Alcohols and Denaturants Hand Rub Sanitizers Used to Curb COVID-19 Pandemic in Kiambu County, Kenya

Martha W. Gacuiga^{1*}, Ruth N. Wanjau², Martin K. Murigi³, Gerald W. Mbugua⁴, Antony M. Ndiritu⁵, Nicholas K. Gikonyo⁶

^{1,2}Department of Chemistry, Kenyatta University, P. O. Box 43844-00100, Nairobi, Kenya
^{3,5,6}National Phytotherapeutics Research Centre, Kenyatta University, P. O. Box 43844-00100, Nairobi, Kenya
⁴Department of Biological and Physical Sciences, Turkana University College, P.O Box 69-30500, Lodwar, Kenya
^{3,6}Department of Pharmacognosy and Pharmaceutical Chemistry, Kenyatta University, P. O. Box 43844-00100, Nairobi, Kenya

*Corresponding Author: wairimuken3@gmail.com

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Abstract— The coronavirus disease outbreak in 2019 (COVID-19) became a pandemic that led to tremendous increase in the use of alcohol-based hand sanitizers globally. Governments and public health agencies across the world advocated for hand hygiene as one of the preventive measures against COVID-19 pandemic. Consequently, washing of hands with water and soap or use of alcohol-based hand sanitizers became mandatory. The efficacy of these sanitizers is dependent on the alcohol concentration in the hand sanitizer. Alcohols commonly used in sanitizers include ethanol and isopropyl alcohol at levels of 60% to 80%. Ethanol used to manufacture the sanitizers is of industrial grade and is usually denatured to prevent human consumption. Denaturants include methanol, pyridine, acetone and denatonium benzoate at levels of ≤ 630 ppm for methanol and 20 to 50 ppm for denatorium benzoate. This paper mull over comparing levels of alcohols and denaturants with label claims of alcohol-based hand sanitizers used to curb the COVID-19 pandemic in Kiambu County, Kenya. Samples of alcohol-based hand sanitizers of different brands were analyzed in triplicates using Attenuated Total Reflectance- Fourier Transform Infrared spectrometry (ATR-FTIR). Each hand sanitizer was given a unique sample identifier code ranging from HS1-HS12. The findings indicated that alcohol-based hand sanitizers contain significant amount of either ethanol or isopropyl alcohol and low concentration of methanol or denatonium benzoate. The percentage of ethanol ranged from 4.607±0.0 to 81.23±0.3. Nine samples showed concentrations above 70% ethanol. The levels found in the study were not in agreement with levels indicated on the labels. Isopropyl alcohol was found in only two samples contrary to the label claims in five samples. The analysis showed that all samples contained either isopropyl alcohol, methanol or denatorium benzoate as denaturants with levels ranging from 0.040±0.02% to 72.6857±0.4241%, while the label claim indicated the presence of denaturants in only five samples. However, two samples gave methanol levels that exceeded threshold limits of 630 ppm (0.063% v/v). In conclusion, the concentration levels of alcohols and denaturants in all alcohol-based hand sanitizers analysed in this study didn't match with the label claim. This calls for stringent measures by regulatory bodies to ensure compliance with set standards in the manufacture of alcohol-based hand sanitizers.

Keywords—COVID-19, Alcohol-based hand sanitizers, Alcohols, Denaturants, Label claims, compliance

I. INTRODUCTION

Globally, in the late 2019 pathogenic coronavirus emerged. It was identified as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The virus started to spread widely leading to a global pandemic termed as "coronavirus disease 2019" (COVID-19) pandemic [1]. Hand hygiene gained popularity since SARS-CoV-2 spread through touch of contaminated surfaces with such pathogens [2, 3]. Washing hands thoroughly and regularly or use of alcohol- based hand rub sanitizers became mandatory to curb the spread of COVID-19, and this made use of alcohol-based hand rub sanitizers (ABHRS) to gain popularity in developing countries as well [4]. Due to high alcohol-based sanitizers demand of there

formulations that were approved by World Health Organisation (WHO) whose compounding is as follows; ethyl alcohol (80% v/v) or isopropyl alcohol (75% v/v), glycerol (1.45% v/v), hydrogen peroxide (0.125% v/v) and deionised water for the remaining % v/v [5]. Moreover, for any hand sanitizer to be effective the levels of ethanol or isopropyl alcohol should be in appropriate range of 60% to 75% [2]. A study of ethanolic content in alcohol-based hand sanitizers by [6], revealed that three out of seven ABHRS had ethanolic content below the range recommended by regulatory agencies of 60-95%. Similar study carried out in Brazil using mid and near infrared spectroscopy showed that only seven out of thirty-four ABHRS samples met the specifications of the recommended range of ethanol content [2]. Ethyl alcohol

