June 3, 2020

DPHSS Memorandum 2020-13

Re: Temporary Policy for Consumer Antiseptic Rubs During COVID-19 Emergency

Pursuant to Executive Order No. 2020-19, the Department of Public Health and Social Services (DPHSS) has developed this temporary policy for COVID-19 related commodities to address the shortage of these products in the market, which adversely impacts the public’s ability to protect themselves during this COVID-19 emergency.

Consumer antiseptic rubs shall mean products that are intended to be used when soap and water are not available, and are left on and not rinsed off with water after application.

This policy does not apply to antiseptic rubs for use by healthcare professionals in a hospital, clinic, or other healthcare settings. Antiseptic rubs used in healthcare settings must comply with local and federal laws, including the temporary guidance documents issued by the U.S. Food and Drug Administration for these products.

This shall policy shall be effective immediately and shall terminate upon the declaration of Pandemic Condition of Readiness 4 or when the public health emergency is rescinded.

In taking a similar approach as the U.S. Food Drug Administration, the Department of Public Health and Social Services does not intend to take action against businesses or individuals who import, distribute, or sell consumer antiseptic rubs, provided that the following criteria are met:

1. The product is properly labeled in English or Chamorro.

2. Labels shall be clear, legible, prominent, conspicuous, and proportionate to the size of the product, as determined by DPHSS.

3. The principal display panel* contains the following information:
   a. Statement of common identity (i.e., “hand sanitizer,” “antiseptic,” “alcohol,” “alcohol sanitizer,” “alcohol disinfectant,” “consumer antiseptic rubs,” or other similar types of identity); and
   b. Declaration of net quantity of contents expressed accurately in either U.S. avoirdupois weight or fluid measure, and/or the equivalency in metric units.

*Note: In some cases, the principal display panel may consist of information on both panels.
4. Alternate Display Panels should include the following on the label:
   a. Name and place of the manufacturer, packer, or distributor.
   b. Country of origin (ex: "Made in Korea").
   c. Uses (ex: “Consumer antiseptic rubs to help reduce pathogens that potentially can cause disease” or similar language).
   d. Adequate warning statements that shall include, but is not limited to, the following:
      - For external use only.
      - Flammable.
      - When using this product, do not use in or near the eyes. In case of contact with eyes, rinse eyes thoroughly with water.
      - Stop use and ask a doctor if irritation or rash appears.
      - Keep away from heat or flame.
      - Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center or dial 911, right away.
   e. Directions for use statement that shall include, but is not limited to, the following:
      - Place enough product on hands to cover all surfaces. Rub hands together until dry.
      - Children under 6 years of age should be supervised when using this product.
   f. A statement of active ingredients shall be limited to ethyl alcohol or ethanol (60% to 95%) or isopropyl alcohol (70% to 91.3%) or benzalkonium chloride.
   g. A listing of inactive ingredients that are safe for use.
   h. Other information related to requirements for storage as specified by the manufacturer [i.e., Store between 15-30°C (59-86°F). Avoid freezing and excessive heat above 40°C (104°F)].
   i. Expiration date statement as indicated by the manufacturer.

Businesses are reminded that it is their responsibility to ensure that their products are in full compliance with the provisions of this temporary policy.

Failure to comply with the terms of this policy shall result in the automatic refusal of admission for those affected products, which shall be destroyed or exported back to the point of origin at the expense of the importer.

LINDA UNGPINGCO DENORCEY, MPH
Director