Columbia, for nonbeverage purposes, including making hand sanitizer.

• An alcohol user permit is required to obtain alcohol from a distilled spirits plant. TTB provides state and local governments with a streamlined application. TTB has dedicated personnel to process such applications seven days a week given the COVID-19 emergency. Please note that the EMERGENCY FDA guidance cited above specifies using denaturants when compounding hand sanitizer.

• During the period of its COVID-19 guidance, TTB is authorizing state and local government permittees to make hand sanitizer for use anywhere, as needed to address the COVID-19 national emergency.
TTB COVID-19 GUIDANCE

Guidance for hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions:

Consistent with 27 CFR Part 22, hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions may obtain alcohol free of tax for their own nonbeverage purpose use and not for resale or use in the manufacture of any product for sale. Manufacturing hand sanitizer is one such nonbeverage use.

• As with state and local governments, such alcohol must be obtained from a distilled spirits plant and may only be obtained by those holding an alcohol user permit from TTB.

• TTB will offer these organizations the same streamlined application, as authorized for state governments. Again, please note that recent EMERGENCY FDA guidance specifies using denaturants when making hand sanitizer.
TAKE NOTE: Although TTB is exempting industry members from certain tax requirements, **industry members must continue to comply with other federal and state law**, and industry members should contact relevant federal or state agencies with questions about guidance issued by those agencies.
As hospitals, nursing homes and others desperately search for antiviral sanitizers amid the COVID-19 outbreak, federal regulators are working with ethanol producers, including distillers who seek to switch production during this pandemic, to try and provide millions of additional gallons of alcohol that can be transformed into sanitizing products.

The challenge for the ethanol industry is that most plants make food-grade ethanol, one step below the highest pharmaceutical grade. But because the DSPs are not certified to comply with stringent production standards designed to protect quality of medicines, food ingredients and dietary supplements, the U.S. Food and Drug Administration typically has not approved the alcohol used for a product to be applied to the skin.

An additional challenge involves alcohol that is not denatured or mixed with a bitter additive to make it non-potable. The FDA insists denaturing is "critical" because of cases of poisoning, sometimes fatal, among young children who have accidentally ingested hand sanitizers. FDA reports that regulators already have seen a rise in poisonings linked to hand sanitizers in recent weeks, and that these incidents require "heightening this public concern."

To address these concerns, the FDA promulgated emergency guidance to secure assurances from the distilling industry that undenatured sanitizers could be distributed in a way that would keep them away from children. These assurances are key to securing the revised guidelines needed from FDA to allow distillers to proceed with confidence in the production of sanitizing agents using undenatured alcohol.
Clarifying Guidance and Removing Roadblocks

The COVID-19 stimulus bill requires distillers to follow the FDA's guidance if they want to receive the waiver of FET tax on alcohol used to make sanitizing agents. Under the latest FDA guidelines, regulators maintain standards for alcohol, requiring producers of sanitizers to use alcohol that meets federal or international standards for use in pharmaceuticals.

The FDA has waived dozens of regulations in recent weeks to boost production of key medical supplies, including coronavirus tests, ventilators, gloves and hand sanitizers. DISCUS is urging the FDA to update its guidance and let distillers use beverage-grade undenatured alcohol for hand sanitizer, but for now FDA continues to insist on the use of denatured alcohol only.

The regulatory hurdles are especially frustrating for Midwest ethanol producers who are facing plunging fuel demand and a petroleum fight between Saudi Arabia and Russia that caused prices to plummet. The factors are forcing more plants to curtail production and close.

DISCUS continues to pursue this issue with FDA because for ethanol producers, as well as DSPs that want to shift from distilling spirits to producing sanitizers, relaxed rules -- including a requirement of the hard-to-acquire denaturant -- would allow them to step in and help in a national emergency.

April 9, 2020
LATEST FDA POSITION:
The FDA will be relaxing its current policies to provide more flexibility on:

- approved denaturing formulas,
- the proof of the alcohol (ethanol OR isopropyl alcohol) being used in the hand sanitizer,
- the grade of alcohol, and
- the grade of hydrogen peroxide.
FDA EMERGENCY GUIDELINES

• The FDA has issued emergency guidance to address the Coronavirus Disease 2019 (COVID-19) public health emergency. The guidance was being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate.

• FDA’s guidance is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

• FDA issued this guidance to communicate its policy for the temporary manufacture of ethanol products by firms that manufacture alcohol for incorporation into alcohol-based hand sanitizer products under the circumstances described in this guidance (alcohol production firms) for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020.

