

# Evaluation of the Quality and Safety of Hand Sanitizers Marketed in Saudi Arabia

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## Abstract

**Background:** Hand sanitizers are an important preventive measure to halt the spread of pathogens, which has become a huge demand during the coronavirus disease (COVID-19). Consequently, their safety and quality are top priorities for regulatory organizations. **Methods:** Saudi Food & Drug Authority laboratories have analyzed numerous samples of hand sanitizers in order to ensure their safety and efficacy. Active ingredients, as well as hazardous impurities, have been checked according to the pharmacopeia. **Results:** In this study, we report the results of the analysis of 1409 samples, which represent the majority of products available in the Saudi Arabian market. The results showed that 196 samples (13.9%) did not meet international standards. Specifically, out of 196 failed samples, 75, 12, and 4 products contained hazardous substances such as methanol, 1-propanol, and acetaldehyde, respectively. Additionally, some failed samples contained foreign particles, were improperly labeled, or contained an inadequate concentration of alcohol. **Conclusion:** The substandard hand sanitizers possess a risk to the community, particularly during pandemics, and hence stringent yet dynamic regulations should be implemented.

## Keywords

Hand Sanitizer, COVID-19, US FDA, Ethanol, Methanol

## 1. Introduction

Coronavirus disease, also known as the COVID-19 pandemic, firstly appeared in December 2019 [1]. COVID-19 has spread globally, being rapidly transferred via aerosol particles or small droplets from the infected individuals. The disease has been reported to circulate most often among people when they are physically

close, and it may also transmit through contaminated surfaces; however, the latter phenomenon is scientifically doubtful [2] [3]. The common symptoms involve loss of smell, fever, fatigue, cough, breathing difficulties, and shortness of breath, while some cases exhibit asymptomatic illness. The period of infection spans up to two weeks in severe cases and seven to twelve days in moderate cases [4]. The major preventive actions for COVID-19 spread are social distancing, wearing a face mask, covering mouth and nose when coughing or sneezing, hand washing, using hand sanitizers, surface disinfecting, air filtering, and isolation of suspected people [5]. To this end, several vaccines against COVID-19 have been developed and are now being circulated worldwide [6].

One of the common preventive measures is the use of hand sanitizers, also called hand rub agents or hand antiseptics, which are used in the form of a gel, foam or liquid and are applied to the hand to remove common disease-causing organisms (pathogens) [7] [8]. Particularly, hand sanitizers are classified into two categories depending on the formulated active ingredients, alcohol-free and alcohol-based hand sanitizers (ABHS). Alcohol-based products (mainly ethanol and isopropanol) should contain a percent of alcohol between 60% and 95% in order to neutralize certain types of microorganisms. On the other hand, alcohol-free products comprise anti-microbial agents, such as triclosan, or substances, such as benzalkonium chloride (BAC) [7]. Furthermore, a hand sanitizer may contain other ingredients, such as glycerin, zinc oxide, mineral oil, paraffin, olive oil, or coconut oil, which are used as either fragrance for soothing the skin, or as thickening agents [8] [9].

During the initial spread of the pandemic COVID-19, the demand for hand sanitizers has tremendously grown globally, overriding the supply from the industry. Consequently, several companies, such as the perfume and distiller industries, started to manufacture hand sanitizers to overcome the shortage of these products. Simultaneously, regulatory standards have to cope with the new hand sanitizer businesses for avoiding the quality defects, which have become inevitable. World Health Organization (WHO) has published guidelines for using chemicals being readily available for the manufacture of hand sanitizers, specifically for the developing countries [10]. Furthermore, WHO recommended using ethanol and/or isopropanol as alcohol in hand sanitizers, as for an effective alcohol-based hand sanitizer, a minimum concentration of alcohol must be at least 60%. Commonly, most commercial hand sanitizers contain alcohol content between 60% and 80%. Moreover, WHO recommended formulations include ingredients, such as hydrogen peroxide (to remove the bacterial spores); antiseptics, such as quaternary ammonium derivatives or chlorhexidine, and finally glycerol (to prevent skin dryness). Fragrances, colorants and foaming agents may also be incorporated into hand sanitizers as non-essential ingredients [10].

