

## Quality of Commercial Alcohol-Based Hand Sanitizers Marketed in Kampala, Uganda during the COVID-19 Pandemic

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**In the year 2020, coronavirus disease-2019 (COVID-19) became a global public health emergency. The World Health Organization recommended wearing of masks, regular hand washing with soap or use of alcohol-based hand sanitizers to prevent human-to-human transmission of the disease. As a result, there was a rapid proliferation of hand sanitizers in the market, leading to concerns about the quality of these products. This study aimed to conduct a qualitative and quantitative evaluation of commercial alcohol-based hand sanitizers marketed in Kampala, Uganda. Commercial products (130) were sampled from five divisions of Kampala city and assessed for appearance, packaging, labelling and conformity with regulator's mark of quality. Additionally, the pH of the samples was determined. Gas chromatography coupled with mass spectrometry and flame ionization detectors were used for qualitative and quantitative analysis of the alcohol-based hand sanitizers, respectively. Only 15 samples (12%) met all the specifications for appearance, packaging, labelling, and regulation characteristics assessed. Alcohol was detected in 128 samples (98%). The permitted alcohols detected in the samples were ethanol (86%), isopropyl alcohol (4%) and ethanol/isopropyl alcohol admixture (3%). However, samples containing methanol, either alone (4%) or mixed with ethanol (1.5%) were encountered. Isopropyl alcohol was found as a denaturant in only one sample contrary to the label claims in seven samples. Twenty-two samples (17%) had a different alcohol from that declared on the label. Seventy-eight samples (60%) had alcohol content within the requisite range of 60-95% v/v while forty-two had less than 60% v/v alcohol, and one contained more than 95% v/v. Sixty-seven samples did not comply with the specifications for pH. The results obtained from the study underscore the need for market surveillance of these products.**

**Key words:** COVID-19, alcohol-based hand sanitizer, Kampala, isopropyl alcohol, ethanol, methanol

### INTRODUCTION

In the year 2019, a new coronavirus disease (COVID-19) was reported in hospitalized patients in Wuhan, China. It presented as an acute respiratory syndrome-2, an air-borne pathogen that also spread through touching contaminated surfaces.<sup>1</sup> COVID-19 was declared a worldwide pandemic and public health emergency by the World Health Organization (WHO),<sup>2</sup> with Uganda reporting

her first case on 21<sup>st</sup> March 2020. Thereafter, the number of cases rose steadily.<sup>3</sup>

The WHO and Centers for Disease Control and Prevention (CDC) recommended regular hand washing with water and soap or use of alcohol-based hand sanitizers, social distancing, respiratory hygiene, proper ventilation of indoor spaces, quarantine and later vaccination as preventative measures.<sup>2,4,5</sup> Hand sanitizers offer a fast and suitable means of eliminating

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pathogens from the hands when water and soap are unavailable.<sup>6</sup> Hand sanitizer formulations exist in liquids, gels, foams, sprays, dispensers, and wipes applied and rubbed on hands to kill microorganisms.<sup>7,8</sup> Hand sanitizers can be categorized as alcohol-based or alcohol-free based on the active ingredients used.<sup>9</sup> The alcohol type, grade and concentration are key to product quality and efficacy against pathogenic microorganisms.<sup>8</sup> The Food and Drug Administration (US-FDA), CDC, and WHO recommend use of 60-95 % v/v aqueous ethanol or isopropanol (IPA),<sup>10-13</sup> and in some cases in combination with other non-alcoholic antiseptic agents<sup>14</sup> for efficacy. In addition to alcohol, other ingredients that may be incorporated are humectants (glycerin), moisturizers (vitamin E, *Aloe vera* extract), thickening agents (carbomers), pH adjusting agents (triethanolamine, tromethamine), viscosity enhancers, fragrances, preservatives, colourants, and denaturants (acetone) depending on formulation type.<sup>14,15</sup> Packaging and labelling of the ABHS are considered secondary to the quality of the ABHS formulation. Polyethylene terephthalate (PET) plastic packaging and glass bottles with leak-proof tops are considered safe for the ABHS packaging.<sup>16,17</sup>

Diverse regulatory agencies specify quality parameters and production requirements of ABHS.<sup>18</sup> The US-FDA categorizes hand sanitizers as drugs and regulates them under biocidal products.<sup>19</sup> The Uganda National Bureau of Standards (UNBS) is mandated with the regulation of hand sanitizers according to the 'instant hand sanitizers standards' (Uganda Standard EAS 789:2013) adapted from the East African Standard (EAS) for purposes of cross-border trade of ABHS.<sup>20</sup> The specified product quality tests include alcohol content, pH and bactericidal efficacy as well as the general requirements on appearance, smell, packaging, and labelling. Unlike US-FDA guidelines, the UNBS has listed n-propanol as one of the permitted alcohols in addition to ethanol and IPA at a minimum content of 60% v/v.<sup>20</sup>

