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Quality Evaluation of Commercial Alcohol-Based Hand Sanitizers in Nairobi, Kenya: A Post COVID-19 Pandemic Survey

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The global public health impact of COVID-19 necessitated multifaceted approaches such as use of alcohol-based hand sanitizers (ABHS) to control transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This study evaluated compliance with Kenya Bureau of Standards (KEBS) specification of commercially available alcohol-based hand sanitizers purchased from selected retail outlets in the Nairobi metropolitan area. Out of the 122 samples analyzed, 63% met KEBS specifications based on visual inspection, while gas chromatography-mass spectrometry (GC-MS) identified methanol as a contaminant in 26% of samples. Quantification of the permitted alcohols, ethanol and isopropanol, using gas chromatography with flame ionization detector (GC-FID) revealed that 44.3% had an alcohol content within the specified range of 60 - 95% v/v, with 5.7% containing neither alcohol. Furthermore, only 10% of samples from local manufacturers met KEBS specifications. These results highlight the need for strict monitoring and regulation of alcohol-based hand sanitizers, particularly in the context of the COVID-19 pandemic. Moreover, the presence of methanol and variations in alcohol content underscore the importance of implementing comprehensive quality control measures to ensure the effectiveness and safety of these highly important public health tools.

Keywords: COVID-19; hand sanitizers; quality assessment, KEBS specification, methanol contamination

INTRODUCTION

The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which led to the global COVID-19 pandemic in the year 2020, highlighted the critical importance of hand hygiene measures such as use of alcohol-based hand sanitizer (ABHS) in preventing the spread of infections.[1] ABHS owe their biocidal effect to the protein denaturing effect of the constituent alcohols, which impairs the integrity of the cell membrane causing cell death.[2] SARS-CoV-2 is an enveloped virus of which, alcohols destroy the lipid bilayer, with fatal consequences.[3] The active ingredients of ABHS are ethanol, isopropyl alcohol and n-propanol, either alone or in combination together with hydrogen peroxide and excipients such as colors, flavors, gelling agents, and humectants.[4,5] The recommended alcohols are 80% v/v isopropyl alcohol or 75% v/v ethanol with 0.125% v/v hydrogen peroxide and 1.45% v/v glycerin in aqueous solution.[6] The World Health Organization (WHO) recommended formula for ABHS specifies an alcohol concentration of at least 60% v/v for effectiveness.[4] In 2021, the Unites States Food and Drug Administration (US-FDA) issued updated guidelines for ABHS manufacturing, stating that the use of engineered fuel/ethanol for ABHS manufacturing is prohibited. In the revised guidance, methanol limit was reduced from the hitherto interim specification of 630 ppm (during the peak of the COVID-19 pandemic) to 200 ppm.[7]

Increased usage of hand hygiene as means of curbing COVID-19 transmission, boosted production, marketing and availability ABHS across various outlets. [8-11] The quality of ABHS

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is not only an important aspect of their safety, but also affects efficacy and acceptability by the users.[5] Therefore, ensuring the quality and adherence to set standards of these antiseptics is of paramount importance in their efficacy. In Kenya, the term 'post-COVID period' describes the period of time that followed the major COVID-19 pandemic waves, particularly after authorities relaxed public health restrictions and vaccines became widely accessible. This period started around the middle to end of 2021, when the government relaxed COVID-19 related restrictions and intensified vaccination efforts. Previous studies on the quality of ABHS in the Kenyan market during the pandemic demonstrated quality problems and regulatory flout with these products.[10,11] The objective of the present study was to conduct a post COVID-19 assessment of commercially available ABHS products in the Nairobi metropolitan area using the Kenya Bureau of Standards (KEBS) specifications for packaging, labeling, pH and alcohol content in accordance to KS EAS 789:2013.[12]

