Safe Drugs Save Lives

GUIDELINES ON HAND SANITIZERS FOR USE DURING THE COVID-19 PANDEMIC

National Drug Authority
Head Office
Rumee Towers
Plot 19, Lumumba Avenue
P. O. Box 23096
Kampala, Uganda.
Tel: +256 - 0414 - 255665/347391/2
E-mail: ndaug@nda.or.ug
Website: http://www.nda.or.ug

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Adoption and approval of these professional guidelines

In EXERCISE of the powers conferred upon the Drug Authority by Section 5(i) of the National Drug Policy and Authority Act, Cap. 206 of the Laws of Uganda (2000 Edition), the Drug Authority hereby ADOPTS and ISSUES these Professional **"Guidelines on Hand Sanitizers for Use during the Covid-19 Pandemic,** Doc. No. INS/GDL/041 Revision No.: 0", made this 3rd day of April 2020, that take effect on 3rd April 2020

Signature

Dr. Medard Bitekyerezo

CHAIRPERSON

National Drug Authority

Kampala, Uganda

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1.0 BACKGROUND

Coronavirus Disease (COVID-19) is an infectious disease that was declared a pandemic by the World Health Organization (WHO). In light of the capacity of the virus to rapidly spread, leading to significant impact on the economy, healthcare systems and societal disruption, the Government of Uganda has taken precautionary measures for limiting the risk of spread of the disease within Uganda, ranging from limitations on public gatherings and closure of educational institutions; among others.

Hand hygiene is a key component of the global response to COVID-19. Washing hands with soap and water for not less than 20 seconds is essential, especially before touching one's mouth, nose or eyes, after going to the bathroom, before eating, and after coughing, sneezing or blowing one's nose. If soap and water are not readily available, the World Health Organization recommends the use of an alcohol-based hand sanitizer that contains at least 60 percent ethanol or 70% isopropyl alcohol.

The National Drug Authority (NDA) is a drug regulatory body established by the National Drug Policy and Authority Act (Cap. 206) to ensure availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory health care and safeguarding the appropriate use of drugs.

Hand sanitisers are drug products in line with section 1(k) of the Act (Cap 206) which defines a drug as **"any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease or for improving physiological functions, or for agricultural or industrial purposes**".

Pursuant to this mandate, NDA hereby issues these guidelines regarding hand sanitizers in relation to the COVID-19 pandemic.

2.0 HAND SANITIZERS ON THE UGANDAN MARKET

2.1 In light of the global COVID-19 pandemic, Uganda is on high alert and some consumers and health care professionals are currently experiencing difficulties accessing alcohol-based hand sanitizers. NDA is also aware of reports that some unscrupulous people are taking advantage of the situation to make hand sanitizers that do not comply with the required standards.

2.2 Several brands of imported and locally made hand sanitizer products are available on the market. However, currently, only alcohol-based sanitizers are recommended for rapid and effective inactivation of a wide array of potentially harmful microorganisms on hands including the corona virus.

2.3 Hand sanitizers imported into Uganda and those manufactured locally shall meet the East African standard for hand sanitisers, number US EAS 789.2013.

2.4 In view of the above, the Drug Authority wishes to guide companies and institutions that would wish to engage in the compounding/manufacture of hand sanitizers, to meet the emergency needs, as follows;

a) National Drug Authority (NDA) shall ensure the quality, efficacy and safety of sanitisers on the market.

b) Licenced manufacturers and institutions shall seek authorisation from NDA, prior to placing products on the market.

c) Companies and institutions not licenced by NDA shall apply to NDA for authorisation to manufacture hand sanitisers.

d) NDA shall have teams on the ground, inspecting manufacturing premises, sampling and testing hand sanitizers on the market

e) NDA shall publicly share updates with the public on the hand sanitisers that are compliant with regulatory requirements.

2.5 Facilities described in part 2.4(c) above shall notify the nearest NDA office in writing, with the following details/requirements:

a) Name of facility

b) Location/address and contact of the facility

c) Description of the product (name, pack size and ingredients).

d) Samples of 3 consecutive batches of the sanitizers for testing as indicated below.

S/N	Pack Size	Sample size for solutions	Sample size for gels
1	60ml and below	20 bottles	20 bottles
2	100ml	10 bottles	20 bottles
3	500ml	4 bottles	6 bottles
4	1L	2 bottles	3 bottles
5	5L	1 container	1 container
6	10L and 20L	1 container	1 container

3.0 LOCAL PREPARATION OF HAND SANITISERS

The following conditions are set for the local preparation of hand sanitizers:

3.1 The maximum acceptable batch size for local compounding / manufacturing shall be 50 litres. This requirement however shall not apply to licensed manufacturing facilities who may manufacture larger batch sizes.

3.2 The recommended formulation for local compounding / manufacturing of a hand sanitizer shall be alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution or Isopropyl Alcohol (75%, v/v) in an aqueous solution with distilled water or boiled cold water. Other ingredients shall include Glycerol (1.45% v/v) and Hydrogen peroxide (0.125% v/v) in line with WHO recommendations.