The utilization of hand sanitizers in COVID-19 prevention resulted in a global surge in demand for ABHS.<sup>18</sup> To exploit this market opportunity,

several chemical industries, breweries and perfumeries switched to hand sanitizer production.<sup>21</sup> Consequently, a large number of substandard, falsified or contaminated ABHS brands were introduced to the market.<sup>22-25</sup> The UNBS registered 136 manufacturers and 182 brands of sanitizers as at July, 2020 in the early stages of COVID-19,<sup>26</sup> with 132 annual manufacturing license renewals in the year 2021.<sup>27</sup> Through the Ugandan media the UNBS cautioned the public against the purchase of 15 blacklisted sanitizer brands which failed mandatory laboratory tests in the year 2020.<sup>28</sup>

The UNBS specification for determining alcohol content utilizes non-specific methods. It employs pycnometry to determine alcohol content based on differences in specific gravity of alcohol-water mixtures at a particular temperature.<sup>20</sup> Based on previous studies conducted in Kenya, USA, and South Africa, use of specific analytical methods such as gas chromatography (GC) for ABHS determination has been recommended to control non-permitted alcohols such as methanol.<sup>24,25,29</sup> At the time of this study, there were no scientific studies on quality evaluation of ABHS products in the Ugandan market. This is a report of the quality of commercial ABHS brands marketed in Kampala city, Uganda.

## MATERIALS AND METHODS

### Study site, sample and sampling

Study samples were purchased from the five Divisions of Kampala namely, Kampala Central, Kawempe, Rubaga, Makindye, and Nakawa<sup>30</sup> through convenience (incidental) sampling. The sampling frame included randomly selected pharmacies, drug shops, supermarkets, cosmetic shops and hawkers in the target areas of the city. Through this approach, a total of 130 unique ABHS samples were collected from each Division over a two-month period (March - April 2022). The target samples were gels and liquids in the smallest packs of commercial ABHS brands available at sampling sites. The samples were transported under ambient temperatures with leak-tight and securely closed packaging, protected against physical damage.

They were stored in their original container in a refrigerator ( $5\pm 3$  °C) until analysis. Analysis of the samples was carried out in the Drug Analysis and Research Unit (DARU) laboratories, Department of Pharmaceutical Chemistry, Pharmaceutics and Pharmacognosy, Faculty of Health Sciences, University of Nairobi, Kenya.

### Materials and reagents

HPLC grade acetonitrile (Carlo Erba reagents S.A.S, Peypin, France), absolute ethanol 99.9% v/v (Scharlab S.L., Sentmenat, Spain), analytical grade isopropyl alcohol 99.5% v/v (Finar Limited, Ahmedabad, India), analytical grade methanol 99.8% v/v (Finar Limited, Ahmedabad, India), and glycerine 99.5% v/v (Finar Limited, Ahmedabad, India) were purchased from local distributors in Nairobi and used as the reference standard solvents for GC analysis. Purified water was freshly distilled using a glass apparatus in the laboratory.

### Equipment

A Jenway® 3510 pH meter (Bibby Scientific Ltd, Stone, UK) was used in pH determination. Identification and quantification of the volatile components were carried out on a Shimadzu GC-2010 plus system (Shimadzu Corporation, Tokyo, Japan) coupled with a mass spectrometer (MS) and alternate flame ionization detector (FID) (Shimadzu Corporation, Tokyo, Japan) using the GC solution software version 2.42 (Shimadzu Corporation, Kyoto, Japan). A ZB wax plus capillary column (Phenomenex, Torrance, CA, USA) of dimensions, 60 m × 0.25 mm, 0.25 µm film thickness was used for chromatographic separation. Analytical instruments were optimized and validated and/or calibrated before use.

### Physical parameters

Samples were visually evaluated for appearance, packaging, labelling, and other regulations as per UNBS standards. The pH of neat samples was measured on a Jenway® 3510 pH meter calibrated with buffer solutions at pH 4.0, 7.0 and 10.0.

### Standard solutions

A 10% v/v internal standard solution (ISS) for GC-MS/FID was made by diluting one ml of acetonitrile to 10 ml with distilled water in a volumetric flask. A standard stock solution (SSS) mixture was prepared by pipetting one ml each of methanol, IPA, ethanol, and glycerine into a 10 ml volumetric flask and topping up with distilled water. The standard solution mixture was prepared by mixing 300 µl SSS, 500 µl ISS and 200 µl distilled water prior to injection.

