

DO THE VARIOUS HAND SANITIZERS USED IN JOHANNESBURG DURING THE COVID-19 PANDEMIC CONTAIN THE RECOMMENDED CONCENTRATION AND QUALITY OF ALCOHOL?

By

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Outline

- Background
- Research problem
- Study aim and objectives
- Methodology
- Results & Discussion
- Study Limitations
- Conclusion
- Recommendations
- Acknowledgements
- References

Background

- Washing with warm water and soap remains the gold standard for hand hygiene
- Outbreak of SARS-CoV-2, Covid-19
- WHO recommended that sanitizer can prevent transmission of coronavirus.
- Disaster Management Act, 2002 and the COVID-19 Direction on Health & Safety in the Workplace issued by DoEL
- Businesses must provide hand sanitizer, free-of-charge, for use by the public and employees at the entrance to their premises.
- Employer must ensure that all work surfaces and equipment are disinfected regularly
- Use of hand sanitizers has increased worldwide and in South Africa
- Boom in the sale of hand sanitizers

How to wash your hands properly



Background (cont'd..) What Constitutes a Proper Hand Sanitizer?

World Health Organization Patient Safety SAVE LIVES A World Allinge for Safer Health Care Clean Your Hands

Guide to Local Production: WHO-recommended Handrub Formulations

Materials required (small volume production)

REAGENTS FOR FORMULATION 1:	REAGENTS FOR FORMULATION 2:	
Ethanol 96%	 Isopropyl alcohol 99.8% 	
Hydrogen peroxide 3%	Hydrogen peroxide 3%	
Glycerol 98%	Glycerol 98%	
 Sterile distilled or boiled cold water 	 Sterile distilled or boiled cold water 	

At least 60% ethanol and 70% isopropanol, are the active ingredients in CDC-recommended alcohol-based hand sanitizers for SARS-CoV-2 and similar viruses.

Hand sanitizers without 60-95% alcohol

- 1) may not work equally well for many types of pathogens
- Sub-lethal effect = merely slows down growth of pathogens rather than kill them outright.
- 3) Unlike alcohol, certain biocidal agents may cause microbial drug resistance

4

Fake Hand Sanitizer = Hand sanitizer "for coronaviruses" without 60-95% alcohol

(Alcohol should be either ethanol or 2-propanol)



CH, -CH

OH

Isopropyl alcohol

(2-propanol)

Background (cont'd..)

Impurities and Additives in Hand Sanitizers

- U.S. FDA; Some impurities allowed in hand sanitizer to combat hand sanitizer shortages during the COVID-19 crisis
- However, inclusion of harmful levels of impurities not allowed!

Table1: Fuel or technical grade ethanol that does not meet USP or Food Chemical Codex (FCC) requirements.

Impurity	Interim Limit
Methanol	630 ppm
Benzene	2 ppm
Acetaldehyde	50 ppm*
Acetal (1,1-diethoxyethane)	50 ppm
Sum of all other impurities	300 ppm

* Acetaldehyde appears to be genotoxic, and potentially carcinogenic, when in direct contact with tissues.

Table 2: Fuel or technical grade ethanol that does not meet the interim limits in Table 1 because the sum of all other impurities exceeds the interim limit of 300 ppm, all individual impurities are identified and meet the interim limits in Table 2 below.

5

Impurity	Interim Limit
Acetone	4400 ppm
n-propanol (1-propanol)	1000 ppm
Ethyl acetate	2200 ppm*
Sec-butanol (2-butanol)	6200 ppm
n-butanol (1-butanol)	1000 ppm
iso-amyl alcohol (3-Methyl-1- butanol)	4100 ppm
Amyl alcohol	4100 ppm
Iso-butanol (2-Methyl-1- propanol)	217000 ppm

Research Problem

SABS warn against uncertified sanitisers

"Uncertified products could be dangerous for a number of reasons," said SABS.

- April 21, 2020

Sinesipho Schrieber 📕 1 minute read







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How counterfeiters are using the Covid-19 pandemic to their benefit



CONSUMER LIVE

INVESTIGATION | Your hand sanitiser might not be keeping you as safe as you think



Wendy Knowler Consumer journalist

08 July 2020 - 06:00

crime 17.7.2020 10:22 pm

'Fake' sanitisers supplied to Eastern Cape school where 204 tested positive

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News24 Wire

6



COVID-19 Arts + Culture Business + Economy Education Environment + Energy Health + Medicine Politics

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South Africans aren't being protected from fake sanitisers: what needs to be done

October 20, 2020 4.52pm SAST



Study Aim and Objectives

Aim

The study is part of NIOH contribution in the fight against the Covid-19 pandemic.

• Aims to create public awareness on the presence of **"fake sanitizers"** against SARS-CoV-2 and other coronaviruses.