used in manufacture of alcohol- based hand sanitizers is denatured by adulterating reagents such as methanol, pyridine, acetone and denatonium benzoate to make it unsuitable for human consumption [7]. The threshold level for methanol is 630 ppm (0.063% v/v) while the recommended concentration of denatonium benzoate in alcohols ranges from 20 to 50 ppm [8, 9]. Reports on quality of alcohol-based hand sanitizers marketed in Nairobi metropolitan area showed that 44 out of 74 samples (59.5%) had methanol levels that exceeded threshold limits [4]. Isopropyl alcohol is used as both an alcohol and denaturing agent [7]. Though manufacturing of ABHS is governed by WHO with formulation of 75-80% alcohol, many countries have specific regulations that govern the production of ABHS [10]. In Kenya each hand sanitizer should be in compliance with Kenya Bureau of Standards (KEBS) [11] of 60 % to 95 % alcohol before it's released into the market. This information must be displayed on the label [12]. Due to high demand of alcohol-based hand sanitizers since the outbreak of COVID-19 early in the year 2020, manufacturers may be forced to use technical grade ethanol that have high impurities of methanol and other contaminants like ethyl acetate [13, 14], which may cause health concern to the user such as dermatitis, pose a risk if its ingested or gets into user's eyes and subsequently social economic crisis [15].

In June 2020 cases of methanol poisoning associated with ingestion of alcohol-based hand sanitizers were reported in Arizona and New Mexico [16]. Other cases of ethanol toxicity as a result of consumption of alcohol-based sanitizers by persons with alcohol use disorder have also been reported in countries like China, India and Russia [17, 18, 19]. The concern of alcohols and denaturants levels in alcohol-based hand sanitizers used in Kiambu County; Kenya has been addressed in this study by analyzing twelve commercial alcohol-based hand sanitizers all in triplicates.

II. MATERIALS AND METHODOLOGY

MATERIALS

The ethanol, isopropyl alcohol, methanol and denatonium benzoate concentration (% v/v) of 12 different ABHRS were evaluated. All products were purchased from local shops and supermarkets within Kiambu County, Kenya and each hand sanitizer given a unique sample identifier code ranging from HS1-HS12. Stock solutions of ethanol, methanol, isopropanol and denatonium benzoate all of analytical grade were used to prepare calibration and validation standards. Calibration standards from 0%-90% (v/v) of ethanol AR grade>99.0%; CAS NO 64-17-5, methanol AR grade >99.5%; CAS NO 67-56-1, isopropyl alcohol AR grade,> 99.5%; CAS NO 67-63-0 and denatonium benzoate AR grade,>99.5%; CAS 3734=33-6 were prepared, by volume.

METHODOLOGY

The Beer-Lambert law was used to generate calibration curves for isopropyl alcohol, ethanol, methanol and denatonium benzoate. The standard curves were derived from the area of the peaks. The results obtained of concentration of isopropyl alcohol, ethanol, methanol and denatonium benzoate present in each sample were tabulated and comparison of each made with respect to the composition of samples as indicated by the manufacturer (label claim).

INSTRUMENTATION

Samples and calibration standards were run using Fourier Transform Infra-Red (FTIR) spectrometer with attenuated total reflectance (ATR) accessory. The FTIR spectrometer Shimadzu-IR spirit with single ATR sampling technique, resolution: 2 cm ⁻¹, IR range: MID 4000 cm ⁻¹ - 400 cm ⁻¹, measurement mode: % transmittance, number of scans: 20, light source: IR with Happ-Genzel apodization employed was employed for the acquisition of spectra data. All spectra acquisitions were performed in triplicate using the parameters shown in table 1.

Table 1: Parameters used for the measurements of hand sanitizers samples and standards

Parameter	Value
Range	4000-400 cm ⁻¹
Resolution	4 cm ⁻¹
Number of scans	4
Correlation	R
Order	1 st

III. RESULTS AND DISCUSSION

LABEL CLAIM OF ALCOHOL-BASED HAND SANITIZERS AS INDICATED ON THE LABELS

Details of composition of each hand sanitizers as per label claims were recorded as shown in table 2