### Sample solutions

A test stock solution (TSS) was prepared by diluting one ml of neat sample to 10 ml with distilled water. The test solution was made by mixing 300 µl TSS, 500 µl ISS and 200 µl distilled water filtered through PTFE 0.22 µm microfilters (Nantong Filter-Bio Membrane Co., Jiangsu, China) before injection.

### Identification and assay

The chromatographic conditions described by the USP method of detection of volatiles,<sup>31</sup> Abuga *et al.*<sup>24</sup> and Zhang<sup>29</sup> were used, with minor modifications, following system suitability tests and method validation, for the identification and assay. The volatiles in ABHS samples were identified by GC-MS,<sup>31</sup> supported by a GC-MS solution software with helium as the carrier gas at 3.0 ml/min flow rate, pulsed split mode of 20:1 and injection volume of 0.2 µl. The oven temperature was programmed as follows: 45 °C for seven min, gradient of 30 °C/min to 240 °C for six min and 240 °C for seven min resulting in a total run time of 26.5 min. The mass selector was maintained at an ion source temperature of 200 °C, and electron impact (EI) mass spectra were obtained at the acceleration energy of 70 eV. Fragment ions were analyzed in the full scan mode over a 20-300 m/z mass range. The filament delay time was set at 0 min.

Gas chromatography with a flame ionization detector operated using GC solution software was utilized in the quantification of volatiles in ABHS.<sup>24,29</sup> The injector was set in pulsed split mode of 20:1 with an injection volume of 0.2  $\mu$ l. The injection port and detector temperature were set at 250 °C. Helium at a flow rate of 3.0 ml/min was used as a carrier gas while the temperature program was operated as described for the GC-MS experiments.

### Data processing, analysis and presentation

Microsoft - Excel® program (Microsoft Corporation, Redmond, WA, USA) was used to analyze appearance, packaging, labelling, UNBS standardization mark conformity, GC and pH data. The alcohols and impurities were identified by comparing peak mass spectral data and retention time matching of +/- 0.1 minute with those of the standards and reference spectra published by library-MS databases. For this purpose, a similarity index threshold of 80-100 % was applied. Quantification of the alcohol and

impurities was calculated by comparison of peak area ratios of the sample components and reference standards to the internal standard, correcting the result for standard purity and the dilution factor. Data was summarized in tables and graphs, using the mean  $\pm$  standard deviation and percentage as descriptive statistics. The alcohol content was reported as % label claim. Uganda National Bureau of Standards specification falling within WHO limit for alcoholic concentration (60–95 %v/v) and pH (6-8) was used for the decision statements.

### RESULTS AND DISCUSSION

A total of 130 brands of ABHS was collected from 70 retail outlets randomly visited around Kampala. Figure 1 shows the percentage compliance of the brands to appearance, packaging, labelling, and other regulations on ABHS regarding UNBS standardization requirements.

