Section 13: Hand Sanitiser Product

In South Africa, hand sanitizer products, **do not** fall under the scope of cosmetics.

They may be categorised into one of the ways shown below:

1. the company must distinguish their product as either falling under the Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act 54 of 1972) and the mandate of the Environmental Health Directorate within the Department of Health (DOH)

or

2. under the mandate of the Medicines Act, 1965 (Act 101 of 1965), and follow the requisite steps and abide by the relevant SABS Standard or NRCS specification. Please refer to the following document for further information: *9.78_Disinfectants_Antiseptics_Germicides_v1_Jul16*: https://www.sahpra.org.za/wp-content/uploads/2019/09/9.78_Disinfectants_Antiseptics_Germicides_v1_Jul16.pdf

Sanitising products may fall into various regulatory groups depending on the:

a. Application surface (human skin or inanimate surface)
b. Environment the sanitiser is used in (place of use)
c. Intended use and function; and
d. Composition

1. Hand sanitisers are generally regarded as “Rub” or “Leave on” products primarily used to sanitise the skin, when soap and water are not available, and are left on and not rinsed off with water. These are controlled under the ambit of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) (FCD Act) and fall within the mandate of the Directorate: Environmental Health within the Department of Health.
2. Hand sanitisers must comply with the South African National Standard (SANS) 490:2013 “Disinfectant alcohol-based handrub”, as well as the Trade Metrology Act, 1973 (Act 77 of 1973), in terms of packaging and labelling,
3. Disinfectants and germicides used on inanimate surfaces in low-risk areas within the home, public venues (schools, restaurants), health institutions, health professional

consulting rooms and clinics are controlled under the ambit of the FCD Act, and fall within the mandate of the Directorate: Environmental Health within the Department of Health. These products must comply with the requirements of the "Compulsory specification for chemical disinfectants VC8054" as set out by the National Regulator for Compulsory Specifications (NRCS), the Trade Metrology Act, 1973 (Act 77 of 1973) as well as all relevant SANS standards.

4. Disinfectants, antiseptics and germicides used on inanimate surfaces in areas of high risk (hospital operating rooms, intensive care units (ICU), burn units, Cath Laboratories), are controlled as medical devices under the ambit of the Medicines & Related Substances Act, 1965 (Act 101 of 1965) (Medicines Act) as amended; and fall within the mandate of the South African Health Products Regulatory Authority (SAHPRA).
5. Disinfectants used to clean medical instruments are controlled as medical devices under the ambit of the Medicines Act as amended; and fall within the mandate of the SAHPRA.
6. Products primarily claiming to kill germs, disinfect or sanitise or using an active antimicrobial ingredient such as the hand sanitisers used in hospitals, are controlled as medicines under the ambit of the Medicines Act as amended; and fall within the mandate of the SAHPRA.
7. Antiseptic and anti-bacterial products specifically for use as surgical scrubs in operating theatres and used on human skin in hospitals' operating rooms, ICU, burn units, and cath laboratories which make claim to treat/ prevent infection are controlled as medicines under the ambit of the Medicines Act as amended; and fall within the mandate of the SAHPRA.
8. Where the intended use or claim for a product mentioned above lies both in a low-risk area and a high-risk area, the product will fall under the regulatory ambit of the Medicines Act as amended; and fall within the mandate of the SAHPRA.