• At such time when the public health emergency is over, as declared by the Secretary, FDA intends to discontinue this enforcement discretion policy and withdraw this guidance.
Because of the public health emergency posed by COVID-19, FDA does not intend to take action against alcohol production firms that manufacture alcohol (i.e., ethanol or ethyl alcohol) for use as the Active Pharmaceutical Ingredient (API) to be used in alcohol-based hand sanitizers or firms that prepare alcohol based-hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, provided the following EIGHT circumstances are present:
1. The hand sanitizer is **manufactured using only the following ingredients** in the preparation of the product:
   a. Select one of two options-
      (1) Alcohol (ethanol) that is not less than 94.9% ethanol by volume; NOTE: lower ethanol content alcohol falls within this policy so long as it is labeled accordingly and the finished hand sanitizer meets the ethanol volume to content concentration of 80%. OR
      (2) Isopropyl Alcohol;
   b. Glycerin (glycerol) United States Pharmacopeia (USP) or Food Chemical Codex (also known as “food grade”);
   c. Hydrogen peroxide;
   d. Sterile water, *e.g.*, by boiling, distillation, or other process that results in water that meets the specifications for Purified Water USP. Water should be used as quickly as possible after it is rendered sterile or purified.

2. The **alcohol (ethanol) is denatured** either by the alcohol producer or at the point of production of the finished hand sanitizer product. TTB regulations in 27 CFR part 20 and 21 provide a number of formulas for denaturing alcohol.

**Formulas for use in hand sanitizers include:**
   a. Formula 40A or 40B with or without the tert-butyl alcohol
   b. Formula 3C (isopropyl alcohol)
FDA EMERGENCY FORMULATION

3. The hand sanitizer is manufactured according to the following formula consistent with World Health Organization (WHO) recommendations:

a. Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution; or Isopropyl Alcohol (75%, v/v) in an aqueous solution.

b. Glycerin (glycerol) (1.45% v/v).

c. Hydrogen peroxide (0.125% v/v).

d. Sterile distilled water or boiled cold water. The firm does not add other active or inactive ingredients, such as ingredients to improve the smell or taste, due to the risk of accidental ingestion in children. Different or additional ingredients may impact the quality and potency of the product.

Beyond denatured alcohol, water, and denaturants (if added at the point of production), the alcohol production firm does not add other ingredients. Different or additional ingredients in the API may impact the quality and potency of the finished hand sanitizer product, and may increase the risk of accidental ingestion in children.
4. The manufacturer pays particular attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used. A simple record should be used to document key steps and controls to assure each batch matches the formula developed for the drug product. If the alcohol is to be distributed to another firm for producing the hand sanitizer, it is labeled with the ethanol content determined by an appropriate test so that the hand sanitizer can be reliably produced at the intended labeled strength.

5. The alcohol is prepared under sanitary conditions and equipment used is well maintained and fit for this purpose.

6. The alcohol production firm uses the most accurate method of analysis available at the site for verification of ethanol content in a sample before each batch is released for distribution or for use in producing the hand sanitizer. Methods can include gas chromatography (GC), specific gravity (e.g., alcoholometer, hydrometer, pycnometer, or gravity density meter), or another test that is at least as accurate. The sample tested can be from the final API before packaging (if distributed as an API) or before actual use in producing the hand sanitizer.
7. The alcohol API, if distributed to other producers, is labeled consistent with the attached labeling in the FDA’s Guidance Appendix A (Labeling for Ethyl Alcohol Formulation Consumer Use), Appendix B (Labeling for Isopropyl Alcohol Formulation Consumer Use), Appendix C (Labeling for Ethyl Alcohol Formulation Health Care Personnel Hand-rub Use), or Appendix D (Labeling for Isopropyl Alcohol Formulation Health Care Personnel Hand-rub Use). Appendices are reproduced in the following slides. Additionally, each label should include the name and contact information of the manufacturer.

8. Alcohol production firms register their facility and list these products in the FDA Drug Registration and Listing System (DRLS); more registration details are accessible online at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/drug-registration-and-listing-system-drls-and-edrls). Upon completion of registration and listing, firms receive automatic confirmation from FDA and do not need to wait for further communication from FDA before they begin to manufacture and distribute these products. FDA relies on registration and listing information to help manage drug shortages, monitor safety issues that may arise with product distributed to the public, and manage product recalls, among other important FDA public safety activities. FDA’s help desk is standing by to assist with facilitating this process and can be contacted by sending an email to: edrls@fda.hhs.gov.

If alcohol production firms receive adverse event reports, they are encouraged to submit them to FDA’s MedWatch Adverse Event Reporting program:

• Complete and submit the report online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm; or
• Download and complete the form, then submit it via fax at 1-800-FDA-0178
### FDA LABELING GUIDELINES

**Appendix A. Labeling for Ethyl Alcohol Formulation Consumer Use**

**PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):**

**Alcohol Antiseptic 80% Topical Solution**  
**Hand Sanitizer**  
**Non-sterile Solution**  
[Insert Volume of Product in mL]  

**DRUG FACTS LABEL**

<table>
<thead>
<tr>
<th>Drug Facts</th>
<th>Active Ingredient(s)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol 80% v/v</td>
<td>Antiseptic</td>
<td></td>
</tr>
</tbody>
</table>

**Usability:**  
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings:**  
For external use only. Flammable. Keep away from heat or flame.