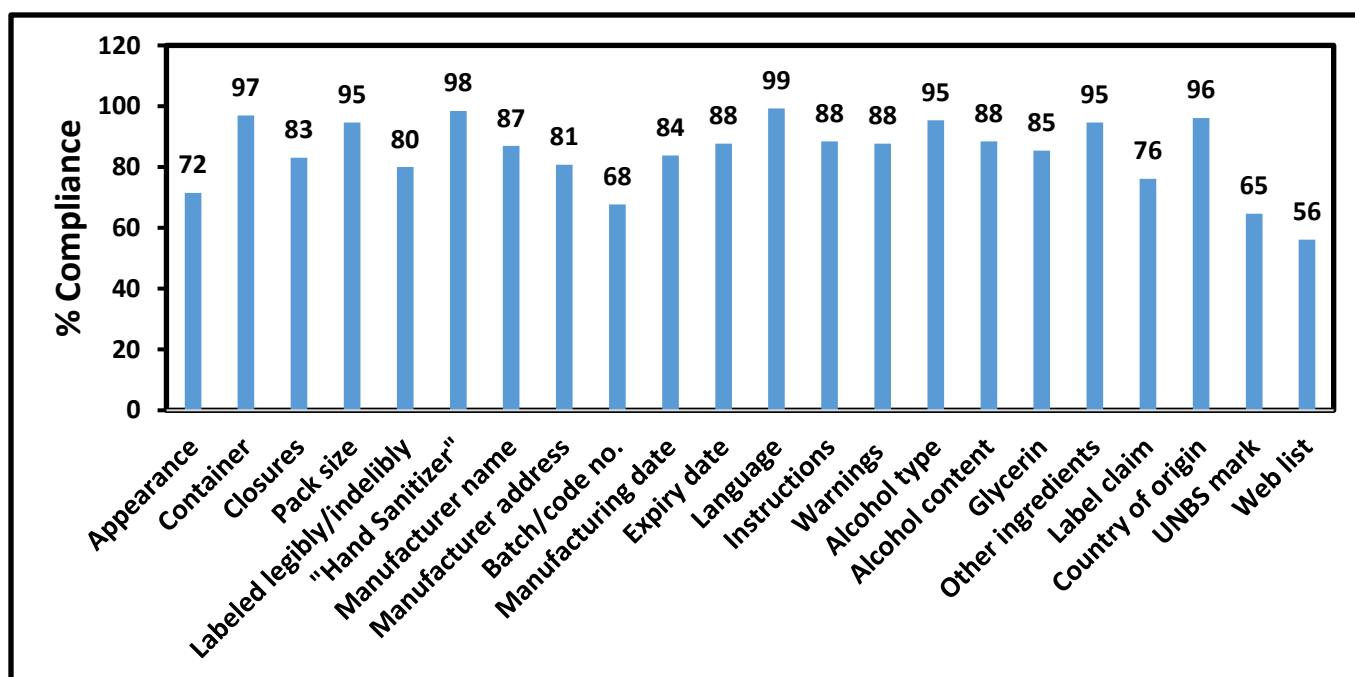


Figure 1: Compliance of ABHS brands with packaging, labelling and regulatory requirements

### Form and appearance

The UNBS specifies, among other general requirements, that ‘hand sanitizer shall be clear, colorless and in the form of liquid or gel.’<sup>20</sup> Majority of the 130 brands in this study were liquids (95, 73%) while 35 (27%) were gels although only eight samples were clearly labelled ‘gel’. These results show that there were more liquid than gel ABHS formulations marketed in Kampala at the time of the study. Most samples (93, 72%) complied with the specification for appearance. Six samples (5%) comprising of one liquid and five gels were blue-, pink-, brown-, and green-colored. Twenty-nine samples (22%) appeared cloudy with precipitates or clear with visible particles. Twenty-four of these samples were liquid formulations while five were gels with blue-colored insoluble particles. The gel formulations demonstrated varying flowability, with twelve samples flowing within 2 seconds of container inversion while sixteen flowed within 5 seconds and seven not at all in this time interval. This observation is similar to that of by Nyamweya and Abuga<sup>22</sup> in a study conducted in Nairobi, Kenya. Conversely, two samples labelled as gel were free-flowing liquids.

### Packaging and pack sizes

According to the UNBS specifications, ABHS should be packaged in suitably well-closed containers which together with the closures should be chemically inert<sup>20</sup> About 84% of the samples (109) were packaged in suitable containers with appropriate closures. One hundred and twenty-six samples (97%) were packaged in clear polyethylene terephthalate (PET) and four (3%) in opaque high-density polyethylene (HDPE) containers. Polyethylene terephthalate (PET) plastic is preferred for packaging ABHS because it enables product viewing through the transparent container. Furthermore, PET plastics can either be recycled or rinsed out and reused. Overall, 75 closures (58%) had spray pumps, 30 (23%) disc top caps, 24 (18%) flip top caps, and one (1%) trigger spray pump as delivery mechanisms. Three samples (2%) had leaking closures. Nineteen samples (15%) were in the inappropriate containers and closures, with seven having flip-

top caps and 12 disc-top closures, which offer minimal protection during handling, transportation and storage.<sup>20</sup> In practice, screw-cap tops, disc-tops, or flip-top closures were encouraged.<sup>16,17</sup>

The pack sizes of ABHS ranged from 30-200 ml, with 52 (40%) having a fill volume of 60 ml, two 30 ml, and one 200 ml. Other packs encountered were 50 ml (27), 53 ml (1), 65 ml (5), 75 ml (2), 80 ml (2), 100 ml (24) and 120 ml (7). Six (5%) samples had no capacity labelled on the packaging or container, while one had a non-matching labelled (500 ml) and actual pack size (60 ml).

### Labelling

Hand sanitizers are required to be legibly and indelibly marked with accurate information.<sup>20</sup> Eighty percent (104) of the samples were legibly and indelibly labelled while majority (128, 98%) of samples were labelled “hand sanitizer”, except for two samples, one of which had a faint label and one that was not labelled (Figure 1). Furthermore, 113 samples (87%) had the manufacturer’s name, while 105 (81%) bore the manufacturer address. Eight samples (6%) showed only the manufacturer’s name without associated physical addresses whilst four samples indicated a mobile telephone number only. Two samples had the batch number, manufacturing date and expiry date erased, while one had these details covered with an overlaid label.

