

**TEMPORARY ALCOHOL-BASED HAND SANITIZER MANUFACTURER
REGISTRATION APPLICATION (COVID-19 EMERGENCY)**
PLEASE COMPLETE THIS FORM FULLY—INCOMPLETE APPLICATIONS WILL BE RETURNED
See Page 2 for Instructions

NEW APPLICANT

| | | | | | |
|---|-------|----------|---|-------------------------------------|--|
| 1. Legal Name of Firm | | | 9. Facility Operator (name and title) | | |
| 2. DBA (List additional DBAs on separate sheet if necessary.) | | | 10. Facility Telephone Number () | 11. Facility FAX Number () | |
| 3. Facility Address (number, street) | | | 12. 24-Hour Emergency Telephone Number () | 13. E-Mail Address | |
| 4. Facility Address (continued) | | | 14. Correspondent (name and title) | | |
| 5. City | State | ZIP Code | 15. Correspondent Telephone Number () | 16. Correspondent FAX Number () | |
| 6. Mailing Address (if different or P.O. Box number) | | | 17. County | | |
| 7. Mailing Address (continued) | | | 18. Website (URL) | | |
| 8. City | State | ZIP Code | | | |

19. Type of Ownership: Individual/Sole Proprietorship Partnership Corporation/Limited Liability Company Nonprofit Other: _____

| | |
|---|--|
| 20. Corporate Name (if applicable) | State of Incorporation |
| 21. Owners' or Officers' Names and Titles | Owners' or Officers' Names and Titles (Attach separate sheet if necessary) |

22. Previous California Department of Public Health – Food and Drug Branch License Number(s): _____
Associated California Board of Pharmacy License Number: _____

23. Size of Facility (square feet): _____
Number of Employees at this Facility _____ Business days and hours _____

24. Intended Product Destination
California Distribution Internal Company Use

25. Manufacturing processes/activities employed or planned in the manufacture of hand sanitizers. Indicate if these processes/activities will be done at this location (in-house) or by a contract. List other processes using additional sheets, if necessary. (Check at least one or more.)

| Processes/Activities | In-house | Contract | Name of Contractor |
|------------------------|----------|----------|--------------------|
| Liquid Mixing | | | |
| Relabel Only | | | |
| Repackage Only | | | |
| Other (Specify): _____ | | | |

26. Payment Code: **Waived per governor executive order N-68-20**

The Food and Drug Branch MUST BE NOTIFIED immediately of any change in the application information as provided by CA Health and Safety Code, §111630. By signature, I declare under penalty of perjury that all information provided herein, including any supplemental documentation hereto, is true and correct.

| | | | |
|------------------------------------|--------------|-------|------|
| 27. President or owner's signature | Printed Name | Title | Date |
|------------------------------------|--------------|-------|------|

PLEASE DO NOT WRITE BELOW THIS LINE.

| | | | | |
|---------------------|--|--|--|--|
| Registration Number | | | | |
|---------------------|--|--|--|--|

**TEMPORARY ALCOHOL-BASED HAND SANITIZER MANUFACTURER REGISTRATION
APPLICATION INSTRUCTIONS (COVID-19 EMERGENCY)**

Due to the Coronavirus Disease 2019 (COVID-19) pandemic, and per the governor's executive order N-68-20, California Department of Public Health, Food and Drug Branch (Department) is issuing a special temporary alcohol-based hand sanitizer manufacturing registration effective until the earliest of the following occurs: (1) the expiration of a six-month registration period, after which that entity may apply for a further temporary registration, (2) the Department suspends or rescinds any applicable temporary registration, or (3) the FDA withdraws or otherwise terminates any applicable federal guidance. Please note that the products manufactured under this registration can only be distributed intrastate. Your registration fee is waived for this application. The registration is non-transferable. A separate application is required for each place of business. Please complete and/or amend this application as is most appropriate to your facility. Unsigned or incomplete applications cannot be processed. The following are further instructions on how to complete this application:

New Applicant: Place an (X) in the box next to New. For any section that does not apply to your company, please indicate with (N/A). **Do not leave any sections blank.**