3.3 No other active or inactive ingredient apart from those listed above shall be added as these may impact the quality and potency of the product.

3.4 The compounding / manufacturing facility shall pay particular attention to ensure that the right amount and concentration of ethanol or isopropyl alcohol active ingredient is used.

3.5 The compounding facility shall maintain documentation per batch of hand sanitizer prepared.

3.6 The hand sanitizer shall be prepared, handled and packed under sanitary conditions.

3.7 Adequate and suitable equipment including stainless steel mixing tanks and rods, measuring cylinders, funnels and alcoholometers, to mention but a few, must be available.

3.8 The shelf life of the sanitizer formulations, produced according to these guidelines shall be 2 years from the date of compounding / manufacturing.

3.9 The hand sanitizer shall be labelled consistent with the attached labelling in: **Appendix 1** (Labelling for Ethanol Formulation) and **Appendix 2** (Labelling for Isopropyl Alcohol Formulation)

4.0 FURTHER PROVISIONS

4.1 These guidelines do not extend to other types of products, such as products that use different active ingredients, that are marketed with therapeutic claims, surgical hand rubs, or whose advertising or promotion is false or misleading in any particular manner.

4.2 The Drug Authority encourages consumers and health care professionals to report adverse events experienced with the use of hand sanitizers to National Drug Authority through NDA's MedSafety mobile app (Available through Google play store) or by following the Guidelines on detecting and reporting adverse drug reactions in Uganda, Doc No. DPS/GDL/013 (available on the NDA website).

4.3 NDA shall from time to time, perform sampling and testing of hand sanitizers on the market in accordance with the post-market surveillance plan. Products that are found no to be compliant with their specifications shall be withdrawn from the market at the cost of the compounder / manufacturer.

5.0 REFERENCES

a) FDA Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry

b) Guide to local production: WHO-recommended Hand rub Formulations

c) The National Drug Policy and Authority Act (Cap 206)

d) US EAS 789:2013, Instant Hand Sanitizers - Specification

e) WHO Guidelines on Hand Hygiene in Health Care

APPENDIX 1: LABELLING FOR ETHANOL FORMULATION

Principal display panel (front of package):

Alcohol Antiseptic 80%* Topical Solution
Hand Sanitizer Non-sterile Solution
[*Insert Volume of Product in mL*]
Batch no: Mfd: Exp:

*This concentration should be derived through appropriate tests of the alcohol content in the finished product

Drug facts label

Drug Facts ***Active ingredient[s] Purpose*** Ethanol 80%* v/v.....Antiseptic
Use[s] Hand sanitizer to help reduce micro-organisms that can potentially cause disease. For use when soap and water are not available.
Warnings **For external use only. Flammable. Keep away from heat or flame** **Do not use** • on children less than 2 months of age • on open skin wounds **When using this product** keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. **Stop use and ask a doctor** if irritation or rash occurs. These may be signs of a serious condition. **Keep out of reach of children.** If swallowed, get medical help right away.
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.
Other information • Store in a cool dry place • Avoid freezing and excessive heat above 40^{0}C
Inactive ingredients: [*State inactive ingredients*] e.g. glycerol, hydrogen peroxide, purified water
Manufactured by ***Name*****.....** ***Address*****.....** ***Contact*****.....**

APPENDIX 2: LABELING FOR ISOPROPYL ALCOHOL FORMULATION.

Principal display panel (front of package):

Isopropyl Alcohol Antiseptic 75%* Topical Solution Hand Sanitizer Non-sterile Solution **[Insert Volume of Product in mL]** Batch no: Mfd: Exp:

*This concentration should be derived through appropriate tests of the alcohol content in the finished product

Drug facts label

Drug Facts ***Active ingredient[s] Purpose*** Isopropyl alcohol 75%* v/v.....Antiseptic
Use[s] Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
Warnings **For external use only. Flammable. Keep away from heat or flame** **Do not use** • on children less than 2 months of age • on open skin wounds **When using this product** keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. **Stop use and ask a doctor** if irritation or rash occurs. These may be signs of a serious condition. **Keep out of reach of children.** If swallowed, get medical help right away.
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry • Supervise children under 6 years of age when using this product to avoid swallowing
Other information • Store in a cool dry place • Avoid freezing and excessive heat above 40^{0}C.
Inactive ingredients: [State inactive ingredients] e.g. glycerol, hydrogen peroxide, purified water
Manufactured by ***Name*****.....** ***Address*****.....** ***Contact*****.....**

6.0 DOCUMENT REVISION HISTORY

Date of revision	Revision number	Document Number	Author(s)	Changes made and reasons for revision
3rd April 2020	0	INS/GDL/041	*Authors:* Frank Kaleebu Moses Akampurira Amos Atumanya *Reviewers:* Solomon Onen Denis Mwesigwa Peter Ssali	First issue

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