About 99% of the samples had instructions for use written in English while one sample had instructions in both Arabic and English, and another one in Chinese and English. One sample did not spell out usage instructions. Sixteen samples (12%) had no cautionary warning, 31 (24%) had partially compliant cautions (with 1-3 of the 4 required warnings), while 64% (83) were fully compliant. One was labelled “Don’t ingest or inhale,” which is inaccurate. Label irregularities included cut-off print portions, faint, obscured, overlaid, poor inking, tiny letters, peeling off, and erased or missing labels. These observations are in agreement with the Nairobi survey which demonstrated several non-conformities in packaging, labeling, and other

established regulatory standards with ABHS samples.<sup>22,32</sup> Appropriate labelling facilitates better identification and understanding of the product, with more user confidence and trust built on it and its distinguished benefit.<sup>22</sup>

### Labelled ingredients

With regard to alcohol type, content, and other ingredients stated on the labels, six samples (5%) did not specify the alcohol used while eight (6%) samples indicated denatured alcohol, seven isopropyl alcohol and one phenoxyethanol as the active ingredient. One sample listed “ethoxylated fatty alcohols”, one “cetyl alcohol” and one wrongly spelt “athyl alcohol” as the actives. Declaration of the alcohol type on the label eases the management of any accidental or intentional ABHS ingestion. The labelled alcohol content was 60% - 85% v/v. The alcohol type and content are vital aspects of the perceived quality of ABHS. The mislabeling illustrated in this study is similar to literature reports from Kenyan and Canadian studies.<sup>24,33</sup>

The other common ingredients listed in 95% (n=123) of samples included hydrogen peroxide, triethanolamine, carbomer, fragrances (perfume), flavour, colours, tocopheryl acetate (vitamin E), aloe, and glycerine. Less common ingredients included propylene glycol, monopropylene glycol, dimethicone, sodium sulphate, betaine, coconut diethanolamide, diethyl phthalate, isopropyl myristate, allantoin, phosphoric acid, perhydrol, 1,2,3-trihydroxypropane, inter-chlorodimethyl phenol, alkyl acrylate cross polymer, triethylamine, lanolin, sodium lauryl ether sulphate, alkyl dimethyl benzyl ammonium chloride, water, polymethyl siloxane, carbopol, methyl paraben, propyl paraben, peppermint, strawberry essential oil, cocoa alkyl, cinnamon, peppermint, kigelia, carbopol and lemon.

Seven samples listed no inactive ingredients, and some had incomplete information about the ingredients with non-standardized abbreviations. Manufacturers of ABHS are mandated to indicate a complete list of ingredients on the label for user information since certain ingredients are potential allergens to some

individuals, preventing harm or providing other reasons for not using.<sup>34</sup>

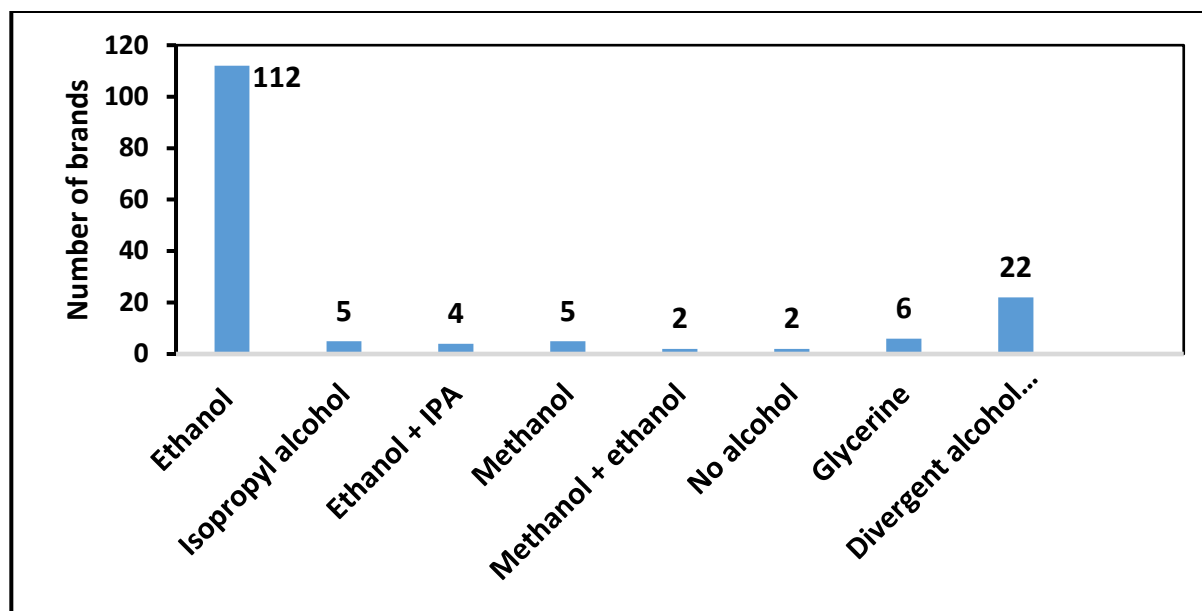
A majority (99, 76%) of samples had label claims concerning efficacy expressed as a percentage of the microbial kill. The values labelled on the containers or packaging were 99%, 99.9%, 99.99%, or 100%. However, one sample had a wrong label claim stating “99.9% without water”. Protein denaturation by alcohol is known to be promoted in the presence of water.<sup>35</sup> The claim on ‘99.99% killing of microorganisms’ has been demonstrated to be factual in other studies.<sup>36</sup> Therefore, experimental data must validate these values to safeguard the users' sense of security.