1. **Name of Firm:** Enter full name of business, corporation, company, or organization applying for registration.
2. **DBA:** Enter any other name(s) your company is doing business as.
- 3.- 5. **Facility Address:** Enter the number, street, city, state, and ZIP code for this facility location.
- 6.- 8. **Mailing Address:** Enter the full mailing address if different from the facility address or P.O. Box.
9. **Facility Operator:** Enter the full name(s) of the person(s) in charge of hand sanitizer manufacturing at this facility and their title(s).
10. **Facility Telephone Number:** Enter daytime business telephone number of this facility.
11. **Facility FAX Number:** Enter facility FAX number.
12. **24-Hour Emergency Telephone Number:** Enter telephone number to be called in the event of an emergency.
13. **E-mail Address:** Enter facility e-mail address.
14. **Correspondent:** Enter the name of the person to contact for information regarding this application and their title.
15. **Correspondent Telephone Number:** Enter the daytime business telephone number of the contact person.
16. **Correspondent FAX Number:** Enter the daytime business FAX number of the contact person.
17. **County:** Enter the county where your facility is located.
18. **Website:** Enter the website address for your business, if applicable.
19. **Type of Ownership:** Place an (X) in the box next to the appropriate legal description of the facility's ownership.
20. **Corporate Name:** Enter corporate name if applicable. Enter state of incorporation if applicable.
21. **Owners' or Officers' Names:** List the business owners' or officers' names and titles. *USE ADDITIONAL SHEETS IF NECESSARY.*
22. List **previous California Department of Public Health – Food and Drug Branch License Number(s)** if applicable.
23. **Size of Facility:** Indicate the approximate size (in square feet) of the facility and the approximate number of employees at the facility and list business days and hours.
24. **Intended Product Destination:** Products manufactured under this special registration can only be distributed intrastate.
25. **Manufacturing Processes:** Place an (X) in the columns adjacent to all applicable processes to be performed in-house and/or contracted out. Leave line blank if the indicated process will not be applied to the manufacturing of hand sanitizers. List additional processes or methods as needed herein or on additional sheets if necessary.
26. **Payment Fee Code:** Your registration fee is waived per the governor's executive order N-68-20.
27. Application is to be signed by the most responsible individual such as the owner or president, print your name, print your title, and enter the date. All signatures must be original. Mail Application to:

Regular Mail: California Department of Public Health
Health Food and Drug Branch - Cashier
MS 7602
P.O. Box 997435
Sacramento, CA 95899-7435

Overnight Mail: California Department of Public
Food and Drug Branch - Cashier
1500 Capitol Avenue, MS-7602
Sacramento, CA 95814

Email: FDBMedDevice@cdph.ca.gov

If you have any questions about this application, please contact the FDB License Desk for Drug Manufacturing at (916) 341-7354, (800) 495-3232.

Temporary Hand Sanitizer Registration of Entities Acting as Drug Manufacturers: Self-Certification of Certain Alcohol-Based Hand Sanitizer Production During the 2020 Public Health Emergency (COVID-19)

I. INTRODUCTION

The U.S. Food and Drug Administration (FDA) has issued a guidance in response to several queries from entities that are not currently licensed or registered drug manufacturers that would like to prepare alcohol-based hand sanitizers, either for public distribution or for their own internal use. Hand sanitizers are regulated as OTC drugs in the U.S. and in California. [The FDA guidance](#) communicates the federal policy for the temporary preparation of certain alcohol-based hand sanitizers by firms that are not federally registered as over-the-counter (OTC) drug manufacturers, but who are interested in preparing these drugs for the duration of the public health emergency declared on January 31, 2020 for COVID-19.

On March 4, 2020, Governor Gavin Newsom declared a State of Emergency for California, and on June 5, 2020, the Governor issued executive order N-68-20 to help increase the availability of over-the-counter drugs, such as hand sanitizer. In response, the California Department of Public Health, Food and Drug Branch (Department) has established this **Temporary Hand Sanitizer Registration** process for California entities not currently licensed by the Department as a Drug Manufacturer but would like to prepare alcohol-based hand sanitizers during the COVID-19 public health emergency. To facilitate the immediate implementation of this temporary process, the Department is adopting the FDA guidance referenced as the prevailing authorization to produce only the specified types of alcohol-based hand rub sanitizers listed therein. The Department will enforce this temporary registration process until the earliest of the following occurs: (1) the expiration of a six-month registration period, after which that entity may apply for a further temporary registration, (2) the Department suspends or rescinds any applicable temporary registration, or (3) the FDA withdraws or otherwise terminates any applicable federal guidance.