Objectives

- Collect at least 90 hand sanitizer samples used in the Johannesburg area for alcohol content analysis.
- Identify sanitizers that do not contain the recommended alcohol content of at least 60% ethanol or 70% isopropanol.
- Identify sanitizers that may contain unapproved impurities and/or additives.

Methodology

- Collection of hand sanitizers from various formal and informal traders around Johannesburg
- 2. Sanitizer sample analysis using an Agilent 6890N GC equipped with a flame ionization detector (HS-GC-FID)
- 3. Supelcowax Column (L=30m, ID=0,25mm and film thickness=0.5µl)
- 4. Data acquisition & processing = Chemstation[™] software
- 5. Statistical analysis = MS Excel using percentages & averages



Gel sanitizer





Analytical Method Validation

- Analytical method validation was conducted as recommended by ISO 17025 by the evaluation of the parameters of
 - selectivity,
 - linearity,
 - accuracy/precision,
 - limit of quantification (LOQ),
 - *limit of detection (LOD)*, as well as the
 - robustness of the method.
- Reference method of United States Pharmacopeia (USP); methodology 611 to quantify alcohol content (Ethanol & Isopropyl alcohol) by gas chromatography - flame ionization detection (GC-FID)

Methodology (cont'd..)

Analytical Method Validation



A good coefficient correlation (r^2) is deemed to be of more than 0.99 for the calibration curves of the alcohols.



Results and Discussion

- > 94 hand sanitizer samples of 89 different brands were collected.
- Observations
 - Some of these sanitizers are supplied in bulk to many workplaces, such as retailers, banks, health facilities and government offices.
 - Major retailers were observed to be mostly using their own store brand sanitizer for their workers and the public.
 - There is overlap between sanitizer brands used by businesses/workplaces and the public.
 - Some sanitizers do not have labels while others claim higher than detected % alcohol

Results & Discussion (cont'd..)

Results and Discussion

- Four (4) preparations were found to contain no alcohol at all.
- Ninety (90) sanitizers contain either ethanol or 2-propanol or a combination of these two.
- Four (4 of 90) preparations contain 1-propanol as the only alcohol component, which is not approved for hand sanitization.
- About 40% (36 of 94) of the sanitizers contain less than the recommended minimum of 60% ethanol (27) or 70% isopropanol (9).
- Generally, majority of gels contain more than 60% ethanol.
- Toxic impurities were detected in some sanitizers denaturants (ethyl acetate) and other non-recommended alcohols (methanol, 1-propanol, isobutanol and 3methyl-butanol)

Results & Discussion (cont'd..)

Alcohol Concentration in Liquid Hand Sanitizers



Alcohol Concentration in Gel Hand Sanitizers



Sanitizer Code

16

Study Limitations

- A good maximum sample size is usually around 10% of the population but sanitizer population is currently unknown
- Sanitizer containers with no labels, labels with untested claims or lack of information according to regulatory specifications
- FID suitable for volatile carbon compounds only, hence unsuitable for detection of non-volatile components of the sanitizers

Conclusion

- Many brands of hand sanitizer (esp. gels) found around Johannesburg contain the recommended content of alcohol (60-75%).
- There are also many that contain less than the recommended content of alcohol.
- Some of these formulations, regardless of proper alcohol concentration, contain the toxic 1-propanol and non-recommended additives, e.g. alcohol denaturants (ethyl acetate)
- And some are tainted with toxic alcohol contaminants, e.g. methanol, isobutanol and 3-methyl-butanol
- Some few sanitizers are alcohol-free and not suitable for sanitation against CoViD-19 and other coronaviruses.

Recommendations

- All consumers (workplaces and the public in general) should be aware of untrustworthy sources and/or brands of hand sanitizer.
- The use of hand sanitizer with no virucidal activity may give a false sense of security against SARS-CoV-2.
- People using those hand sanitizers with unacceptable ingredients (toxic components) will likely suffer from the associated risks.
- Regulatory authorities and public health bodies should take an active role in ensuring the safety and quality of hand sanitizer preparations at every stage of the products' lifecycle, including manufacture, distribution and import.

References

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- 6. Fernando S. & Fonseca Jr.a b. Determination of Ethanol in Gel Hand Sanitizers Using Mid and Near Infrared Spectroscopy. J. Braz. Chem. Soc. vol.31 no.9 São Paulo Sept. 2020 Epub Aug 19, 2020 (7 out of 34 samples had an ethanol content of 70% (m/m) or higher)

Acknowledgements

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Division of the National Health Laboratory Service

The End!

Break the cycle of diseases clean hands save lives Remember to wash your hands for 20 seconds



ALC: OF BRIDE STREET

CORRECT



INCORRECT



22