MATERIALS AND METHODS

Sampling

ABHS samples were collected between December 15, 2021 and January 15, 2022 using convenient sampling method. A reconnaissance visit was conducted to project the number of brands available in the sampling frame prior to the actual survey. Purchases were made in the smallest pack size available in supermarkets, shops, pharmacies and cosmetics stores in the Nairobi metropolitan area (Figure 1). For this purpose, sampling was conducted in Nairobi central business district (NCBD), Nairobi city suburbs, Kikuyu, Limuru, Kiambu, Githunguri, Ruiru, Thika, Murang'a, Gatanga, Kandara, Kitengela, Ngong, Kiserian, Ongata Rongai, Kajiado and Machakos. A total of 122 brands were obtained, with one brand selected per site, with the exception of two cases where a sample of the same brand from a different location was selected due to similar names but different product consistency and labeling. For blinding purposes, the ABHS identity was coded numerically (S-1 to S-122).

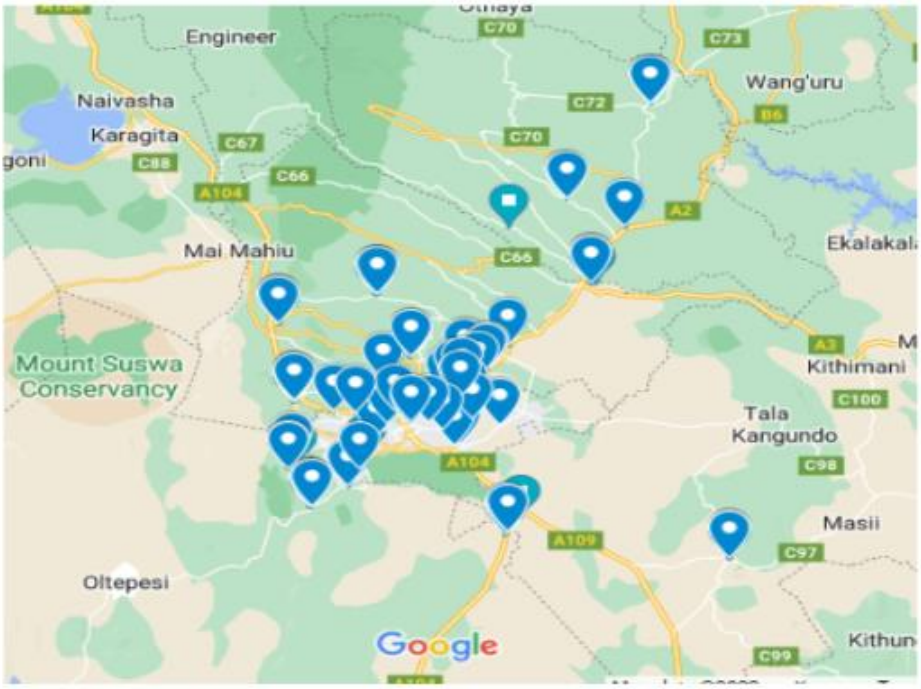

Figure 1: Satellite map of Nairobi Metropolitan showing sampling sites. *Google Maps*, 2021

REAGENTS

Reagents were purchased from local suppliers operating in Nairobi city. The internal standard used in the assay experiments was HPLC grade acetonitrile from Carlo Erba reagents S.A.S (Dasit Group Limited, Val-de-Reuil, France). Analytical grade isopropyl alcohol (99.5% v/v), methanol (99.8% v/v) and glycerine (99.5% v/v) from Finar Limited (Ahmedabad, India), absolute ethanol (99.9% v/v) from Scharlab S.L (Sentmenat, Spain) were used as the standards for gas chromatography (GC) analysis. Freshly distilled water was prepared in the laboratory. Test solutions were filtered through polytetrafluoroethylene (PTFE), 0.22 µm micro filters (Nantong Filter-Bio Membrane Co., Jiangsu, China) prior to analysis.

Instrumentation

A Shimadzu GC-2010 plus gas chromatograph (Shimadzu Corporation, Kyoto, Japan) operated using GC solution software version 2.42 (Shimadzu Corporation, Kyoto, Japan), and equipped with alternate mass spectrometry and flame ionization detectors was employed in the identification, characterization and quantification of analytes as appropriate. Chromatographic separation was achieved using a ZB wax plus column (Phenomenex, Torrance, CA, USA). The chromatographic conditions were based on a published validated method[13], with modifications on temperature program to facilitate analysis of glycerin (Table 1).