### Regulatory requirements

Commercial products are expected to have the “UNBS Quality Mark” stamped on the primary and secondary packaging. The UNBS mark is intended to create consumer confidence on the quality of ABHS products. Additionally, the product should be listed in the annual UNBS website list of authorized brands.<sup>20</sup> A majority of samples analyzed (112, 86%) were manufactured in Uganda, while 13 (10%) were imported from the United Kingdom, People’s Republic of China, Indonesia, Turkey, United Arabs Emirates, South Africa and Kenya. Five (4%) samples did not state the country of origin. Although 84 (75%) of the locally manufactured samples had the quality mark, only 35 (31%) appeared on the list of certified ABHS as at July 2021. None of the imported products had a “UNBS Quality Mark”, nor appeared on the UNBS list of certified ABHS. Six samples (4.6%) had both the UNBS mark and National Drug Authority (NDA) Uganda mark.

### Identification and assay

The results of GC-MS profiling and assay of the volatiles are shown in Figure 2 and Tables 1 respectively. Ethanol (112, 86%), isopropyl alcohol (IPA) (5, 4%), and ethanol/IPA admixture (3%, n=4) were detected in several samples as shown in Figure 2. Two samples (one imported and one locally manufactured) did not contain any active ingredient.



**Figure 2: Gas chromatography-mass spectrometry (GC-MS) profiling of alcohols in ABHS samples**

IPA - Isopropyl alcohol

The study identified 22 ABHS samples with different alcohol types from those declared on the label. In these samples, ethanol (7), IPA (10), cetyl alcohol (2), and methanol (3) was indicated on the label as the active ingredient (s) or one of the actives were not detected. Two samples found to contain no active ingredient were labelled as ethyl alcohol or ethoxylated fatty alcohols products. One sampled labelled “Athyl alcohol” was found to contain ethanol.

Ten samples stated that denatured alcohol was the active ingredient, with eight specifying denaturants such as IPA (7) and phenoxyethanol (1). Two samples did not specify the denaturant used but only one was found to contain IPA as the denaturant. Seven samples simply stated “alcohol” on the label. Two samples with no active ingredient declared on the label, were found to contain ethanol. Alcohol denaturants such as IPA, methanol and denatonium benzoate are added in low concentrations to ABHS to offer an unpleasant taste and hence deter ingestion.<sup>37,38</sup>

The alcohol content of the samples analyzed ranged from 9.33% - 98.95% v/v (average  $63\pm 15\%$ ) as presented in Table 1. About 60% (78) of the samples complied with WHO

specifications for alcohol content in ABHS with an average alcohol content of  $69\pm 8\%$  v/v. In 43 samples, the alcohol concentration was found to fall outside the limits with 42 (32.3%) having less than 60% v/v alcohol. Of the 42 samples, 21 had a UNBS quality mark, 32 samples were locally manufactured, six were imported and four samples did not state the country of origin. One locally manufactured sample contained 98.95% v/v sum of the permitted alcohols, thus exceeding the upper limit of 95% v/v while two brands of ABHS had no alcohol.