During the COVID-19 pandemic, several reports documented the existence of hand sanitizers in the market that contained unsafe raw materials, such as methanol [11]. Methanol, or wood alcohol, is a substance that can be toxic when

absorbed through the skin or ingested, and can possibly lead to life-threatening situations. Moreover, a number of hand sanitizers and disinfectants exhibit contamination due to the presence of 1-propranol, which is a toxic substance. Skin or eye exposure to 1-propranol can result in irritation and rare cases of allergic skin reactions. Furthermore, a group of disinfectants and hand sanitizers have been found contaminated with acetaldehyde [12], a chemical that can cause irritation in the respiratory tract, skin and/or eyes as a result of direct exposure. Finally, many hand sanitizers and disinfectants could contain safe raw materials, but with insufficient concentrations, rendering them less effective [13].

In the current paper, the majority, if not all, of hand sanitizers and disinfectant brands (a total of 1409 samples) were sampled from the Saudi Arabian market, ports, and Saudi Food and Drug Authority (SFDA) branches in different regions. Then, samples were analyzed at the SFDA Laboratories to scrutinize their raw materials, and evaluate their safety and quality. Results from the current investigation revealed some substandard products while other products contained hazardous chemicals. Manufacturers should comply with standards released by well-recognized regulatory bodies in order to produce effective and safe products that will ultimately help combat the current pandemic as well as other microbial-related illnesses.

## 2. Materials and Methods

The total number of samples was 1409, and their distribution was as follows: 432 samples from the central region, 209 samples from the eastern region, 629 samples from the western region, 55 samples from the northern region, and finally, 84 samples from the southern region.

Reference standard absolute alcohol was obtained from AppliChem, Panreac, ITW companies, USA. Reference standards 2-Propranol and 1-propranol were received from Central Drug House (CDH). Methanol 99.8% reagent grade was obtained from Central Drug House (CDH), and finally, acetaldehyde was purchased from ACS Chemicals.

The headspace analysis was performed on an Agilent 7694E gas chromatograph with a flame ionization detector equipped with stationary phase Polysiloxane substituted with 3% of cyanopropyl groups, 3% of phenyl groups, and 94% of methyl groups (film thickness 3  $\mu\text{m}$ ), having column material: fused silica, size  $l = 30\text{ m}$ ,  $\text{Ø} = 0.53\text{ mm}$ , carrier gas: helium for chromatography, flow rate: 3 mL/min, and split ratio: 1:50.

The analytical methods in the current study were mainly adapted from British Pharmacopoeia Appendix VIII F for the determination of ethanol, and Appendix VIII L for residual solvents. Ethanol standard preparations were mainly prepared in water at five calibration curve levels: 0.05%, 0.075%, 0.1%, 0.12% and 0.15%, respectively. Samples were prepared by dilution of a volume of the product to be tested equivalent to 1 g, and then it was diluted to 50.0 mL with deionized water. Then, 1.0 mL of this solution was taken and subsequently diluted to