**DIRECTIONS:**  
- Use alcohol-based hand sanitizers that contain at least 60% alcohol. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

**Other Information:**  
- Store between 15-30°C (59-86°F)
- Avoid freezing and freeze-thaw cycles

**Inactive Ingredients:**  
- Propylene glycol, purified water USP

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**Appendix B. Labeling for Isopropyl Alcohol Formulation Consumer Use**

**PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):**

**Isopropyl Alcohol Antiseptic 75% Topical Solution**  
**Hand Sanitizer**  
**Non-sterile Solution**  
[Insert Volume of Product in mL]  

**DRUG FACTS LABEL**

<table>
<thead>
<tr>
<th>Drug Facts</th>
<th>Active Ingredient(s)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl alcohol 75% v/v</td>
<td>Antiseptic</td>
<td></td>
</tr>
</tbody>
</table>

**Usability:**  
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings:**  
For external use only. Flammable. Keep away from heat or flame.

**DIRECTIONS:**  
- Use alcohol-based hand sanitizers that contain at least 60% alcohol. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

**Other Information:**  
- Store between 15-30°C (59-86°F)
- Avoid freezing and freeze-thaw cycles

**Inactive Ingredients:**  
- Propylene glycol, purified water USP

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April 9, 2020  
COVID-19 Sanitizer Production EPISODE 2
FDA LABELING GUIDELINES

Appendix C. Labeling for Ethyl Alcohol Formulation Health Care Personnel Handrub Use

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Alcohol Antiseptic 80%
Topical Solution
Antiseptic Hand Rub
Non-sterile Solution
[Insert Volume of Product in mL]

DRUG FACTS LABEL.

<table>
<thead>
<tr>
<th>Active ingredients</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>Antiseptic</td>
</tr>
</tbody>
</table>

Use(s):
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings:
For external use only. Flammable. Keep away from heat or flame.

Precautions:
- In children less than 3 months of age
- In open-use containers

When using this product:
- Keep out of reach of children; if swallowed, get medical help or contact a Poison Control Center right away
- Wash out of reach of children; if swallowed, get medical help or contact a Poison Control Center right away

Directions:
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information:
- Store between 65-70°F (18.9-21.1°C)
- Avoid freezing and extreme heat above 100°F (37.8°C)
- Alcohol ingredients:
  - Ethanol
  - Glycerin
  - Propylene glycol
  - Purified water USP

Appendix D. Labeling for Isopropyl Alcohol Formulation Health Care Personnel Handrub Use

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Isopropyl Alcohol Antiseptic 75%
Topical Solution
Antiseptic Hand Rub
Non-sterile Solution
[Insert Volume of Product in mL]

DRUG FACTS LABEL.

<table>
<thead>
<tr>
<th>Active ingredients</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol</td>
<td>Antiseptic</td>
</tr>
</tbody>
</table>

Use(s):
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings:
For external use only. Flammable. Keep away from heat or flame.

Precautions:
- In children less than 3 months of age
- In open-use containers

When using this product:
- Keep out of reach of children; if swallowed, get medical help or contact a Poison Control Center right away
- Wash out of reach of children; if swallowed, get medical help or contact a Poison Control Center right away

Directions:
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information:
- Store between 65-70°F (18.9-21.1°C)
- Avoid freezing and extreme heat above 100°F (37.8°C)
- Alcohol ingredients:
  - Isopropyl Alcohol
  - Water
  - Glycerin
The World Health Organization (WHO) has determined that alcohol-based hand-rubs are the only known means for rapidly and effectively inactivating a wide array of potentially harmful microorganisms on hands.

A scalable version of WHO Formula #1 is as follows:

<table>
<thead>
<tr>
<th>Name</th>
<th>Code</th>
<th>liters</th>
<th>kg</th>
<th>1 liter values (mL)</th>
<th>% Vol</th>
<th>%ABV</th>
<th>LPA</th>
<th>g/mL</th>
<th>%TotAlc</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHANOL 96% ABV</td>
<td>GNS</td>
<td>4,166.67</td>
<td>3,364.58</td>
<td>833.33</td>
<td>83.33</td>
<td>96.0</td>
<td>4000.0</td>
<td>0.80</td>
<td></td>
</tr>
<tr>
<td>WATER, DEMINERALIZED</td>
<td>WD</td>
<td>552.33</td>
<td>551.34</td>
<td>110.47</td>
<td>11.047</td>
<td>0.0</td>
<td>0.0</td>
<td>0.991</td>
<td></td>
</tr>
<tr>
<td>GLYCERINE, 98%</td>
<td>GLY</td>
<td>72.50</td>
<td>91.35</td>
<td>14.50</td>
<td>1.450</td>
<td>0.0</td>
<td>0.0</td>
<td>1.26</td>
<td></td>
</tr>
<tr>
<td>HYDROGEN PEROXIDE 3%</td>
<td>H2O2</td>
<td>208.50</td>
<td>231.44</td>
<td>41.70</td>
<td>4.170</td>
<td>0.0</td>
<td>0.0</td>
<td>1.11</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>5,000.00</td>
<td>4,258.71</td>
<td>1,000.00</td>
<td>100.0</td>
<td>4,000.0</td>
<td>4,000.0</td>
<td>4,000.0</td>
<td>4,000.0</td>
</tr>
</tbody>
</table>

**Batch Size (Liters):** 5,000.0

**Target %ABV:** 80
o **Alcohol Grade**: Ethanol used can be USP, FCC or technical grade, provided no additives would remain in the product. FDA has specified that alcohol (ethanol) used for this purpose must be derived from distillation or fermentation processes typically used for consumable goods. Alcohol derived from synthetic processes can be used only if it meets USP or FCC grade.

o **Glycerin/Glycerol**: FDA clarified that these are the same chemical and that both USP and FCC grade glycerin is acceptable.

o **Hydrogen peroxide**: Technical grade hydrogen peroxide falls within this policy if the concentration is within that of Hydrogen Peroxide Concentrate USP or Hydrogen Peroxide Topical Solution USP. FDA requests that firms formulate to a final strength of 0.125% v/v hydrogen peroxide using Hydrogen Peroxide Concentrate USP or Hydrogen Peroxide Topical Solution USP (in the latter case provided the alcohol (ethanol or isopropyl alcohol) concentration remains within the specified level of 80% for ethyl alcohol or 75% for isopropyl alcohol).

• **Denatured**: FDA requires the use of denatured alcohol and mandates the use of one of three TTB denaturing formulas: 40-A and 40-B (both of which can be used with or without the tert-butyl alcohol), and 3-C, which contains isopropyl alcohol.
APPROVED PRODUCTION FORMULAS

• **40-A 27 CFR § 21.75 Formula No. 40-A Formula.** To every 100 gallons of alcohol add one pound of sucrose octaacetate and 1/8 gallon of tert-butyl alcohol.

• **40-B 27 CFR § 21.76 Formula No. 40-B Formula.** To every 100 gallons of alcohol add one-sixteenth avoirdupois ounce of denatonium benzoate, N.F., and 1/8 gallon of tert-butyl alcohol.

• **3-C, 27 CFR § 21.37 Formula No. 3-C Formula.** To every 100 gallons of alcohol add five gallons of isopropyl alcohol.

FDA stated as recently as March 30, 2020, that other potential formulas, including the inclusion of acetone (TTB Formula 23-A), **currently ARE NOT approved for denaturing.** Firms that wish to use different denaturants (bitterants) should contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov.
Minimum Proof:

FDA requests that the alcohol be not less than 94.9% ethanol by volume prior to denaturing, which is consistent with the USP and FCC grade requirements for purity.

Lower ethanol content alcohol IS ALLOWED within the FDA’s COVID-19 policy so long as:

(i) it is labeled accordingly and

(ii) the finished hand sanitizer meets the ethanol volume to content concentration of 80%.

Registration and Listing Required:

FDA’s guidance requires that companies register their facility and list these products in the FDA Drug Registration and Listing System (DRLS).

Information regarding how to register your facility and hand sanitizer product can be found in the guidance document.
WHO APPROVED PRODUCTION METHODS

WHO Recommended Preparation Methods

1. The alcohol for the chosen formulation is poured into the large bottle or tank up to the graduated mark.

2. H$_2$O$_2$ is added using the measuring cylinder.

3. Glycerol is added using a measuring cylinder. As the glycerol is very viscous and sticks to the walls of the measuring cylinder, it can be rinsed with some sterile distilled or cold boiled water to be added and then emptied into the bottle/tank.

4. The bottle/tank is then topped up to the corresponding mark of the volume (10-litre or 50-litre) to be prepared with the remainder of the distilled or cold, boiled water.

5. The lid or the screw cap is placed on the bottle/tank immediately after mixing to prevent evaporation.

6. The solution is mixed by gently shaking the recipient where appropriate (small quantities), or by using a wooden, plastic or metallic paddle. Electric mixers should not be used unless “EX” protected because of the danger of explosion.