II. MANDATORY SELF-CERTIFICATION REGISTRATION PROCESS

Hand hygiene is an important part of the U.S. response to COVID-19. **Washing hands often with soap and water for at least 20 seconds** is the essential primary prevention practice recommended. If soap and water are not readily available, the Centers for Disease Control and Prevention (CDC) recommends consumers use an alcohol-based hand sanitizer that contains at

least **60 percent alcohol** (also referred to as ethanol or ethyl alcohol).¹ Again, these products are regulated as drugs.

Under normal circumstances, California’s statutory licensing requirements to manufacture drug products are comprehensive and rigorously based on federal regulations to ensure safe and effective drug products are produced within the State. If, however, you are an entity not currently licensed by the Department as a drug manufacturer nor familiar with State and federal drug manufacturing laws and regulations, yet would like to help reduce the demand for alcohol-based hand rub sanitizers, the Department is requiring your compliance with this temporary registration process and all other applicable laws in order to prepare hand sanitizer products in California for the public use during this emergency.

Please identify and self-certify your intent to temporarily manufacture these drugs, by completing all of the following elements, marking the appropriate boxes, and returning this form with the registration application to the Department at the address provided. **The Registration process will not commence if this Self-Certification Form is submitted incomplete.**

III. TEMPORARY REGISTRATION ELEMENTS

A. Identify your main, principal business activity or company profile:

| |
|--|
| Industry Affiliation: |
| Principal Activities Normally Performed Where Drug Production is planned: |
| Identify All Regulatory Authorities with Jurisdiction Over Your Facility or Operations: |
| List All Industry-specific Licenses Applicable to Your Normal Activities or Products: |
| List All Modes of Distribution for the Hand Sanitizers Produced (i.e.: donation/give away, wholesale distribution, retail sale, internal company use, etc.): |
| Identify Intended Geographic Distribution of drugs made (<i>select all that apply</i>): California Distribution; Interstate; Export; Local Availability; Internal Company Use |
| Additional Comments Relevant to Drug Preparation by Temp. Registration Applicant: |

¹ Isopropyl alcohol and ethyl alcohol are the only active ingredients authorized for use in the temporary production of hand sanitizers under the Department’s Temporary Hand Sanitizer Registration process.

B. The hand sanitizer is manufactured using **only the following ingredients** in the preparation of the product:

1. **Alcohol (ethanol)**,² that is not less than 94.9% ethanol by volume³; (**or**) **Isopropyl Alcohol USP** (United States Pharmacopeia = pharmaceutical grade)⁴

[Refer to FDA Guidance paragraph titled, “Additional Considerations for Ingredients...” concerning suitability for human use, alternative alcohol grades and potential harmful impurities associated with them.]

2. **Glycerin (glycerol)**, **USP** or **FCC** [Food Chemical Codex (FCC; aka “food grade”)]
3. **Hydrogen Peroxide**⁵
4. **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.

C. The hand sanitizer is manufactured according to the following **formula** consistent with World Health Organization (WHO) recommendations:⁶

1. **Alcohol:** Ethyl Alcohol (**80%, volume/volume (v/v)**) in an aqueous solution; (**or**) Isopropyl Alcohol USP (**75%, v/v**) in an aqueous solution.⁷
2. **Glycerin (glycerol)** (1.45% v/v)⁸
3. **Hydrogen peroxide** (0.125% v/v).⁹
4. **Water:** Sterile distilled water, boiled cold water.

² Alcohol (ethanol) used for this purpose is derived from distillation or fermentation processes typically used for consumable goods. Alcohol derived from synthetic processes is used only if it meets United States Pharmacopoeia (USP) or Food Chemical Codex (FCC) grade.