Ethanol has been shown to have better activity against viruses, whereas IPA demonstrated better bactericidal activity.<sup>35</sup> In addition, 70-95% v/v ethanol has been reported to display a more potent and broader virucidal activity covering several clinically relevant viruses,<sup>39</sup> whereas 60-100% v/v isopropyl alcohol demonstrated better bacterial and fungal inhibition activity.<sup>40</sup> Therefore, formulations of ABHS with an alcohol content of 85%-95% have been recommended for improved antimicrobial spectrum.<sup>40</sup> Hand sanitizers formulated with an alcohol content of less than 60% demonstrated reduced efficacy in other studies, increasing the risk of transmission of infection.<sup>41,42</sup> Conversely, excessively high alcohol concentration was

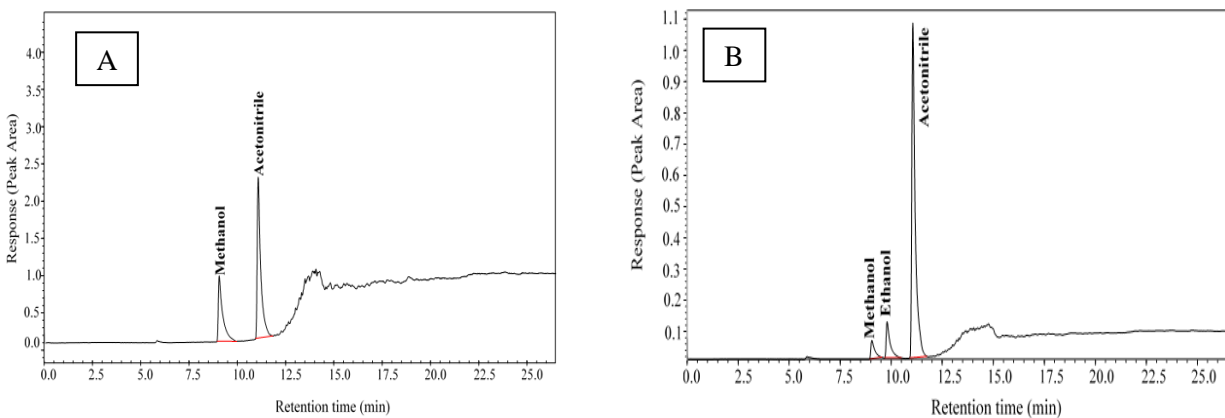
known to render the preparation less effective since water is required for activity.<sup>35</sup> The results indicate a need to validate the antimicrobial efficacy of ABHS post-pandemic as laxity is likely to occur among manufacturers, regulatory bodies, and consumers.<sup>43</sup>

Methanol and n-propanol in ABHS are considered as impurities or contaminants harmful for human use by the US-FDA. The warning for n-propanol was targeted towards prevention/reduction of misuse as drinkable alcohol substitutes rather than as a result of its toxicity following use as hand sanitizer.<sup>44</sup> In contrast, the UNBS has included n-propanol as one of the permitted alcohols in addition to ethanol and isopropanol at a minimum content of 60% v/v.<sup>20,45</sup>

Seven samples contained either methanol alone (5) indicating substitution or in combination with ethanol (2) as illustrated in Figure 3. Methanol substitution for ethanol was encountered with three products and for isopropyl alcohol with two products. All seven samples found to contain methanol were locally manufactured. Methanol content in the seven (5.4%) ABHS liquid samples ranged from

25.7% - 98.0% v/v. The USP has set the interim limit of methanol at 200 ppm (200  $\mu$ l/l or 0.020% v/v),<sup>46</sup> while the US-FDA identifies methanol as a “level 1 impurity” with an adjusted interim limit of less than 630 ppm (0.063% v/v or 630  $\mu$ l/l).<sup>31</sup> However, the UNBS specification does not include methanol limits. Reports from South Africa and Kenya, found ABHS samples containing less than 60% v/v ethanol or isopropyl alcohol, methanol substitution or methanol contamination and failed pH range.<sup>24,25</sup> Out of seven samples that failed in the methanol limits, two were found on the UNBS website as certified brands with a UNBS quality mark at the time of the study.<sup>27</sup>

From the literature, the presence of methanol in low concentration could be used as a denaturant in the ABHS.<sup>37</sup> The establishment of the methanol content is critical because its metabolites, formaldehyde and formic acid, are known to be toxic.<sup>47,48</sup> Methanol-induced desquamation and dermatitis are manifestations of skin absorption following prolonged exposure to methanol-containing ABHS.<sup>49,50</sup> There is a need for sensitization of the public on the health risks associated with using ABHS adulterated with high methanol content.