Table 2: Composition of hand sanitizers samples as per the label claim

ENTRY	LABEL CLAIM	ETHANOL	IPA
HS1	denatured alcohol, aqua, IPA, glycerine, propylene, glycol, tea-tree oil	70%	20%
HS2	isopropyl alcohol, aqua, glycerine, triethanolamine, carbomer, parfum	0%	70%
HS3	Ethyl alcohol denat, aqua, glycerine, carbomer, triethanolamine, parfum, benzyl alcohol, butylphenyl, Methyl propional, coumarin, geraniol, limonene, linalool	67%	0%
HS4	Water, ethanol. isopropyl alcohol, glycerin, isopropyl Myristate carbonate	70%	20%
HS5	Alcohol denat, aqua, alkyl acrylate, cross polymer, hydroxydichlorodiphenyl ether, triethanolamine propylene, glycol, parfum	70%	0%
HS6	Ethyl alcohol, isopropyl alcohol, glycerine, carbomer, aqua, tea-tree oil	65%	20%
HS7	Isopropyl alcohol, ethyl	70%	10%

	alcohol, aqua, carbomer, triethanolamine		
HS8	Dent alcohol, water, glycerine, solubilizer, perfume, copolymer	70%	0%
HS9	Deionized water, tea Carbopol, ethanol. perfume, glycerine	70%	0%
HS10	Aqua, alcohol, acrylpolys, triethanolamine, neem extract, beads, perfume	68%	0%
HS11	Ethyl alcohol, glycerol, pH 6.4 to 6.9	80%	0%
HS12	Denatured alcohol, glycerol, carbomer	70%	0%

The results in table 2 showed that HS1, HS4, HS5, HS7, HS8, HS9 and HS12 were indicated to contain 70 % ethanol on the label, while samples HS3, HS6, HS10 and HS11 were indicated to contain 67%, 65%,68% and 80% respectively which were within KEBS [11] thresholds but only one had met the WHO [20] threshold. On the other hand, the label claim indicated isopropyl alcohol percentage of the samples as follows, HS2 had the highest of 70%, samples HS1, HS4, and HS6 had 20% each and HS7 had 10%. The HS3, HS5, HS8, HS9, HS10, HS11 had 0% isopropyl alcohol (IPA). Seven manufacturers did not indicate if the alcohols used were denatured or not, however four used isopropyl alcohol which is also a denaturing agent, hence leaving three (25%) without denaturing agents.

ISOPROPYL ALCOHOL IN THE SAMPLES

The isopropyl alcohol in each sample was obtained from C-O stretch of wave number of $1118-1143 \text{ cm}^{-1}$ while quantification was done at 1131cm^{-1} and with linearity of R^2 =0.998 from calibration and the results presented in table 3.

Table 3: ABHRS isopropanol concentration levels in percentage using FT-IR analysis

SAMPLE CODE	HS1	HS2	HS3	HS4	HS 5	HS6	HS7	HS8	HS9	HS10	HS11	HS12
IPA Conc.	ND	ND	ND	72.6857 ±0.4241	ND	ND	53.6053 ±2.4939	ND	ND	ND	ND	ND
(x ±SD, n=3)												

From table 3 only two samples HS4 and HS7 contained IPA mean percentage of 72.6857±0.4241 and 53.6053±2.4939 respectively while all the others had undetectable IPA levels. This translated to 16.67% IPA positive and 83.33% negative. Studies on quantification of ethanol and isopropyl alcohol in hand sanitizers using a Perkin Elmer FT-IR spectrometer with ATR accessory gave IPA percentage concentration of 41% and 72% for two models of hand sanitizers analysed agreed with known concentration of the two samples which had 43% and 73% respectively [21].

COMPARISON OF LEVEL OF ISOPROPYL ALCOHOL IN EACH SAMPLE OBTAINED USING FTIR AND THE LABEL CLAIM

From the label claims, five samples had IPA. The label claims were compared with the experimental results and tabulated in table 4.

Table 4: Comparison of percentage of isopropyl alcohol obtained by FTIR and the one indicated on label claim

SAMPLE CODE	%IPA LABEL	EXPERIMENTAL				
Sample HS1	20 %	ND				
sample HS2	70 %	ND				
sample HS4	20 %	72.6857±0.4241%				
Sample HS6	20 %	ND				
sample HS7	10 %	53.6053±2.4939%				

From table 4, according to the label claim samples HS1, HS2 and HS6 contained 20%, 70% and 20% isopropyl alcohol respectively. However, upon analysis by FTIR the IPA levels were undetectable. On the other hand, samples HS4 and HS7 which had 20% and 10% respectively from the label claim recorded 72.6857±0.4241 % and 53.6053±2.4939 % respectively from ATR-FTIR results. Using t-test the mean of the label claim is significantly different from the experimental mean percentage of isopropyl in the sample.