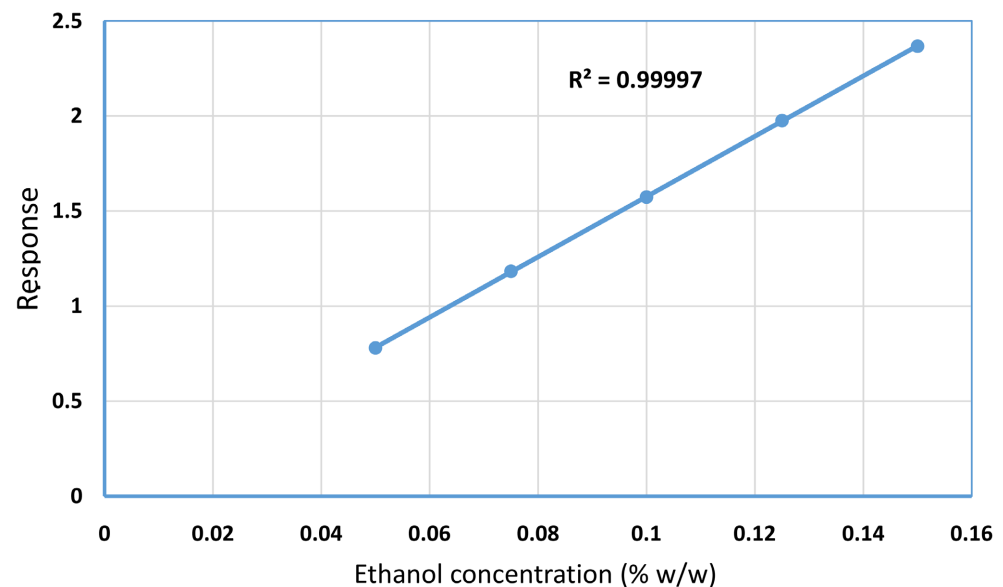
20.0 mL with deionized water, if necessary. 1-propanolol was used as an internal standard, and it was added in equal portions to the standards and sample solutions. For all analytes, the area ratio was calculated by dividing the area of each analyte of interest over the area of the internal standard. Then, the area ratio was used to quantify all analytes in this study by plotting them into the calibration curve (ethanol) or performing single-point calculations (methanol and acetaldehyde). As described in the British Pharmacopeia, calculation using single-point quantitation is sufficient for methanol and acetaldehyde quantitation. All system suitability measurements were successfully implemented according to the British Pharmacopeia requirements.

### 3. Results

Quantification of ethanol demonstrated good linearity and precision (**Figure 1**). The calibration curve using known standard concentrations yielded a linear relationship with an  $R^2$  of 0.999. The relative standard deviation for each point was <2%. Collectively, samples of hand sanitizers were analyzed at SFDA laboratories and the results showed that out of 1409 samples, 196 samples were Out-of-Specification (OOS) (**Table 1**). In addition, **Table 2** illustrates the underlying reasons for samples to be considered as OOS.

### 4. Discussion

During the period of the spread of the COVID-19 pandemic, the Saudi Food and



**Figure 1.** Calibration curve for the quantification of ethanol in hand sanitizers.

**Table 1.** Number of the OOS samples and their statistics compared to the total samples.

Total Samples	1409	100% total samples
OOS samples	196	13.9% of the total samples

**Table 2.** Data for impurities and/or other reasons rendering the product to be classified as OOS.

OOS sample justification	Numbers	Percentage <sup>1</sup>
Methanol	75	38.3%
1 propanol	12	6.1%
Acetaldehyde	4	2.0%
Improper labeling	10	5.1%
Foreign particles	4	2.0%
Ethanol below threshold	50	25.5%
Ethanol + IPA blend below threshold	29	14.8%
IPA below the threshold	12	6.1%
Net value	196	100.0%

<sup>1</sup>Percentage relative to the total OOS samples.

Drug Authority (SFDA) issued on the 6<sup>th</sup> of April, 2020, a temporary guide for marketing of hand sanitizer products and warned consumers against a number of hand sanitizers that contained elevated levels of methanol [14]. Similarly, the United States Food and Drug Administration (U.S. FDA) observed a sudden rise in hand sanitizer products in the market that were labeled to contain the proper concentration of ethanol. However, upon laboratory testing, those samples have tested positive for methanol as a contaminant ingredient, which was not declared on the label of those hand sanitizers. Thus, U.S. FDA issued a warning letter for health care providers and consumers stating the possible hazards associated with the use of those unsafe sanitizers [11].

