FAQs on Hand Sanitizer Production for DSPs

Please Note: *(March 29, 2020) This document is based on the latest information. We hear new guidance may be coming down from FDA and we will update as appropriate with any official notice from FDA/TTB or other governing bodies.*

FDA Questions/Comments

1. FDA CDER Direct won't let me register our facility without a FEI number they have issued for the location. Any advice on getting correctly registered with the FDA quickly? Can you walk through steps with the FDA?--*The FDA document can be found here. There is a webinar from 3/27 available to view on this topic.*
2. If the hand sanitizer is only made for internal employee use does my plant have to register in the FDA drug registration and listing system? -- *FDA registration is required for producing this OTC drug product.*
3. Can you speak to some specifics on the registration with the FDA. When creating an account there are check boxes with Form Access that are quite foreign to us.--*The FDA document can be found here. There is a webinar from 3/27 available to view on this topic..*
4. Does isopropyl need to be on the label? The FDA label does not list it. -- *It does not appear to list the ingredients used for denaturing on the label.*
5. Do you need a TIB for isopropyl alcohol from a brewery? -- *Isopropyl alcohol is denatured and not subject to FET, therefore a TIB is not required.*
6. If we don't charge anyone for it, do we have to register with the FDA? -- *Yes.*
7. How do you know what other information needs to go on your label besides what the FDA put out? -- *Your state may have additional requirements as well.*
8. Where can we find the FDA guidelines. You mentioned a handout? -- *All documents are available on the ACSA COVID page at: https://americancraftspirits.org/covid-19/*
9. Has there been penalty language provided by the FDA for any released product, donated or sold, not following their guidelines?-- *FDA has indicated they will not be taking enforcement action during the Public Health Emergency, providing guidance is followed. I recommend every firm follow the guidance to the best of their ability.*
10. Do we need to put the FDA number on the bottles? -- *It is not called out in the guidance for bottles. The FDA registration number (DUNS) is required on the bulk alcohol for Active Ingredient use.*
11. What information should the label include? -- *Use the FDA label guidance. Include a batch number and date of manufacture. Include a phone number or email address for adverse events.*
12. With issues of sourcing bottles for sanitizer, do you think it is reasonable that we omit any volume statement? -- *FDA guidance requires a volume statement.*
13. Does the label have any font size requirements? -- *No details are provided. The best practice is to ensure readability.*
14. What's the best way to identify the manufacture date and batch? -- *I recommend making a space to write on the label.*
15. What back label info is needed? -- *The FDA guidance on sanitizers shows the exact back label information. The TTB does not address labels. State agencies may have a request. We recommend contacting your state*

alcohol licensing agency and ask them if they have any guidance on hand sanitizer production beyond that of the FDA and TTB.

Ingredient and Formula-related Questions/Comments

1. What about ESD shoes and proper bonding and grounding? -- *This is all using high proof, flammable alcohol. Review OSHA guidance for handling and ensure that your people are trained and equipped to handle this safely. Let's stay safe out there!*
2. Are they concerned with glycerine vs. glycerol? Can you explain glycerol (98%) vs. vegetable glycerin? Propylene glycol vs glycerin? Can we use Glycerin or Glycerol? They are both referenced but I've also read that glycerols are the triol compound used for many purposes in pure or mixed form, but glycerine is the commercial name of glycerol, which is not pure ,which contain mostly 95% of glycerol, it can't be used when pure glycerol is required. -- *Glycerol or glycerin that is food grade, FCC or USP, can be used in the latest guidance.*
3. What are some substitutes for glycerol? -- *None according to the formulas which are pre-approved, formula approval can be sought for other formulations*
4. What about Methanol? Can we leave the heads in the alcohol? Do we need to do head cuts? -- *The ethanol used should be produced from distillation processes used for consumable goods. Methanol is not addressed in the guidance. I would not recommend including it.*
5. Can you speak about using higher concentration of hydrogen peroxide? Does Hydrogen peroxide need to be USP grade? Is technical grade ok? All ingredients should be USP grade per the guidance. -- *Higher percentages of H2O2 should be diluted shortly before use to 3%, reviewing the MSDS for safety and handling. Technical grade is OK, if the concentration is within that of the USP counterpart.*
6. Isn't H202 dangerous to handle? -- *Please review MSDS for all ingredients to handle safely.*
7. What about consumer grade hydrogen peroxide? -- *If it is 3%, and USP, it may be used.*
8. Why is hydrogen peroxide needed to kill spores? -- *Please refer to the WHO document.*
9. To be clear the final product must be at least 75% alcohol so 150 proof? Must be at least 75% at the end correct? -- *Per WHO guidelines, the final concentration should be 70% v/v/ for isopropyl and 80% v/v for ethanol.*
10. What are the necessary percentages of active ingredients? -- *Pages 2 and 3 of WHO Guide.*
11. For labeling, are there any circumstances that do not require the "Drug Facts" noted in Appendix A? -- *None that the guidance directs.*
12. How do you put a non beverage formula into formulas online? -- *Per TTB, formula approval is not required if you are using the WHO formula. My recollection is that there is another place on the drop down you can select to get to that part.*
13. Are TIBs required for denatured ethanol solutions? -- *No. TIBs are required for alcohol that is not tax paid. Because denatured alcohol is not taxed, no TIB is required.*
14. Reverse Osmosis water? Is that not compliant? How about deionized water? -- *Reverse osmosis water is, per the FDA guidance for the component ethanol issued on 3/24/2020. The previous guidance for making sanitizer did not include RO water.*
15. Original recipe suggested 60% ABV? -- *That is CDC guidance, not the guidance referenced by either TTB or by FDA. The FDA is the agency ultimately in charge, not the CDC.*

