Department of Health Policy for Preparation of Alcohol-Based Hand Sanitizer Products during the Public Health Emergency (COVID-19) Guidance for Manufacturers and Importers

INTRODUCTION

The Public Health Authority plays a critical role in protecting the Seychelles from emerging infectious diseases, such as the Coronavirus Disease 2019 (COVID-19) pandemic. The Public Health Authority is issuing this guidance to communicate its policy to non - pharmaceutical manufacturers that would like to prepare alcohol-based hand sanitizers for public distribution. This policy also is applicable to importers of alcohol based hand sanitisers products.

BACKGROUND

There is currently a pandemic. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). SARS-CoV-2 has demonstrated the capability to spread rapidly, leading to significant impacts on healthcare systems and causing societal disruption. The potential public health threat posed by COVID-19 is high, both globally and to the Seychelles. Hand hygiene is an important part of the Public Health response to COVID-19. Washing hands often with soap and water for at least 20 seconds is essential, especially 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 Public Health Authority recommends consumers use an alcohol-based hand sanitizer as per WHO specification that contains at least 80 percent alcohol and Hydrogen peroxide 0.125%. At present, alcohol-based handsanitizers are the only known means for rapidly and effectively inactivating a wide array of potentially harmful microorganisms on hands.

RECOMMENDATIONS

1. The hand sanitizer is manufactured using only the following ingredients in the preparation of the product a.

a) Select one of two options:

I. Alcohol (ethanol) that is not less than 96% ethanol by volume;

OR

II. Isopropyl Alcohol 99.8%

b) Glycerin (glycerol) 98%

c) Hydrogen peroxide 3%

d) Sterile water (e.g., by boiling, distillation, or other process that results in water that meets the specifications for Purified Water USP). Water should be used as quickly as possible after it is rendered sterile or purified.

Additional Considerations for Ingredients in Preparation of the Product:

Alcohol (ethanol) that is produced using fermentation and distillation processes typically used for consumable goods, and that is made in a facility used for producing consumable goods, may be considered for use in hand sanitizer.

Alcohol derived from synthetic processes may be considered for use in hand sanitizer only if it meets USP or FCC16 grade. Alcohol produced in facilities normally producing fuel or technical grade alcohol (ethanol) may be considered for use in hand sanitizer provided the following circumstances are present: (i) the alcohol is produced using fermentation and distillation processes typically used for consumable goods, and no other additives or other chemicals have been added to the ethanol;

2. **The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product.**

Denaturing is critical because there have been reports of adverse events, including deaths, from ingestion of hand sanitizer. Most reports are from unintentional ingestion by young children.
The alcohol should be denatured at either
(1) the point of production by the alcohol production firm or
(2) the point of manufacture or compounding of the hand sanitizer.

3. The finished hand sanitizer product is manufactured according to the following formula consistent with World Health Organization (WHO) recommendations:

a. Alcohol (ethanol) (formulated to 80%, volume/volume (v/v)) in an aqueous solution; **or** Isopropyl Alcohol (formulated to 75%, v/v) in an aqueous solution.
b. Glycerin (glycerol) (1.45% v/v
c. Hydrogen peroxide (0.125% v/v).
d. Sterile distilled water or boiled cold water.

4. The manufacturer does not add other active or inactive ingredients, such as ingredients to improve the smell or taste, due to the risk of accidental ingestion in children. Different or additional ingredients may impact the quality and potency of the product.

5. The manufacturer pays particular attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used. A simple record should be used to document key steps and controls to assure each batch matches the formula developed for the drug product.

6. The hand sanitizer is prepared under sanitary conditions and equipment utilized is well maintained and fit for this purpose.

7. The manufacturer uses the most accurate method of analysis available at the site for verification of alcohol content in samples of the finished drug product before each batch is released for distribution. Methods can include gas chromatography (GC), alcoholmeter, hydrometer, or other chemical analysis of at least equivalent accuracy. The sample tested can be performed on in-process material before filling into the final containers to be distributed. Importers must submit a Certificate of Analysis for each consignment of hand sanitizer imported.

8. The hand sanitizer product is produced as an aqueous solution as per the WHO specification. The firm packages the finished hand sanitizer product in packaging appropriate for liquid drug products that will seal sufficiently to prevent evaporation of the alcohol. Manual pump sprays that seal sufficiently to prevent evaporation are consistent with this policy.

9. Imported gel products must meet the WHO specification.

10. The hand sanitizer is labeled consistent with the following

Labeling for Ethanol Formulation Consumer Use

Minimum labelling information:

Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution [Insert Volume of Product in mL]

Expiry date:
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 • in children less than 2 months of age • on open skin wounds
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.
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.

Labeling for Isopropyl Alcohol Formulation Consumer Use

Minimum labelling information:

Isopropyl Alcohol Antiseptic 75%
Topical Solution Hand
Sanitizer Non-sterile Solution
[Insert Volume of Product in mL]
Expiry date:
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 • in children less than 2 months of age • on open skin wounds
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.
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.

Reference

Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry - March 2020 Updated June 1, 2020
Guide to Local Production: WHO-recommended Handrub Formulations