**Table 2** shows that 38.3% of total OOS samples (75 samples out of 196) contained methanol, rating this chemical as a major reason for sample rejection. This finding is in agreement with a recent paper in which methanol was detected in 33 samples out of 34 samples [15]. In contrast, another study that assessed the safety of seven hand sanitizers demonstrated methanol to not be identified during the analysis [16]. Broadly, the existence of methanol in sanitizers could be due to two sources. Firstly, methanol can be found as an impurity in ethanol technical grade chemicals as it is difficult to separate these two solvents during the distillation process [17]. Secondly, methanol can be deliberately added to sanitizers so as to achieve antiseptic effects. Interestingly, the latter was documented during the COVID-19 pandemic [18]. The results of our current study with regards to the existence of methanol demonstrate both practices to be observed in tested samples. The magnitude of obscure methanol levels in the recent studies and our study reflect the manufacturing attitudes and practices compromising the quality of hand sanitizers, which necessitate precise regulatory actions to correct and/or reinforce the power of authority to guarantee consumer safety.

Exposure to methanol involves negative health consequences. Topical exposure symptoms are usually less severe than those related to the ingestion of methanol. Ingestion of large doses of methanol can potentially lead to vomiting, blurred vision, coma, headache, and permanent blindness due to the destruction of the optic nerve [19]. In addition, hand sanitizers or disinfectants containing methanol are of high risk for teens or adults, as well as children who could drink them as a substitute for ethyl alcohol. U.S. FDA has broadly clarified that methanol can be life-threatening when ingested and can be toxic and dangerous when absorbed through the skin [19] [20]. Therefore, U.S. FDA has declared methanol as unsafe and not accepted as an ingredient to be used in hand sanitizers due to its hazardous effects [20]. Furthermore, methanol has not been recommended or approved for use as a hand sanitizer by any public health or reputable governmental authorities, such as the United States Centers for Disease Control and Prevention (U.S. CDC) or WHO. On the other hand, the European Union (EU) has imposed restrictions on using methanol in certain consumer products, a limit that should be equal to or not greater than 3% per weight. However, the use of methanol in other products has been abandoned, and the EU does not recommend using methyl alcohol because of the potential risk to consumers, especially children [21]. Due to the high demand for alcohol-based hand sanitizers, U.S. FDA has issued guidance for hand sanitizer manufacturers, and importantly, has allowed certain limits of impurities as interim limits to be present in hand sanitizers. Interestingly, one of these impurities is methanol content in ethanol, and it is limited to be not more than (NMT) 630 ppm. To that end, hand sanitizers with a high level of methanol have been removed from the market in a number of countries [21] [22] [23] [24] [25].

The second ingredient displayed in **Table 2** was 1-propanol, present in 12 samples out of 196 OOS samples, representing 6.1% of the total OOS samples. Approximately, the main source for 1-propanol occurrence is an impurity within chemical-grade ethanol. Furthermore, 1-propanol could be, in some cases, incorporated in sanitizers (60% v/v) instead of isopropanol, as the WHO has previously discussed this formulation for pre-surgical hand formulation [10]. However, a WHO expert group later released a consensus opinion that does not support the selection of 1-propyl alcohol as an ingredient in hand rub formulation owing to the lack of evidence regarding its safety profile. In the current study, all the products found to contain 1-propanol were from cosmetic manufacturers, and the minimum concentration measured was 58% (data not shown). It seems that the lack of regulation insights by such industries has led them to misconceive 1-propanol as a substitute or the same chemical as isopropanol. In line with this observation, a recent study has found that sanitizers marketed as cosmetic products contain less ethanol content than their biocide counterparts [16]. Thus, the authors recommended that understanding regulatory guidelines with regard to sanitizers' quality assessment is an important aspect to mitigate product non-compliance [16]. To that end, a study from Canada found 1-propanol

to be present in 26 out of 42 samples, while its levels were observed to be within the acceptable limits according to Health Canada guidelines [12].