7. After mixing, the solution is immediately divided into smaller containers (e.g. 1000, 500 or 100 ml plastic bottles). The bottles should be kept in quarantine for 72 hours. This allows time for any spores present in the alcohol or the new or re-used bottles to be eliminated by H$_2$O$_2$. 

April 9, 2020

COVID-19 Sanitizer Production
WHO APPROVED PRODUCTION METHODS

WHO Recommended Local Production Methods

- **Volume of production, containers**
  - **10-liter** preparations: glass or plastic bottles with screw-threaded stoppers can be used.
  - **50-liter** preparations: large plastic (preferably polypropylene, translucent enough to see the liquid level) or stainless steel tanks with an 80 to 100 liter capacity should be used to allow for mixing without overflowing.
  - The tanks should be calibrated for the ethanol/isopropyl alcohol volumes and for the final volumes of either 10 or 50 liters. It is best to mark plastic tanks on the outside and stainless steel ones on the inside.

**Quality control**

- If concentrated alcohol is obtained from local production, verify the alcohol concentration and make the necessary adjustments in volume to obtain the final recommended concentration. An alcoholometer can be used to control the alcohol concentration of the final use solution; H₂O₂ concentration can be measured by titrimetry (oxydo-reduction reaction by iodine in acidic conditions).

- A higher level quality control can be performed using gas chromatography and the titrimetric method to control the alcohol and the hydrogen peroxide content, respectively. Moreover, the absence of microbial contamination (including spores) can be checked by filtration.

- For more detailed guidance on production and quality control of both formulations, see the “WHO-recommended hand antisepsis formulation - guide to local production” (Implementation Toolkit available at [http://www.who.int/gpsc/en/](http://www.who.int/gpsc/en/)).
OSHA-MANDATED PRODUCTION SAFETY

MSDS Safety Data Sheet for Hand Sanitizer

- A Material Safety Data Sheet (MSDS) is a safety document required by the Occupational Safety and Health Administration (OSHA) that contains data about the physical properties of a particular hazardous substance.

- MSDS sheets are created for a variety of hazard materials including compressed gases, flammable and combustible liquids, oxidizing materials, poisonous or infectious material, corrosive material and dangerously reactive materials. Sanitizer falls within this classification.

- The purpose of the Material Safety Data Sheet information is to convey chemical safety and hazard information to the end user (employees exposed to hazardous chemicals, employees who store dangerous chemicals, and emergency responders such as: firefighters, hazardous material crews, and emergency medical technicians).

- Material Data Safety Sheets are a critical component of the United States OSHA Hazard Communication Standard, which states that “anyone who might handle, work with or be exposed to hazardous materials must have access to the Material Safety Data Sheets.”
OSHA-MANDATED PRODUCTION SAFETY

MSDS Safety Data Sheet for Hand Sanitizer

An MSDS sheet is a safety document with at least eight sections detailing the toxicity, use, storage, handling and emergency procedures of hazardous substances. The OSHA requirements for MSDS format include placing the following categories on every Material Safety Data Sheet:

• Section I. Manufacturer’s Name and Contact Information;
• Section II. Hazardous Ingredients/Identity Information;
• Section III. Physical/Chemical Characteristics;
• Section IV. Fire and Explosion Hazard Data;
• Section V. Reactivity Data;
• Section VI. Health Hazard Data;
• Section VII. Precautions for Safe Handling and Use; and
• Section VIII. Control Measures.
OSHA-MANDATED PRODUCTION SAFETY

MSDS Safety Data Sheet for Hand Sanitizer

From OSHA Site

Be careful about your SDS Sheets as the penalties are set by OSHA as listed below:

OSHA Penalties

Below are the penalty amounts adjusted for inflation as of Jan. 2, 2018.

<table>
<thead>
<tr>
<th>Type of Violation</th>
<th>Penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious</td>
<td>$12,934 per violation</td>
</tr>
<tr>
<td>Other-Than-Serious</td>
<td></td>
</tr>
<tr>
<td>Posting Requirements</td>
<td></td>
</tr>
<tr>
<td>Failure to Abate</td>
<td>$12,934 per day beyond the abatement date</td>
</tr>
<tr>
<td>Willful or Repeated</td>
<td>$129,336 per violation</td>
</tr>
</tbody>
</table>
Both chemical manufacturers and employers with chemicals in the workplace must comply with GHS MSDS regulation. Distillers making sanitizer also must comply.