ETHANOL IN THE SAMPLES

The concentration of ethanol in each sample was obtained from C-O stretch where quantification was done at 1011cm⁻¹and wave number of 1005-1067 cm⁻¹ with linearity of R²=0.998 during calibration was presented in table 5.

Table 5: ABHRS ethanol concentration levels in percentage using FT-IR analysis

					an	arysis						
Samp le Code	HS 1	HS 2	H S3	H S4	HS 5	H S6	H S7	H S8	H S9	H S1 0	HS 11	H S1 2
EtOH	73.	75.	73	4.	71.	81	6.	67	79	80	80.	72
(x ±S	87±	86±	.4	60	41±	.2	15	.9	.5	.9	50±	.8
D,	1.1	1.1	6±	7±	0.0	4±	8±	0±	0±	2±	0.6	4±
n=3)	28	79	1.	0.	63	0.	0.	0.	0.	0.	15	0.
			11	0		3	14	09	84	19		30

The results in table 5 showed that all samples contained various amounts of ethanol with sample HS1, HS2, HS3, HS5, HS6, HS9, HS10, HS11 and HS12 having 70% and above ethanol. Sample HS4, HS7and HS8 had less than 70% ethanol while HS4 and HS7 had the lowest percentage of 4.607±0.0% and 6.158±0.14% respectively, which also were found to have IPA mean percentage of 72.6857±0.424 and 53.6053±2.494 respectively. A similar study carried out in Brazil revealed that only seven out of thirty-four samples contained 70% and above ethanol [2]. Another study in Khon Kaen -Thailand found that among 10 alcohols-based hand sanitizers used in community hospital and institution that were analyzed only one had not met effective ethanol concentration of $\geq 70\%$ [22]. This is in line with a recent study carried out in Nairobi metropolitan areas in Kenya which showed out of 62 samples analyzed 24 contained ethanol as the only alcohol while 32 contained mixture of both ethanol and IPA giving total of 56 ABHS that contained ethanol and only seven ABHRS among 56 that complied with KEBS standard of \geq 60% ethanol content [4].

COMPARISON OF LEVEL OF ETHANOL WITH LABEL CLAIM

The levels of ethanol in each sample were compared to the indicated composition by the manufacturer and tabulated in table 6

Table 6: Comparison of percentages of ethanol obtained by FT-IR and that indicated in the labels claim

Sample Code	% Levels of	% Levels of ethanol obtained
	ethanol on label claim	by FTIR ($\bar{x} \pm SD$, n =3)
Sample HS1	70 %	73.87±1.12
Sample HS2	0 %	75.86±1.17
Sample HS3	67 %	73.46±1.11
Sample HS4	70 %	4.607±0.0
Sample HS5	70 %	71.41±0.06
Sample HS6	65 %	81.23±0.3
Sample HS7	70 %	6.158±0.11
Sample HS8	70 %	67.90±0.09
Sample HS9	70 %	79.50±0.84
SampleHS10	68 %	80.92±0.19
Sample HS11	80%	80.39±0.15
Sample HS12	70 %	72.84±0.31

From table 6 the label claim indicated all samples contained ethanol except sample HS2. Upon analysis sample HS2 showed significant high level of ethanol of 75 % and not 0% as indicated on the label, sample HS4 and HS7 showed low concentration than indicated on the label. Other samples HS1, HS3, HS5, HS6, HS8, HS9, HS10, HS11 and HS12 showed almost the same concentration percentage as indicated on the label claim.

ANALYSIS OF PRESENCE OF DENATONIUM BENZOATE IN THE SAMPLES USING FTIR

To obtain concentration of denatonium benzoate in the samples the FTIR peak area of $1420-1440~\text{cm}^{-1}$, and linearity of $R^2=0.982$ was used during calibration and the results presented in table 7

Table 7: ABHRS Betrix (Denatonium Benzoate) concentration levels

Sample Code	HSl	HS2	HS3	HS4	HS5	HS6	HS7	HS8	HS9	HS10	HS11	HS12
Betrix conc.	ND	ND	ND	ND	0.049±0.02	ND	ND	0.049±0.02	ND	ND	ND	0.040±0.02
$(\bar{x} \pm SD, n=3)$												

The results shows that 25% the samples analysed contain denatorium benzoate in low concentration ranging from 0.040±0.02% for sample HS12 to 0.049±0.02% in sample HS5 and HS8.