Acetaldehyde is a simple aldehyde that is frequently used as an intermediate during the synthesis of chemicals. Additionally, it is produced in large amounts for industrial purposes. Importantly, acetaldehyde is potentially carcinogenic and genotoxic, particularly when it comes in direct contact with tissues. It is considered a human carcinogen (Group 1) according to The International Agency for Research on Cancer (IARC), which means that there are sufficient studies and evidence for its carcinogenicity in humans [26]. Its existence in sanitizers is commonly as an impurity within ethanol, and it has regulatory control limits. According to a study from Canada, acetaldehyde is the most concerned impurity in hand sanitizers [12]. In that study, 28 samples out of 42 samples contained acetaldehyde in a range between 17 and 251  $\mu\text{L/L}$  (*i.e.*, ppm). In the current study, four hand sanitizers out of 196 OOS samples (2%) contained acetaldehyde (**Table 2**). The four samples had high levels of acetaldehyde in their formulation, *i.e.*, above 50 ppm (data not shown). Lately, the United States Pharmacopeia (USP) and Federal Communication Commission (FCC) have permitted an acceptable interim limit of acetaldehyde content in ethanol used for hand sanitizers. This permission was granted considering the challenges posed by the COVID-19 pandemic and the urgent high demand for alcohol-based hand sanitizers. Therefore, higher than 10 ppm of acetaldehyde impurity or ethanol-containing acetaldehyde would not be considered to meet the USP or FCC requirements in hand sanitizers [27]. Furthermore, the U.S. FDA has allowed using a temporary limit for acetaldehyde content in ethanol substances used to manufacture hand sanitizers. The new U.S. FDA guidance has allowed the presence of acetaldehyde in hand sanitizers up to the limit of NMT 50 ppm as a temporary policy [28]. On the contrary, other countries have adopted different limits on acetaldehyde depending on the need at the time of the initial spread of COVID-19. For example, Health Canada gradually decreased the upper limit for acetaldehyde in ethanol sanitizers from 1000 to 75 ppm [12]. The diverse regulations may highlight the importance of global harmonization of the requirements for such crucial products.

Impurities in hand sanitizers are not the only reason rendering samples to fail regulatory testing. Physical observation of foreign substances is one of the reasons that have led the samples to be out-of-specification. Specifically, there are four samples of hand rubs that have been found contaminated with foreign particles, and do not comply with the certificate of analysis from the manufacturer of those products. USP and FCC in the Excerpted USP-National Formulary (USP-NF) and FCC Standards: A Hand Sanitizer Resource have mentioned that impurities and foreign substances might be introduced from external sources or as a consequence of changing the processing methods. Consequently, the detection of any foreign substances or impurities in the product should not be tolerated according to the international guidelines, which have identified the ac-



ceptable limits of each foreign substance. For example, Health Canada's guidelines have set the limit of 300 ppm for all other impurities or foreign substances, and this limit is in alignment with the U.S. FDA's temporary policy [27] [29].

During the analysis of the current samples, some alcohol-based hand sanitizers were claimed by the manufacturer to contain specific type(s) of alcohol in their formulations (**Table 2**). Experimentally, the results of the analysis of those samples demonstrated them to have either only one type or different types of alcohol-based hand sanitizers. For example, samples claiming to contain both ethanol and isopropanol were found to contain only the alcohol isopropanol. These findings rendered those products to be classified as counterfeit and/or mislabeled samples, and they were determined as non-compliant. Depending on regulatory decisions and public demand, manufacturers could ask for a marketing waiver after changing the product label so that it reflects the actual alcohol present in the sanitizer.