Volatile Composition

Gas chromatography with mass spectrometric detection (GC-MS) was used for identification and characterization of the volatiles in the ABHS samples. Post-separation, volatile components were identified by comparing their fragmentation patterns to the offline National Institute of Standards and Technology (NIST) mass spectral database. Utilizing electron impact for ionization at 70 eV, the GC-MS system maintained an ion source temperature of 200°C. Fragment ion analysis occurred in full scan mode within 20-300 m/z range, with a filament delay time set at 0 min.

Table 1: Gas Chromatographic conditions for ABHS analysis

Gas chromatography (GC) Parameters	
Split inlet	250 °C, split ratio 20:1
Injection volume	0.2 µl
Carrier gas	Helium
Column flow rate	1.36 ml/min, constant flow mode
Oven	45 ºC (7 min), 240 ºC at 30 ºC/min for 6 min and 240 ºC at 35 ºC/min for 7 min
Column	ZB-WAX plus, 60 m × 0.25 mm ID, 0.25 µm film thickness
Run time	26.5 min

ID = Internal Diameter

Quantification

To determine the alcohol content of the ABHS samples, a validated and published method for determining ethanol content in illicit drinks [14] was employed. The alcohol content was calculated using an external standard whereby the peak area ratios of individual components to the internal standard against standards were compared.

Appearance, packaging, and labelling

Visual inspection of ABHS focused on product characteristics, including appearance, consistency (gel or liquid), net contents, ingredients, batch number, manufacturing and expiry dates, usage instructions, and cautionary warnings. While the KEBS specification mentions the absence of disagreeable odor or smell, this test was not performed due to its subjectivity. Product features were recorded in a Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) sheet for statistical analysis. KEBS brand verification involved sending a text in the format, standardization mark

(SM)# ***** of the permit number to 20023. The response included details on product name, brand name, manufacturer, SM issuance and expiry dates, and the status of the permit (valid or not valid).[15]

Standard and Sample solutions

A stock solution of the internal standard was prepared by transferring 1.0 ml of HPLC grade acetonitrile in a 10.0 ml volumetric flask and diluting to the mark with distilled water. Thereafter, 500 µl was measured out using a micropipette and added to standard and sample preparations prior to analysis.

The standard stock solution was prepared by measuring out 1.0 ml of each of the standard solvents of methanol, isopropyl alcohol, ethanol and glycerin into a 10.0 ml volumetric flask and topping up with distilled water. The final standard solution was prepared by measuring out 300 µl of the standard stock solution, 500 µl of the internal standard and 200 µl of distilled water.

Sample solutions were prepared by diluting 1.0 ml of the neat sample to 10.0 ml with distilled water. An aliquot equivalent to 300 µl was micropippeted, mixed with 500 µl of internal standard solution and diluted to 1.0 ml with distilled water prior to injection.

RESULTS AND DISCUSSION

Out of the 122 ABHS samples evaluated, 15 (12.3%) were characterized as solutions based on consistency, with their closure mechanisms supporting proper fluid delivery. Thus, gels were more abundant during the sampling period, accounting for 105 (86.1%) of the samples purchased. The widespread preference for gels over liquids is attributed to the reduced risk of spillage and improved feeling of moisture [16]. Dyes were incorporated in 7% of samples, probably due to enhanced product appeal to consumers.[17] For such colored products, caution is however advised and further safety information required due to potential allergenicity.[18]

In two cases, the opacity of the container prevented immediate determination of product consistency by visual inspection. Regarding color and consistency, eight samples (6.6%) showed coloration (light blue or light pink), while four (3.3%) were cloudy and contained visible particulate matter. Approximately 77 (63%) samples complied with all packaging and labeling requirements, including ABHS product name, manufacturer address, net contents, alcohol and other ingredients, instructions for use, date of manufacture, expiry date, batch number and warnings. This compliance is consistent with an Ethiopian study in which 59.5% samples met these requirements.[19] Two sets of samples from different sampling sites had the same brand names but varied in manufacturer information. These findings were consistent to another study in the COVID-19 peri-pandemic period.[10]