LEVELS OF METHANOL IN THE SAMPLES USING FTIR

The concentration of methanol in each sample was obtained from C-O stretch during calibration with linearity of R²=0.988 where quantification was done between 975-1045.5 cm⁻¹ and data obtained shown in Table 8

Table 8: The ABHRS methanol levels in percentage using FTIR analysis

Sampl	HS	H	HS	H	H	H	H	H	HS	H	HS	H
e Code	1	S	3	S	S5	S	S	S	9	S1	11	S1
		2		4		6	7	8		0		2
MeOH	0.0	N	0.0	N	N	N	N	N	14.	0.3	24.	N
(x ±SD	60±	D	52±	D	D	D	D	D	202	5±	140	D
, n=3)	0.0		0.0						±0.	0.0	±0.	
	01		15						01	05	012	

From the analysis the results shows that 41.7% of the samples contained methanol with percentage concentration ranging from 0.035±0.005 to 24.140±0.012. Methanol was expressed in three decimal points to permit direct comparison with the US-FDA interim limits of 630 ppm (0.063% v/v) [8]. From the results HS9 and HS11 had exceeded methanol threshold limits.

COMPARISON OF DENATURANTS IN SAMPLES WITH WHAT IS INDICATED IN THE LABEL CLAIM

The data of percentage concentration of denatonium benzoate and methanol was tabulated as shown in table 9.

Table 9: Denaturants as indicated in the label claim and the results

Sample Code	HS1	HS2	HS3	HS 4	HS 5	HS 6	HS7	HS8	HS9	HS10	HS11	HS12
LC	DE NT	IPA as DE NT	DEN T	IP A as DE NT	DE NT	IP A as DE NT	IPA as DE NT	DEN T	NI	NI	NI	DEN T
Betrix conc. (x ±SD, n=3)	ND	ND	ND	ND	0.0 49 ±0. 02	ND	ND	0.049 ±0.02	ND	ND	ND	0.04± 0.02
MeOH. conc. (x ±SD, n=3)	0.06 0±0. 001	ND	0.052 ±0.0 15	ND	ND	ND	ND	ND	14.20 2±0.0 1	0.035 ±0.00 5	24.14 0±0.0 12	ND

LC- Label claim, NI- Not indicated, ND- Not detectable, DENT-Denatured, MeOH- Methanol

Denatonium benzoate, isopropyl alcohol and methanol are used as denaturants [7]. According to label claim HS1, HS3, HS5, HS8 and HS12 were indicated to be denatured, from the analysed results HS1 and HS3 were denatured using methanol which was within threshold limit of 630 ppm (0.063% v/v) [8], HS5, HS8 and HS12 were found to be denatured using denatonium benzoate that was within allowed levels of 20 to 50 ppm [17]. Though HS2, HS4, HS6, HS7 were not indicated to be denatured in the label claim they were indicated to contain isopropyl alcohol which is a denaturing reagent [4], however only HS4 and HS7 were found to contain isopropyl alcohol during analysis hence HS2 and HS6 were not denatured since didn't contain either denatonium benzoate, methanol or isopropyl alcohol. HS9, HS10 and HS11 though were not indicated to be denatured upon analysis it was found to contain methanol which is a denaturing reagent however HS9 and HS11 were found to exceed the threshold level for methanol of 630 ppm (0.063% v/v) [8].

IV. CONCLUSION AND RECOMMENDATIONS

Use of hand sanitizers is one of the alternative methods for controlling the spread of Covid-19. The result obtained from this study indicate that alcohol-based hand sanitizers used in Kiambu County, Kenya contain significant amount of either ethanol or isopropyl alcohol and low

concentration of denaturants that are within recommended levels by WHO and KEBS. However, levels found in the study were not in agreement with levels indicated on the labels. The percentage of ethanol ranged from 4.607±0.0 to 81.23±0.3. Nine samples showed concentrations above 70% ethanol. Isopropyl alcohol was found in only two samples contrary to the label claims in five samples. The analysis showed that all samples contained either isopropyl alcohol, methanol or denatorium benzoate as denaturants with levels ranging from 0.040±0.02% to 72.6857±0.4241%. 98% of samples analysed showed allowed levels of denaturants except two samples which had significantly higher levels than the indicated ones. This calls for stringent measures to be implemented and observed by relevant authorities to avoid possible health risks to the users in case of accidental ingestion, inhalation or spilling on skin.

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AUTHORS PROFILE

Martha W. Gacuiga pursued Bachelor of Education Sciences (Chemistry /Maths) Kenyatta 2008. She University currently pursuing Masters of Science (Chemistry) in Kenyatta University and working as a Trainer in The Nyeri National Polytechnic, Nyeri County



Kenya. Her main research work focuses on Organic chemistry and Analytical chemistry.