**Figure 3: A typical chromatogram of ABHS with methanol substitution (A) and methanol contamination (B)**

Notably, although 111 samples (85%) had glycerine labelled as one of the ingredients only 6 samples (3 liquids and 3 gels) were found to contain glycerine. One of the 6 samples had not indicated glycerine as one of the ingredients on

its label. Three of these six samples were locally manufactured, one was imported, and two had no country of origin stated. Two of the six samples with glycerine also contained methanol. Six (4.6%) of the ABHS comprising three liquid



and three gel formulations containing glycerine as the humectant, had the concentration ranging from 4.55% - 57.43% v/v (mean 18.05±22%) as shown in Table 1. None of the ABHS samples with glycerine complied with the WHO current specification of 1.45% v/v glycerine.<sup>17</sup> Adding glycerine to the formulation lowers the antimicrobial activity of alcohol, especially 2-

propanol, due to reduced alcohol diffusion with increasing viscosity. However, a balance between the effect and efficacy of ABHS has to be struck.<sup>51</sup> Nevertheless, excellent antimicrobial activity was demonstrated with ABHS formulated with WHO specifications of either ethanol (80% v/v) or isopropanol (75% v/v) mixed with glycerine (1.45% v/v).<sup>43</sup>

**Table 1: Results of assay and pH values of hand sanitizers analyzed**

ABHS content characteristics	Number of brands	Mean± standard deviation (% v/v)
Total alcohol	128	63.0±15
Sum of permitted alcohol (ethanol + isopropyl alcohol)	121	61.9±14
Sum of permitted alcohol between 60-95	78	69.1±8
Sum of permitted alcohol less than 60	42	47.6±13
Sum of permitted alcohol more than 95	1	99.0±0
Glycerine	6	18.0±22
Methanol substitution	7	70.4±26
Sum of permitted alcohol in liquid samples	87	65.5±12
Sum of permitted alcohol in gel samples	34	52.8±17
No alcohol	2	0.0

The percentage of the sum of permitted alcohol (ethanol, isopropyl alcohol) in liquid samples was 65.5±12% v/v and 52.8±17% v/v in the gel samples as shown in Table 1. The percentage of sum of permitted alcohol in all samples was 61.9±14% v/v, slightly less than the total alcohol content (including methanol).

#### pH determination

The UNBS recommends a pH range of 6-8 for hand sanitizers.<sup>20</sup> The pH of the ABHS samples of ranged between 2.6 and 8.9. Forty-eight percent (63) comprising of 36 liquid and 27 gel formulations of the samples of ABHS had a pH between 6 and 8, with. About half (67, 52%) failed the pH test as per the UNBS pH specification range.<sup>20</sup> Among the formulations of ABHS which failed the test, 88% (59) were liquid, and 12% (8) gel. The non-compliance with the pH specification was comparable to the findings from the study by Abuga *et al*<sup>24</sup> The

failure could be associated with the presence of the listed excipients most likely used in the formulation, such as triethanolamine, phosphoric acid, tocopheryl acetate, polymethyl siloxane, dimethicone, 1,2,3-trihydroxypropane, and diethyl phthalate which are pH modifying agents.<sup>52</sup>

The results of this study where only 15 samples (12%) met all the requirements for appearance, packaging, labelling, and regulatory requirements, four samples (3%) manufactured with the WHO specified reagents and 78 samples (60.0%) formulated with the WHO recommended content of permitted alcohols, are comparable to those in literature from countries like Canada, Singapore, Turkey, South Africa, Rwanda, Ethiopia, and Kenya.<sup>22-25,32,53-55</sup> Substandard/falsified and ineffective ABHS products predispose individual users to adverse events and compromise efforts of regulatory agencies regarding controlling COVID-19 and

other infections. Therefore, the consumer safety depends on the combined efforts of the manufacturer and regulator to ensure only quality products are released to the market.

## CONCLUSION

This study demonstrates that substandard and falsified ABHS formulations were in circulation in Kampala during the COVID-19 pandemic when the demand was considerably increased. Since most products are manufactured or imported/distributed through Kampala, the results may represent quality profile across the country (Uganda). Irrespective of the vaccination rate, ABHS remains the first-line defense for COVID-19 and other infectious diseases transmitted through contact. Hence, the need for producing quality ABHS as per current

good manufacturing practices. Besides the “UNBS Quality Mark,” this study demonstrates a need for a product permit number, strengthening the regulatory institution and improving surveillance mechanisms. Furthermore, testing of ABHS should employ specific and validated test methods like GC-MS/FID. This calls for revision of UNBS specification for “instant hand sanitizers” to “specification for alcohol-based hand sanitizers” to be more specific and accommodate stricter requirements on assay and control of impurities.

## SUPPORTING INFORMATION

Supporting information is available free of charge at:

<https://uonjournals.uonbi.ac.ke/ojs/index.php/ecajps/libraryFiles/downloadPublic/26>.

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