OSHA violations (failure to comply with OSHA requirements) may result in OSHA citations and OSHA penalties upwards of $100,000+ per willful violation per instance.
## Production Safety

### Section 2: Hazards Identification

<table>
<thead>
<tr>
<th>GHS Classification</th>
<th>Flammable liquids: Category 2</th>
<th>Eye irritation: Category 2A</th>
</tr>
</thead>
</table>

### GHS Label Elements

- Hazard pictograms: 
- Signal word: Warning

### Safety Data Sheet

**PURELL® VF481™ Hand Sanitizer Gel**

**Version**: 1.1  
**Sds Number**: 490000004475  
**Revision Date**: 01/25/2021

- **Hazard statements**: H226 Flammable liquid and vapour.  
  H319 Causes serious eye irritation.

- **Precautionary statements**
  - **Prevention**: P220 Keep away from heat/sparks/open flames/hot surfaces.  
  - **Control/Prevention**: P233 Keep container tightly closed.  
  - **Protection**: P264 Wash after handling or contact with skin and before eating or drinking.  
  - **Response**: P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
  - **First aid measures**: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  

### Section 3: Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Hazardous component</th>
<th>CAS-No.</th>
<th>Concentration (w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol</td>
<td>67-62-5</td>
<td>70 - 78</td>
</tr>
</tbody>
</table>

### Section 4: First Aid Measures

- **General advice**: In case of accident or if you feel unwell, seek medical advice immediately.  
  - When symptoms persist or in all cases of doubt seek medical advice.

- **If inhaled**: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
  - If easy to do, remove contact lenses; if worn.

- **In case of skin contact**: Wash with water and soap as a precaution.  
  - Get medical attention if irritation develops and persists.

- **In case of eye contact**: Wash with water and soap as a precaution.  
  - Get medical attention if irritation develops and persists.

- **If swallowed**: Do not induce vomiting.  
  - Rinse mouth with water.  
  - Seek medical advice.

- **Most important symptoms and effects, both acute and delayed**
  - Causes serious eye irritation.

- **Protection of first-aiders**: First Aid responders should pay attention to self-protection and use the recommended protective clothing.

### Safety Data Sheet

**PURELL® VF481™ Hand Sanitizer Gel**

**Version**: 1.1  
**Sds Number**: 490000004475  
**Revision Date**: 01/25/2021

- **Seek medical advice**.

- **If swallowed**: Do not induce vomiting.  
  - Rinse mouth with water.  
  - Seek medical advice.

- **Most important symptoms and effects, both acute and delayed**
  - Causes serious eye irritation.

- **Protection of first-aiders**: First Aid responders should pay attention to self-protection and use the recommended protective clothing.
SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting:
- Do not use a solid water stream as it may scatter and spread fire.
- Cold closed containers exposed to fire with water spray.
- Flash back possible over considerable distance.
- May form explosive mixtures in air.
- Exposure to decomposition products may be a hazard to health.
- Carbon oxides

Hazardous combustion products: Carbon oxides

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.

Further information:
- Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
- Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Ensure adequate ventilation.
- Remove all sources of ignition.
- Evacuate personnel to safe areas.
- Keep people away from and upwind of spill/leak.
- Material can create slippery conditions.

SAFETY DATA SHEET

PURELL® VF481™ Hand Sanitizer Gel

Version 1.1 SDS Number: 400000000475 Revision Date: 01/29/2018

Environmental precautions:
- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapours/mists with a water spray jet.
- Keep in suitable, closed containers for disposal.
- Clean contaminated floors and objects thoroughly while observing environmental regulations.
SECTION 7. HANDLING AND STORAGE

Advice on safe handling:
For personal protection see section 8.
Keep away from heat and flame.
Use with local exhaust ventilation.
Avoid contact with eyes.

Conditions for safe storage:
Take measures to prevent the build up of electrostatic charge.
Keep in properly labelled containers.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Store in accordance with the particular national regulations.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>64-17-5</td>
<td>TWA</td>
<td>1,000 ppm / 1,900 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>1,000 ppm / 1,900 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Isopropyl Alcohol</td>
<td>67-63-0</td>
<td>TWA</td>
<td>200 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>400 ppm / 980 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST</td>
<td>500 ppm / 1,225 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>400 ppm / 980 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
</tbody>
</table>

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol</td>
<td>67-63-0</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of</td>
<td>40 mg/l</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>clear, greenish-blue</td>
</tr>
<tr>
<td>Odour</td>
<td>alcohol-like</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>3.8 - 5.2, (20 °C)</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>75.00 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>26.50 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td></td>
</tr>
<tr>
<td>Upper explosion limit</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Version 1.1**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower explosion limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>0.8742 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Thermal decomposition</td>
<td>The substance or mixture is not classified self-reactive.</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>80 - 600 mm²/s (20 °C)</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
PRODUCTION SAFETY

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Vapours may form explosive mixture with air.
Conditions to avoid: Heat, flames and sparks.
Incompatible materials: Strong oxidising agents.
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation: No data available.
Eye contact: No data available.
Skin contact: No data available.
Acute toxicity: Not classified based on available information.