³ This is consistent with the USP and FCC grade requirements for purity. 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%.

⁴ Isopropyl alcohol used as the active ingredient should be USP grade (see 1a above). If a firm wishes to use other sources of isopropyl alcohol as an active ingredient, provide analytical data of the isopropyl alcohol tested against all of the elements of the USP monograph, including listed impurities, to COVID-19-Hand-Sanitizers@fda.hhs.gov and include “ISOPROPYL ALCOHOL DATA” in the subject line, for FDA’s assessment regarding the use of this ingredient under this policy.

⁵ Hydrogen Peroxide Concentrate USP, Hydrogen Peroxide Topical Solution USP, or technical grade hydrogen peroxide. The hand sanitizer formula should be adjusted based on the actual concentration of hydrogen peroxide used.

⁶ WHO’s recommendations, titled “Guide to Local Production: WHO-recommended Handrub Formulations,” are available at https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf; review 21 CFR 211.56;

⁷ One benefit of FDA’s policy relying on use of the WHO formula is that minor errors in production are still likely to result in a finished hand sanitizer product that exceeds 60% alcohol content (see FDA’s 1994 TFM and the [CDC Statement for Healthcare Personnel on Hand Hygiene during the Response to the International Emergence of COVID-19](#)).

⁸ Although WHO’s recommended formulation includes glycerol 1.45% (v/v), reports indicate that glycerol negatively impacts effectiveness of isopropyl alcohol (<https://www.ncbi.nlm.nih.gov/pubmed/28670452>), and reports studying the effectiveness of WHO’s formulation have suggested a reduction from 1.45% to 0.725% (<https://www.ncbi.nlm.nih.gov/pubmed/23388358/>).

⁹ Formulate to a final strength of 0.125% v/v hydrogen peroxide using Hydrogen Peroxide Concentrate USP or Hydrogen Peroxide Topical Solution USP or technical grade hydrogen peroxide, ensuring that the alcohol (ethanol or isopropyl alcohol) concentration remains within the specified level of 80% for ethyl alcohol or 75% for isopropyl alcohol.

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.

- D. **Denaturing** is critical because there have been reports of adverse events, including deaths, from unintentional ingestion of hand sanitizer, particularly in young children.¹⁰ Therefore, the alcohol (ethanol) shall be **denatured** either: **by the alcohol producer, or** at the point of production of the finished hand sanitizer product (*select one*).¹¹

Identify supplying source or production point of the *denatured* alcohol API:

| | |
|---|--|
| Supplier Name: | |
| Address: | |
| Phone #: | |
| Any CA Dept. of Public Health, or CA License #: | |
| Any federal Est. License/Reg. #: | |

The firm must specifically identify which alcohol denaturing process is employed, that complies with the applicable Federal Alcohol and Tobacco Tax and Trade Bureau regulations to produce hand sanitizers [Title 27, Code of Federal Regulations (CFR) part 20 and 21]. Select which Denaturing Formula is used (*select one*):¹²

Formula 40A or 40B with or without the tert-butyl alcohol

Formula 3C (isopropyl alcohol)

[Attachment I of the FDA Guidance document (ver. 04/15/20) provides more information on the formulas used to denature alcohol before it is used in alcohol-based hand sanitizers. It reproduces Appendix C from FDA guidance for industry entitled, "Temporary Policy for Manufacture of Alcohol for Incorporation into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)."]

- E. The firm pays attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used. **A simple Batch Production Record** should be used to document key steps and controls to assure each

¹⁰ Every month, there are hundreds of calls to Poison Control centers for unintentional ingestion of hand sanitizer. As indicated from data provided by the American Association of Poison Control Centers (AAPCC), in March 2020 (during the COVID-19 pandemic), calls to Poison Control centers related to hand sanitizer increased by 79% compared to March of 2019. Most of these calls were for unintentional exposures in children 5 years of age and younger.

¹¹ See FDA guidance for industry *Temporary Policy for Manufacture of Alcohol for Incorporation into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)*.