The antimicrobial efficacy of various forms of alcohol, including ethanol, isopropanol and *n*-propanol, varies because of variations in their molecular structures.[1] Previous research indicates that ethanol might have a marginally higher efficacy against specific viruses, whilst isopropyl propanol offers benefits such as quicker evaporation and possibly reduced skin irritation[1]. Therefore, disclosure of the kind and amount of alcohol in ABHS promotes consumer decision-making and guarantees adherence to safety and efficacy requirements. In this study, information about the alcohol present was missing in 8 (6.6%) samples while the SM number was missing in 17 (13.9%) samples and illegible in 14 (11.5%) samples. KEBS verification procedures revealed that 23 samples which bore SM approval numbers had an invalid response with two samples yielding no response. Two samples produced responses for unrelated products, thus highlighting the value of this verification method in detecting counterfeit products. Two samples had identical names but different manufacturer information implying possible falsification. In practice, product names should be distinctive and exclusive.[20] The standardization mark (SM) is an important indicator of the registration status of a product. Thus, lack of and/or non-authenticity of the SM implicates substandard or falsified products.

Packaging details showed that 84 samples (69.4%) used recyclable polyethylene terephthalate (PET), while a glass container was

used for one sample. In 37 samples (30.6%), the packaging material, although plastic, was not expressly declared as such. ABHS samples were packaged into various volumes (35 ml, 50 ml, 65 ml, 100 ml, and 120 ml), with 50 ml being the most common (45.2%). Closure mechanisms included 52 (42.6%) disk top caps, 55 (45.1%) flip-top caps, and 12 (9.8%) spray pump closures. With reference to the prevailing forex exchange rate during the sampling period, a 50 ml pack, cost an average of KES 85.40 (0.73 USD) while that of the 100 ml pack was KES 106 (0.91 USD). Compared to a 2020 study[10], the price of a 100 ml pack had decreased significantly during the current study, possibly due to reduced demand or increased supply following the relaxation of COVID-19 preventive measures. According to manufacturer information, 93 (76.2%) samples were local, 15 (12.3%) were imported and 14 (11.5%) did not specify the country of origin.

A product's adherence to KEBS labeling specifications, including details such as ingredient lists and warnings, elicits trust in the user of a product. Informed users can identify potential irritants and act promptly in the event of accidental ingestion or eye contact. Therefore, it is imperative that product labels contain all relevant details as outlined by KEBS.[12]

For 109 (89.3%) of the samples, the pH value was in the 6.0 - 8.0 range in compliance with KEBS specifications. A lower pH range (5.0 - 6.5) was included on some product labels, emphasizing the need for precise pH information. Labels of 41 (33.6%) samples indicated the presence of pH modifiers, with triethanolamine being the most common in 38 (31.1%) samples. The use of pH regulating agents, particularly triethanolamine, is crucial for neutralizing carbomers and other thickeners and maximizing their thickening potential [11].

The KEBS specification permits the use of ethanol, isopropanol, or n-propanol in ABHS formulation.[12] The permitted alcohols, ethanol and isopropyl alcohol, were found in 105 (86.1%) samples. The labels of 28 (23%) samples showed incorporation of denaturants, with the most common being 3.3% v/v isopropyl alcohol. Denaturation is aimed at discouraging use of ABHS as surrogate alcohols.[12]

In 61 samples (50%), the standardization mark was imprinted on the label as well as the compositional information matching the identities of the components found by chromatographic analysis. For the remaining 50%, the label information did not correspond to the results obtained with respect to peak identities. Similar findings on the discrepancies between labelled and analytical compositions have reported in literature.[11] The KS EAS 789:2013 specification sets the alcohol content limit at ≥ 60% v/v [12] while US-FDA defines 60% - 95% v/v range. [20] In 50 samples (41%), the total amount of permitted alcohols fell below the specified limit, with 67% of these samples having an alcohol content < 55% v/v. Such products mislead users by giving a false sense of confidence yet they are like to yield insufficient microbicidal activity. Fifty-seven samples (46.7%) complied with assay limits (≥60% v/v) while three samples (2.5%) exceeded 95% v/v. ABHS products with high alcohol content are less effective since water is required for the biocidal effect of alcohols.[11]