16. Where is the reg on holding it for 72 hours after production? -- That is guidance per WHO in their Guide to local production
17. I thought FDA labelling says it should contain nothing other than their formula -no isopropyl alcohol. -- *The alcohol used in the formula must be denatured according to 27 CFR parts 20 and 21; the formulas 40-B, 40-A, and 3C may be used to denature (denatonium benzoate, NF (with or without tert-butyl alcohol), sucrose octaacetate (with or without tert-butyl alcohol) and isopropyl alcohol) .*
18. Will the high alcohol percentage leave rashes on the skin? -- *This is the FDA guidance. WHO has studied this formulation and found it to be safe and effective.*
19. The end result - is it very liquidy? Watery? -- *It is indeed watery.*
20. For help with doing the calculations *Hoochware has created another calculator that you are welcome to check out https://www.hoochware.com/calculate/handsanitizer*
21. Very interested in knowing how to dilute it accurately. I can't find a calculator, but assume it is similar to alc proofing? -- *Here is a link to WHO guide to local production and two other calculators are linked to above.*

All things Denaturing

1. Is that 5% of the total volume of the final solution? -- *Denaturing should be completed before formulating the sanitizer solution.*
2. What is the FDA regulation for denaturing? Can we use the TTB antiseptic formula for denaturing? Can we use a different denaturing agent as listed by the CFR (code of federal regulations). -- *The latest guidance calls for denaturing according to 27 CFR parts 20 and 21; formulas 40-B, 40-A, and 3C may be used to denature. Any other formulas need to contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov*
3. Denatonium benzoate is an approved denaturer by the CFR (27 cfr 21.151) -- *Yes.*
4. Are there any denaturing formulas available by weight? -- *Review 27 CFR parts 20 and 21; the formulas in Appendix C of the latest FDA guidance 40-B, 40-A, and 3C may be used to denature.*
5. There is another TTB formula for denaturing alcohol that allows for certain essential oils for antiseptic use. Is there a reason that you are not recommending that alternate formulation? -- *The latest guidance calls for denaturing according to 27 CFR parts 20 and 21; formulas 40-B, 40-A, and 3C may be used to denature. Any other formulas need to contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov*
6. With the severe shortage of IPA (isopropyl alcohol for denaturing) for example, can we use an alternative? The 27 Code of Federal Regulations 21.151 is a long list of approved denaturing agents. -- *The latest guidance calls for denaturing according to 27 CFR parts 20 and 21; formulas 40-B, 40-A, and 3C may be used to denature. Any other formulas need to contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov*
7. What are the quantities / ratio to denature with isopropyl? -- *For every 100 gallons of ethanol, add 5 gallons of isopropyl alcohol per 27 CFR 21.37*
8. Is the 5% Isopropyl alcohol to denature by weight or volume? -- *By Volume.*
9. What is the minimum amount of IPA needed to render something "denatured"? -- *For every 100 gallons of ethanol, add 5 gallons of isopropyl alcohol per 27 CFR 21.37*
10. Can a DSP buy GNS, denature it, and send it to someone else for co-packing? -- *Yes.*
11. Can the compound pharmacy provide the denaturant? -- *Yes.*