Components:
Ethyl Alcohol:

PRODUCTION SAFETY

PURELL® VF461™ Hand Sanitizer Gel

Acute oral toxicity: LD50 (Rat) > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat) 128.7 mg/l
Exposure time: 4 hr
Test atmosphere: vapour

Isopropyl Alcohol: Acute oral toxicity: LD50 (Rat) > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat) 72.8 mg/l
Exposure time: 4 hr
Test atmosphere: vapour

Acute dermal toxicity: LD50 (Rat) > 5,000 mg/kg

Skin corrosiveness/irritation: Not classified based on available information.

Components:
Ethyl Alcohol:
Species: Rat
Method: OECD Test Guideline 408
Result: No skin irritation

Isopropyl Alcohol:
Species: Rat
Method: OECD Test Guideline 408
Result: No skin irritation

Serious eye damage/irritation: Causes serious eye irritation.

Components:
Ethyl Alcohol:
Species: Rat
Method: OECD Test Guideline 408
Result: Irritation to eyes, recovery within 21 days

Isopropyl Alcohol:
Species: Rat
Method: OECD Test Guideline 408
Result: Irritation to eyes, recovery within 21 days

Respiratory or skin sensitisation: Not classified based on available information.

Components:
Ethyl Alcohol:
Test Type: Local lymph node assay (LLNA)
Species: Mouse
Method: OECD Test Guideline 408
Result: Negative

Isopropyl Alcohol:
Test Type: Local lymph node assay (LLNA)
Species: Mouse
Method: OECD Test Guideline 408
Result: Negative

Carcinogenicity: Not classified based on available information.

Components:
Ethyl Alcohol:
Species: Rat
Method: OECD Test Guideline 408
Result: Negative

Isopropyl Alcohol:
Species: Rat
Method: OECD Test Guideline 408
Result: Negative

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by OSHA.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or probable carcinogen by NTP.

Reproductive toxicity: Not classified based on available information.
PRODUCTION SAFETY

SECTION 12. ECOLOGICAL INFORMATION

Toxicity

Components:

Ethyl Alcohol:

Toxicity to fish:

LC50 (Fathead minnow): >1,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:

LC50 (Daphnia magna, 21d): >1,000 mg/l

Exposure time: 48 h

Toxicity to algae:

EC50 (Chlorella vulgaris, 72h): >275 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC (Daphnia magna, 21d): 9.6 mg/l

Exposure time: 21d

Toxicity to bacteria:

EC50 (Phoebacutrum phosphorum): 32.1 mg/l

Exposure time: 96 h

Isopropanol Alcohol:

Toxicity to fish:

LC50 (Fathead minnow): >10,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:

EC50 (Daphnia magna, 21d): >10,000 mg/l

Exposure time: 48 h

Toxicity to bacteria:

EC50 (Pseudomonas putida): >1,000 mg/l

Exposure time: 16 h

Persistence and degradability

Components:

Ethyl Alcohol:

Biodegradability: 86%

Biodegradation: 20 d

Isopropanol Alcohol:

Biodegradability: Result: Rapidly biodegradable

Bioaccumulative potential

Components:

Ethyl Alcohol:

Partition coefficient n-octanol/water: log Pow: -0.35

Isopropanol Alcohol:

Partition coefficient n-Octanol/water: log Pow: 0.05

Mobility in soil

No data available

Other adverse effects

No data available

Product:

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods:

Waste from residues: Dispose of in accordance with local regulations.

Consented packaging:

Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulation

IATA-DSR

UN/ID No.: UN 1987
Propper shipping name: Alcohols, n.o.s.

Class: 3
Packaging group: III
Packaging instruction (cargo aircraft): 336
Packaging instruction (passenger aircraft): 365

IMO Code

UN number: UN 1987
Propper shipping name: ALCOHOLS, N.O.S.

Class: 3
Packaging group: III
Labels: 5
EmS Code: F-E, S-D
Marine pollutant: no

National Regulations

49 CFR

UN/ID/NA number: UN 1987
Propper shipping name: Alcohols, n.o.s.

Class: 3
Packaging group: III
ERG Code: 127
Marine pollutant: no

COVID-19 Sanitizer Production EPISODE 2
**PRODUCTION SAFETY**

**SECTION 15. REGULATORY INFORMATION**

**EPCRA - Emergency Planning and Community Right-to-Know Act**

**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

<table>
<thead>
<tr>
<th>SARA 313/312 Hazards</th>
<th>Fire Hazard</th>
<th>Acute Health Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SARA 302</strong></td>
<td>No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.</td>
<td></td>
</tr>
<tr>
<td><strong>SARA 313</strong></td>
<td>The following components are subject to reporting levels established by SARA Title III, Section 313.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Isopropyl Alcohol</td>
<td>67-63-0</td>
</tr>
</tbody>
</table>

**Clean Air Act**

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemicals are listed under the U.S. Clean Air Act Section 112 (40 CFR 68.130): Ethanol Alcohol 64-17-5, 65.2821 % Isopropyl Alcohol 67-63-0, 3.406 %

This product does not contain any VOC or VOC exemptions listed under the U.S. Clean Air Act Section 609.