¹² The U.S. FDA is continuing to evaluate other potential formulas, including the inclusion of acetone, for denaturing. Firms who wish to use different denaturants (bitterants) should contact FDA at COVID-19-Hand-Sanitizers@fda.hhs.gov with "DENATURANTS REQUEST" in the subject line.

batch matches the formula developed for the drug product.¹³

- F. The hand sanitizer is prepared under **sanitary conditions and equipment** utilized is well maintained and fit for this purpose.¹⁴
- G. The firm uses the **most accurate method of analysis** available at the site for verification of alcohol content in samples of the finished drug product before each batch is released for distribution. Sample testing can be performed on in-process material before filling into the final containers to be distributed. Methods can include (*select all that apply*):
- Gas Chromatography (GC); Alcoholmeter; Hydrometer; or other chemical analysis of at least equivalent accuracy (identify): _____.
- H. The hand sanitizer product is an **aqueous** solution, not a gel, foam, or aerosol spray.¹⁵
- I. **Product packaging** is appropriate for liquid drug products that will seal sufficiently to prevent evaporation of the alcohol or IPA.¹⁶ Manual pump spray bottles that seal sufficiently to prevent evaporation are consistent with this policy.
- J. The hand sanitizer is **Labeled** consistent with one of the labeling templates listed in the FDA Guidance (*select one*):
- Appendix A (**Ethyl Alcohol** Formulation Consumer Use);
Appendix B (**Isopropyl Alcohol** Formulation Consumer Use);
Appendix C (**Ethyl Alcohol** Formulation Health Care Personnel Hand Rub Use);
Appendix D (**Isopropyl Alcohol** Formulation Health Care Personnel Hand Rub Use).¹⁷
- K. Firm has registered their facility and listed these products in the **U.S. FDA Drug Registration and Listing System (DRLS)**, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/drug-registration-and-listing-system-drls-and-edrls>).

¹³ Review Drug GMP section 21 CFR 211.28, 211.188

¹⁴ Review 21 CFR 211.56; Facilities must prevent insanitary conditions.

¹⁵ This policy does not apply to hand sanitizer gel or foam products because different or additional ingredients may impact the quality and potency of the product. This policy does not apply to aerosol sprays because aerosol sprays with propellant added to the formulation can result in altered potency of the finished hand sanitizer. Aerosol sprays with propellant outside of the formulation (bag on valve) may have safety and potency concerns due to the increased flammability risks of ethanol in an aerosol, risk of overspraying, variability of delivery of the product, rapid evaporation of alcohol, and inhalational toxicities.

¹⁶ Note that hand sanitizer offered for transportation or transported in commerce may be subject to the applicable requirements of the U.S. Department of Transportation's Hazardous Materials Regulations (49 CFR Parts 171-180) or guidance issued by the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA). More information is available on PHMSA's website at: <https://www.phmsa.dot.gov/news/phmsa-issues-temporary-relief-companies-transporting-hand-sanitizer-highway>. These regulations include classification, packaging, marking, labeling and other requirements relevant to transportation; 21 CFR 211.94.

¹⁷ The label shall include the name and contact information of the manufacturer. If manufacturers have already ordered or printed their labels without this information, please prepare a supplemental method to make this info available to consignees or applied to undistributed packaging; Review HSC 111340; 21 CFR 211.184.

Include a copy of the automatic federal Registration confirmation from the FDA, (or) identify the following:

| | |
|---|--|
| Facility Address: <i>(If Different form above)</i> | |
| Person/Title who registered: | |
| Date Registered: | |
| Registration # issued: | |

Firm has established a way to accept adverse event reports for any products they manufacture and commits to reporting them to the FDA and the Department when known.¹⁸ (For more information, please see FDA's guidance on adverse event reporting requirements.)

M. Firm has established a strategy to effectively communicate and initiate any potential recall of drug product suspected or determined to be adulterated or otherwise unfit for consumer/public use as defined in State law (HSC §§111250-111325; §111635)¹⁹

N. Signed under penalty of perjury, by the Applicant Firm.

President or Owner's Signature

Date

Printed Name

Title

¹⁸ See Section 760 of the FD&C Act (21 U.S.C. § 379aa); Review 21 CFR 211.198

¹⁹ Review 21 CFR 211.150, 211.180