Methanol contamination was detected in 16 (13.1%) samples and was identified alongside permitted alcohols. Figure 2 shows methanol contamination in one of the ABHS samples (S-118). Methanol in ABHS poses risks through intentional or accidental ingestion, as well as through inhalation and transdermal absorption.[21-24] In 10 ABHS samples (8.2%), contrary to the KEBS specifications, methanol was the predominant alcohol, hence substitution for the licit alcohols (Figure 2). Although the KEBS [12] specification does not set limits of methanol in ABHS, exceeding US-FDA limits (200 ppm or 0.02% v/v) raises safety concerns especially in cases of ingestion. With the increasing use of ABHS, cases of methanol toxicity are emerging, associated with serious consequences such as seizures and permanent vision loss, mainly due to intentional ingestion of ABHS in individuals with alcohol dependence.[25-27] Children are also at risk of accidental ingestion.[28]

Seven ABHS samples (5.7%) showed no detectable ethanol nor permitted alcohols, suggesting deliberate marketing of ABHS devoid of active ingredients. This not only means

consumers miss out on health benefits, but also results in an economic loss and is a form of economically-motivated consumer fraud.

Glycerin, propylene glycol and polyethylene glycol have been identified as likely added thickeners that contribute to improved efficacy and consumer perception. Glycerin, a humectant for alcohol-related skin dryness, was present in three samples (2.5%). Its concentration, however, must be carefully considered (0.5% - 0.73% v/v) to avoid interfering with the antimicrobial effect of alcohols. Propylene glycol (PEG), present in 11 samples (9%), acts as a thickener and increases microbicidal effectiveness.

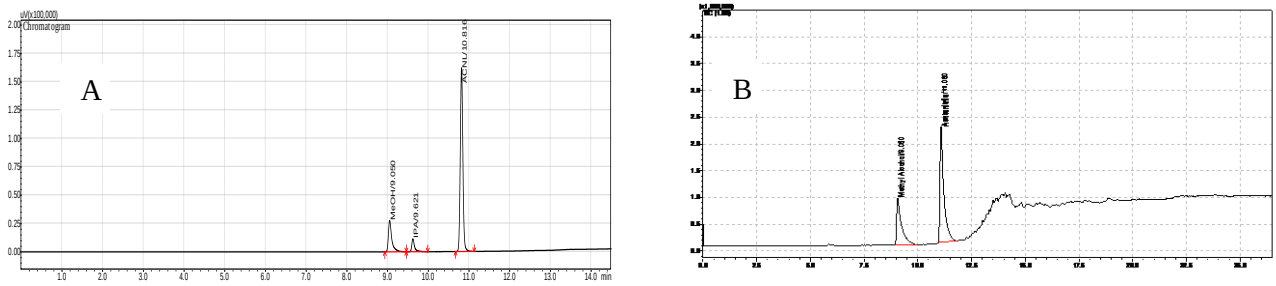

Figure 2: Chromatograms showing; (A) methanol contamination in S-118, (B) methanol substitution in S-36 ,

Polyethylene glycol and its derivatives, observed in 52 samples (42.6%), serve as humectants, surfactants and emulsifiers which counteracts alcohol-related skin dryness. The propylene glycol content, expressed as glycerin, is within the recommended range (2% – 5% v/v).[8]

Through GC-MS analysis, all 122 samples were characterized and identified ethanol, isopropyl alcohol and methanol while *n*-propanol was not detected. Overall, only ten locally manufactured samples (8.2%) met all specifications, suggesting that substandard or counterfeit products are widespread (92%). A detailed summary of the analytical results is shown in Table 2.