**Clean Water Act**

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307.

**US State Regulations**

**Massachusetts Right To Know**

| Ethanol Alcohol | 64-17-5 | 60-70 % |
| Isopropyl Alcohol | 67-63-0 | 1-5 % |

**Pennsylvania Right To Know**

| Ethanol Alcohol | 64-17-5 | 60-70 % |
| Water (Aqua) | 7732-18-5 | 30-50 % |
| Isopropyl Alcohol | 67-63-0 | 1-5 % |

**New Jersey Right To Know**

| Ethanol Alcohol | 64-17-5 | 60-70 % |
| Water (Aqua) | 7732-18-5 | 30-50 % |
| Isopropyl Alcohol | 67-63-0 | 1-5 % |

**California Prop 65**

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

The components of this product are reported in the following inventories:

| TSCA | On TSCA Inventory |
| ACES | On the inventory, or in compliance with the inventory |
| DSSL | On the inventory, or in compliance with the inventory |
| ENCS | On the inventory, or in compliance with the inventory |
| ISHL | On the inventory, or in compliance with the inventory |
| KECI | On the inventory, or in compliance with the inventory |
| PICCS | On the inventory, or in compliance with the inventory |
| IECCSC | On the inventory, or in compliance with the inventory |
| NZDCC | On the inventory, or in compliance with the inventory |

**Inventories**

| ACES (Australia), DSSL (Canada), IECCSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZDCC (Australia), PICCS (Philippines), TSCA (Taiwan), TSCA (USA) |

**SECTION 16. OTHER INFORMATION**

**NFPA:**

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Health/Materials Compatibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

**HMS III:**

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Physical Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

| 5 = not significant, 1 = slight, 2 = Moderate, 3 = High, 4 = Extreme, 6 = Critical |

**Revision Date:**

April 9, 2020

COVID-19 Sanitizer Production EPISODE 2
Storage, Distribution, Marketing and Public Relations

Storage:
Product may be stored away from the licensed premises if space is a concern;

Getting your produced sanitizer into the right hands (delivery logistics):
- Product may be transported in bulk for easier distribution away from the place of manufacture, and packaging in consumer friendly package sizes is not necessary at that point in the process;
- *Detailed record keeping is recommended.*

Getting the word out about your good efforts
CONCLUSION: What Remains to be Done:

Be prepared if you are audited two years later – Best practices for record-keeping.

Support Other Industry Members – especially retailers and their employees:


- **Another Round, Another Rally Fund**: We’re offering $500 relief grants for hospitality workers who lost their jobs or had their hours slashed in the wake of the COVID-19 outbreak. We’re also collecting donations from community members willing to help their hospitality-industry friends and neighbors stay afloat in this time of uncertainty. To apply for a grant or make a donation, use the links below.

- **Lift Your Spirits Fund**: Make a video in which you mix your favorite drink, say a toast to those affected in the restaurant, foodservice and hospitality industry, and post it to your social media accounts using #LiftYourSpirits. The last step is to challenge your friends to do the same and to send a gift to the National Restaurant Association Educational Foundation (NRAEF) that turns a tip into a donation for restaurant, foodservice and hospitality workers impacted by the COVID-19 crisis!

- **USBG Emergency Fund**: Bartender emergency assistance program available to all bartenders or the spouse or child of a bartender.

- **RWCF Crisis Relief Fund**: A crisis relief fund to direct money to organizations leading on-the-ground efforts in the restaurant community, to provide zero-interest loans to businesses to maintain payroll during closure or re-open once this crisis has passed, and to establish a relief fund for individual workers facing economic hardships or health crises as a direct result of COVID-19.

- **OFW Emergency Fund**: Providing free, cash assistance to restaurant workers, delivery drivers and other tipped workers and service workers — who are seeing their income decline during this disaster, or aren’t able to work because of quarantines or other health concerns.

- **CORE Gives**: CORE grants support to children of food and beverage service employees navigating life-altering circumstances.

- **Rent Assistance**: RentAssistance provides a directory of rental assistance agencies and organizations that will help you pay your rent. Some listings are government organizations other are non-profits and charities that offer rental assistance programs.

- **Dining Bonds Initiative**: A Dining Bond works like a savings bond, where you can purchase a "bond" at a value rate to be redeemed for face value at a future date.

- **Go Tip ‘Em!**: Pick a bartender, and send them a tip for the drink not served.