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Media Release

## **Amendment to SANS 490 defining alcohol-based hand rubs and sanitisers to contain minimum alcohol content.**

The South African Bureau of Standards (SABS) has published the amendments to the national standard, SANS 490 that specifies the requirements for all alcohol-based hand sanitisers and hand rubs in the form of liquids, gels, foams and aerosols. These changes have been driven by global guidelines such as the requirements specified by the World Health Organisation and locally by the South African Health Products Regulatory Authority (SAHPRA) in the fight against the coronavirus pandemic.

The amended South African National Standard (SANS) 490 was published in October 2020 and is freely available on the SABS website. The amended SANS supersedes the 2013 version and is effective from the date of publication.

“The amended SANS 490 provides greater and more detailed requirements for hand sanitisers and hand rubs. It is now specified that a minimum of 70% alcohol content is required if - alcohol, such as ethanol, isopropanol or n-propanol is the main ingredient; and that 60% alcohol content is required if there are other active ingredients. Solvents such as acetone (propanone), methanol, methylated spirits or other spirits are not allowed to be used as they can cause toxicity and even fatalities, if absorbed through one’s skin,” explains Jodi Scholtz, Lead Administrator.

Scholtz said that manufacturers must ensure that they now submit evidence that their products will retain their physicochemical properties and efficacy, for the duration of the expected shelf life of the product until the expiry date as stated on the product’s label. Packaging must clearly indicate the details of the manufacturer, the ingredients of the product, the volume and type of alcohol, and the expiry date of the product.

“Since the outbreak of the coronavirus, the SABS and its technical committee, together with regulatory authorities, have been working vigorously to review and publish South African National Standards that are able to respond efficiently to protect the health and safety of South African citizens. Even though SANS 490 was amended and published in October 2020, the testing protocols of sanitisers to verify the alcohol content was implemented prior to the publication of the standard. SAHPRA published the requirements for alcohol-based hand rubs and sanitisers in July 2020 and the amended standard includes those product requirements,” clarifies Scholtz.

The process of developing, reviewing or amending national standards is underpinned by international best practice principles amongst others, consensus development within the SABS technical committees (TC) represented by a diverse portfolio of stakeholders. The SABS TC 1022: Antiseptics, Disinfectants and Detergent-disinfectants was responsible for the much-needed amendments.

The duration of testing against SANS 490, if conducted by SABS is approximately 20 days. For certification, or the ‘SABS Approved’ Mark Scheme requirements the duration is approximately three months as audits of the product and the production processes need to be conducted. These audits include the provision of the required documentation of the production processes and shelf testing by the manufacturer.

**Ends**

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**Notes:**

1. SANS 490: 2020 can be downloaded from [SABS webstore](#)
2. The SAHPRA requirements are contained in the SAHPRA communication published on the site of the [South African Medical Research Council \(SAMRC\)](#)
3. Hand rubs, sanitisers or disinfectants that are intended to be used to protect against germs, fungi, bacteria, spores or other substances can be manufactured against other standards such as SANS 1853, SANS 51276, SANS 51650, SANS 53704, SANS 54885, or SANS 53610