CONCLUSION

The present study emphasizes the need for a sensitive and specific analytical technique for monitoring the quality of ABHS, such as gas chromatography, given the limitations of the current KEBS specification, which relies on pycnometry, thus incapable of distinguishing acceptable alcohols (ethanol, n-propanol and isopropanol), from contaminants such as methanol, which may pose a risk to public health. The findings of this study aim to add important information to the ongoing discussion about the role of ABHS in containing the spread of COVID-19 by shedding light on compliance of commercial products with established standards post-pandemic. Recommendations from this study include strengthening post-market surveillance, refining standardization processes, and ensuring strict adherence to current good manufacturing practices, particularly in sourcing of raw materials.

Table 2: Results of pH, alcohols and glycerin content of alcohol based hand sanitizers analyzed

SAMPLE CODE	pH	PERMITTED ALCOHOLS (% v/v)			Methanol (% v/v)	Glycerin (% v/v)
		< 60	60-95	> 95		
S-1	8.0	57.20	-	-	25.06	ND
S-2	7.9	9.73	-	-	69.66	ND
S-3	5.1	-	72.54	-	ND	ND
S-4	8.0	-	67.38	-	ND	ND
S-5	5.9	-	69.43	-	ND	ND
S-6	8.0	-	59.80	-	ND	ND
S-7	7.9	-	63.17	-	ND	ND
S-8	4.7	-	-	108.17	ND	ND
S-9	5.4	-	68.34	-	ND	ND
S-10	8.2	-	91.13	-	ND	ND
S-11	8.3	-		97.46	ND	ND
S-12	6.9	-	86.39	-	ND	ND
S-13	5.5	54.93	-	-	ND	ND
S-14	6.7	55.87	-	-	ND	ND
S-15	6.6	59.04	-	-	ND	ND
S-16	8.3	12.81	-	-	ND	ND
S-17	5.3	18.50	-	-	ND	ND
S-18	7.3	-	88.14	-	ND	ND
S-19	5.7	54.61	-	-	ND	ND
S-20	8.8	20.14	-	-	62.54	ND
S-21	6.8	-	79.86	-	ND	ND
S-22	4.6	-	71.21	-	ND	ND
S-23	7.9	ND	ND	ND	74.65	ND
S-24	7.2	54.05	-	-	ND	ND
S-25	8.2	-	66.10	-	ND	ND
S-26	8.1	-	61.17	-	ND	ND
S-27	6.3	-	60.41	-	ND	ND
S-28	6.9	34.48	-	-	ND	ND
S-29	5.3	-	71.51	-	ND	ND
S-30	6.3	-	68.41	-	ND	ND
S-31	7.9	-	-	-	ND	ND
S-32	7.2	ND	ND	ND	17.52	ND
S-33	8.1	12.29	-	-	71.69	ND
S-34	8.3	-	74.25	-	ND	ND
S-35	7.0	6.39	-	-	ND	0.16

SAMPLE CODE	pH	PERMITTED ALCOHOLS (% v/v)			Methanol (% v/v)	Glycerin (% v/v)
		< 60	60-95	> 95		
S-36	7.7	ND	ND	ND	88.62	ND
S-37	7.2	-	86.49	-	ND	ND
S-38	5.3	49.65	-	-	38.17	ND
S-39	5.4	ND	ND	ND	ND	ND
S-40	5.9	ND	ND	ND	ND	0.60
S-41	5.4	-	75.09	-	ND	ND
S-42	7.9	ND	ND	ND	ND	ND
S-43	7.6	47.40	-	-	19.15	ND
S-44	5.7	2.95	-	-	28.58	ND
S-45	6.1	ND	ND	ND	19.84	ND
S-46	7.6	-	69.63	-	ND	ND
S-47	6.6	40.88	-	-	ND	ND
S-48	5.9	ND	ND	ND	12.74	ND
S-49	7.8	-	79.26	-	ND	ND
S-50	6.0	-	-	95.78		ND
S-51	4.0	-	83.14	-	ND	ND
S-52	8.3	33.27	-	-	ND	0.30
S-53	8.1	55.41	-	-	ND	ND
S-54	6.3	ND	ND	ND	63.88	ND
S-55	6.2		66.89	-	ND	ND
S-56	5.7	53.54	-	-	ND	ND
S-57	5.6	ND	ND	ND	72.48	ND
S-58	8.9	59.35	-	-	ND	ND
S-59	7.8	-	72.28	-	ND	ND
S-60	6.5	-	79.74	-	ND	ND
S-61	6.9	55.70	-	-	ND	ND
S-62	5.9	-	63.85	-	ND	ND
S-63	7.4	ND	ND	ND	78.80	ND
S-64	5.4	16.76	-	-	25.97	ND
S-65	7.0	42.67	-	-	ND	ND
S-66	6.1	-	60.61	-	ND	ND
S-67	8.7	-	76.31	-	ND	ND
S-68	6.1	-	78.34	-	ND	ND
S-69	5.6	-	92.55	-	46.80	ND
S-70	5.3	-	64.14	-	ND	ND
S-71	6.8	ND	ND	ND	ND	ND