The remaining OOS samples were found to have the correct alcohol labeling identity, however, with concentrations that were below the threshold necessary to denature the proteins of microbes and to exhibit considerable effectiveness (**Table 2**). Current analysis shows that 91 hand sanitizers out of 196 OOS samples contained lower levels of alcohol compared to the acceptable limits. Interestingly, all of these 91 failed samples comprised below 60% of alcohol, and surprisingly some samples contained only 10% or even 8.34% alcohol (data not shown). These findings were never mentioned on the label by the manufacturers of these products, and obviously, those products were unlikely to be effective. Effective sanitizers should have alcohol content between 60% and 95%. Center for Disease Control and Prevention (CDC) recommends that consumers use hand sanitizers or hand rubs containing at least one of the following: 60% ethyl alcohol (ethanol) or 70% of isopropanol [30]. Moreover, SFDA during the COVID-19 pandemic has issued a temporary guideline for the marketing of hand sanitizers in Saudi Arabia, where products should include at least 60% of ethanol or 70% of isopropanol in order to be available in the market [31]. Several studies have focused on alcohol-based hand sanitizers because these types of sanitizers are recommended by the WHO. Additionally, alcohol-based hand sanitizers provide certain advantages, such as the quick onset of action, coverage of a broad spectrum of organisms, and importantly, protection against bacteria and viruses compared to other types of hand sanitizers [20] [32] [33]. A previous study has illustrated that not all antimicrobial hand sanitizer products effectively reduce bacterial counts on hands. That study assessed the effectiveness of four different antimicrobial hand sanitizers against species of microorganisms, and concluded the effectiveness of alcohol increased from 60% to 90%, where 2-propanol was reported as the most effective agent followed by ethanol [34]. Furthermore, another research compared two types of hand sanitizers and showed hand sanitizers with 62% - 95% alcohol-based formulations as the most effective products, being able to inactivate viruses and alter the protein of microbes [20]. The latter



study suggested that 60% of alcohol content is needed as a minimum amount to exert the antimicrobial effect [20].

## 5. Conclusion

During the COVID-19 pandemic, SFDA has analyzed more than 1400 hand sanitizers to assess their safety and quality. Multiple alcohol-based hand sanitizers were not found to meet international standards and did not comply with the SFDA temporary guideline for marketing of hand sanitizers in Saudi Arabia. The tested products did not meet guidelines for a number of reasons that included physical as well as chemical justifications. Regulatory guidelines harmonization for specifications of sanitizers is an important requirement, which has come to the surface during the COVID-19 pandemic. Finally, active and continuous communications with the rapidly growing industry of hand sanitizers are critical to ensure delivering safe and effective products, thereby protecting the society.

## Authors' Contribution

Ibrahim A. Al Othaim wrote the original draft; Turki F. Al-Mutari; Nasser S. Bakiri and Khalid M. Bin Shehail designed the methodology and experimentation; Fouza K. Al-Enazi & Yahya M. Alshehri performed results interpretation; Anwar S. Al Suhaibani and Fahad S. Aldawsari contributed to editing and revising.

## Disclaimer

The views expressed in this paper are those of authors and do not necessarily reflect those of the SFDA or its stakeholders. Guaranteeing the accuracy and validity of data is a sole responsibility of the research team.

## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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### **List of Abbreviations**

COVID-19: Coronavirus disease 2019  
SFDA: Saudi Food & Drug Authority  
ABHS: Alcohol-based hand sanitizers  
BAC: Benzalkonium chloride  
WHO: World Health Organization  
USA: The United States  
OOS: Out-of-specifications  
U.S.FDA: The United States Food and Drug Administration  
NMT: Not more than  
v/v: Volume/Volume  
IARC: The International Agency for Research on Cancer  
USP: United State Pharmacopeia  
FCC: Federal Communication Commission  
ppm: Part per million  
GC: Gas chromatography  
FID: Flame Ionization detector  
USP-NF: United State Pharmacopeia-National Formulary  
CDC: Centers for Disease Control and Prevention