TTB/FET

1. With the vast shortage of isopropyl can we work with TTB to allow undenatured ethanol in its place and requesting they waive the FET requirement? -- *The guidance from TTB has been changed to align with FDA guidance.* ***Only denatured ethanol in hand sanitizer****.*
2. If we are not selling the product and donating it. Does that matter for bonding? -- *Excise tax applies to undenatured alcohol-check out this TTB Link. TTB has made it possible to give tax-free undenatured alcohol to certain governmental and institutional entities so they can make their own hand sanitizer. Guidance is here.*
3. Can you sell bulk alcohol if you pay the excise tax? -- *Yes, to TTB permittees authorized to receive such distilled spirits.*
4. With the current cost of isopropanol it might be cheaper to pay the tax for a small distiller? -- *The latest guidance calls for denaturing according to 27 CFR parts 20 and 21; formulas 40-B, 40-A, and 3C may be used to denature. Any other formulas need to contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov*
5. Is it possible to produce hand sanitizer with undenatured ethanol and simply pay the FET? -- *Both the FDA and TTB now require denatured ethanol to be used in hand sanitizer.*
6. Did TTB lift the TIB limits? Is it in writing? -- https://www.ttb.gov/news/covid-19-hand-sanitizer and https://www.ttb.gov/public-guidance/ttb-pg-2020-1a Keep good records.
7. Bond limits lifted by TTB? -- https://www.ttb.gov/news/covid-19-hand-sanitizer and https://www.ttb.gov/public-guidance/ttb-pg-2020-1a
8. Can you record all product removed from processing account for sanitizers on line 11. Where do we record it if not? -- *As I understand it, If the spirit is being denatured it will go on line 11. If it is being removed to make sanitizer without denaturing it should be included in line 13.*

Sourcing, Packing, Shipping, Selling, Distributing

1. Tamper seal required? What about fill line and expansion? -- *No guidance provided.*
2. If you are able to get the ingredients should we be concerned it will it be taking them away from emergency responders? -- *I don't have information about that.*
3. Can we pack and ship in 55 gal containers for bulk use in the healthcare industry? -- *This may be an OSHA and DOT issue due to the flammability of the hand sanitizer. There is a webinar next Wednesday on shipping hand sanitizer.*
4. For the consumer side is anyone supplying sanitizer in spray bottles? -- *Unknown.*
5. Are we still bound to our fill volume restrictions? 1.75 largest container for fill? Or can we go bulk? Our state has asked for 55 gallon drums and 270 gallon totes. -- *No guidance has been given. Be careful and advise as to OSHA concerns. There is a shipping webinar next week about hazmat and shipping sanitizer.*
6. Are there any restrictions or prohibitions on selling the sanitizer to recoup costs, pay labor, etc.? -- *None, except be aware that keeping pricing reasonable is important*
7. Where do you source isopropyl alcohol? Mine called for tert butanol and Denabenzoate Denatonium -- *The latest guidance calls for denaturing according to 27 CFR parts 20 and 21; formulas 40-B, 40-A, and 3C may be used to denature. Any other formulas need to contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov*
8. Can you legally sell alcohol to a hospital/pharmacy if they're not a DSP? -- *I believe so, you may want to ask them about necessary permits. If denatured, yes. If undenatured it must be taxpaid, and these are weird times. I guess we need additional guidance. Guidance is here.*

9. Does anyone know what a gallon should be sold for? To a state for instance? We don't want to do this if our costs will exceed a reasonable price. -- *We cannot advise as to pricing as this could be interpreted as price-fixing. Use your best judgement and an eye to fairness.*
10. What steps do you need to take if you plan on selling vs. just handing it out? i.e. UPC, etc? -- *Run through the full FDA process and make sure that you are following state guidance. Review with your insurance carrier.*
11. Provided that our employees are running full scale hand sanitizer production; are we as business owners still able to package, prep, and ship other orders during this time as a method to help keep our people employed and earning? -- *Yes.*
12. Is getting reimbursed for the cost still selling? Not adding any profit. -- *Yes.*
13. We were told we needed child resistant caps which don't seem to be available. Is this accurate? -- *This is not in the guidance. The only mention we have made on the child resistant caps was from an insurance company suggested guidelines. Be sure to check with your insurance company as to their requirements to address liability.*
14. We have a lot of customers (retail and on premise) looking to buy said hand sanitizer – but I'm not sure if distributors are allowed to sell it? We already sell non-potable alcohol in the form of bitters, etc. -- *I believe it can be sold. I have heard from distributors who are interested. Be sure to check with your state license.*
15. We'd like to give this away, as well as sell some to recoup some of our costs, can you please help me understand what steps we'd need to take in order to get this out in the market? i.e. will this need a UPC, etc? Can you reach out to your community and ask them who is selling and what additional steps they took besides the exact formula and label before getting their product out on the market? -- *Run through the full FDA process and make sure that you are following state guidance. Review with your insurance carrier.*

Other

1. What liability protection do we need in case someone claims damages because our hand sanitizer didn't work and they got sick? -- *Run through the full FDA process and make sure that you are following state guidance. Review with your insurance carrier.*
2. How should we record this on the monthly report of processing operations? -- *As I understand it, If the spirit is being denatured it will go on line 11. If it is being removed to make sanitizer without denaturing it should be included in line 13*.
3. Our local hospital has requested documentation to keep on file for the hand sanitizer, similar to a Safety Data Sheet. I'm not sure what to send to them. Can anyone advise me? -- *Yes, we now have a template SDS for hand sanitizer. Be sure to download the PDF and enter the required information prior to sharing it with your local hospital.*