SAMPLE CODE	pH	PERMITTED ALCOHOLS (% v/v)			Methanol (% v/v)	Glycerin (% v/v)
		< 60	60-95	> 95		
S-72	7.4	-	70.81	-	ND	ND
S-73	6.1	51.93	-	-	ND	ND
S-74	5.7	58.82	-	-	ND	ND
S-75	5.6	-	60.06	-	ND	ND
S-76	6.3	51.05	-	-	ND	ND
S-77	5.7	56.68	-	-	ND	ND
S-78	6.5		62.56	-	ND	ND
S-79	7.9	48.61		-	34.50	ND
S-80	6.8	-	83.33	-	ND	ND
S-81	6.0	-	94.17	-	ND	ND
S-82	7.8	-	74.48	-	ND	ND
S-83	6.5	42.61		-	ND	ND
S-84	7.1	-	75.60	-	ND	ND
S-85	5.8		67.61	-	18.34	ND
S-86	7.0	54.88		-	ND	ND
S-87	7.6	-	70.25	-	ND	ND
S-88	7.1	-	93.70	-	ND	ND
S-89	7.1	-	72.61	-	ND	ND
S-90	6.2	-	77.19	-	ND	ND
S-91	6.7	53.95	-	-	ND	ND
S-92	5.5	53.55	-	-	ND	ND
S-93	7.0		67.54	-	ND	ND
S-94	7.5	59.38	-	-	ND	ND
S-95	6.8	55.59	-	-	ND	ND
S-96	6.9	21.54	-	-	ND	ND
S-97	6.6	10.43	-	-	10.30	ND
S-98	7.7	-	68.60	-	ND	ND
S-99	6.9	50.69		-	8.032	ND
S-100	7.0	-	66.83	-	ND	ND
S-101	7.2	-	64.03	-	ND	ND
S-102	7.4	47.04	-	-	ND	ND
S-103	5.5		-	-	67.36	ND
S-104	7.6	23.76	-	-	49.60	ND
S-105	6.5	51.43	-	-	ND	ND
S-106	7.0	56.28	-	-	ND	ND
S-107	5.7		60.29	-	ND	ND

SAMPLE CODE	pH	PERMITTED ALCOHOLS (% v/v)			Methanol (% v/v)	Glycerin (% v/v)
		< 60	60-95	> 95		
S-108	7.3		60.39	-	ND	ND
S-109	7.0	34.07	-	-	ND	ND
S-110	5.7	-	62.52	-	ND	ND
S-111	6.5	-	59.88		ND	ND
S-112	6.0	38.88	-	-	34.93	ND
S-113	7.4	-	89.60	-	ND	ND
S-114	7.1	58.13	-	-	ND	ND
S-115	6.0	53.46	-	-	19.64	ND
S-116	7.3	58.83	-	-	ND	ND
S-117	6.8	12.30	-	-	53.35	ND
S-118	7.3	30.48	-	-	ND	ND
S-119	5.5	-	66.74		ND	ND
S-120	6.8	31.64	-	-	ND	ND
S-121	5.7	-	63.59	-	ND	ND
S-122	6.9	20.1	ND	ND	ND	ND

ND – Not detected, - Not applicable

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