

MEDICINES CONTROL COUNCIL



POSITION STATEMENT: STATUS OF DISINFECTANTS, ANTISEPTICS AND GERMICIDES

To all Applicants

Kindly be advised that at a meeting of the Medicines Control Council on the 29th July 2016, Council resolved on the status and control of disinfectants, antiseptics and germicides under the ambit of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended.

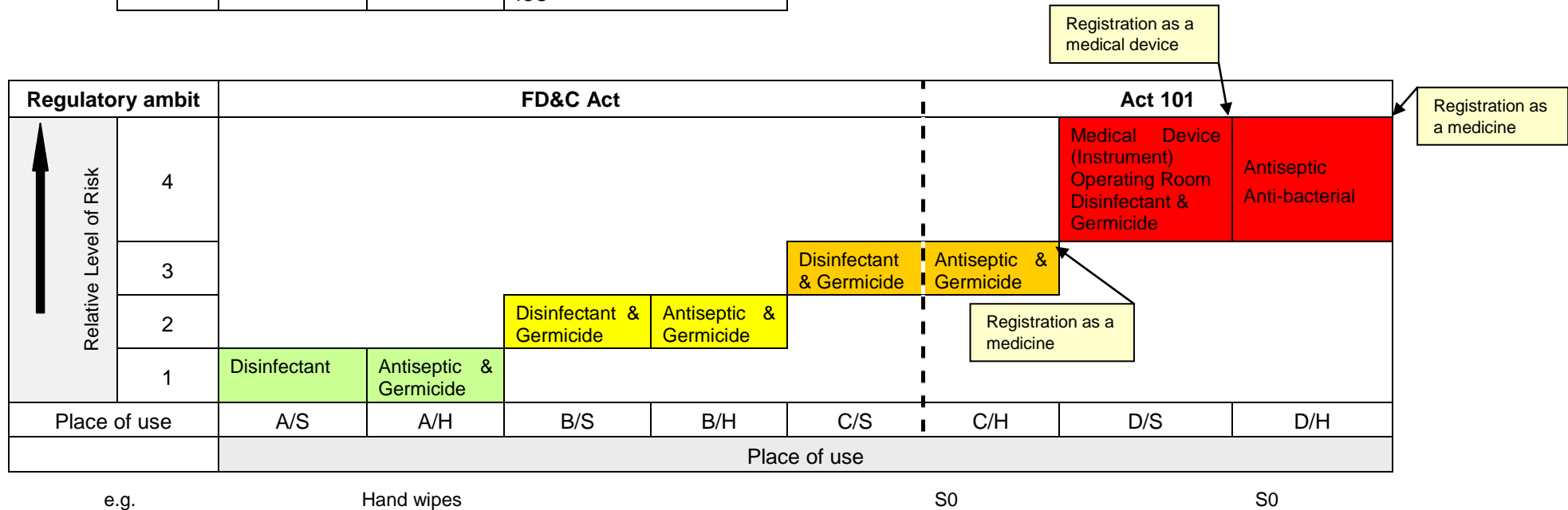
Disinfectants, antiseptics and germicides are governed by multiple Acts: the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), the Medicines and Related Substances Act, 1965 (Act 101 of 1965), and the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), as well as by the standards set by the National Regulatory Compulsory Specifications (NSRC), established by the National Regulator for Compulsory Specifications Act, 2008 (Act 5 of 2008). This has caused significant complexity and confusion with regard to the control of these products.

Since there is overlap with regard to the place of use and the control of the disinfectants, antiseptics and germicides, a risk based approach is utilised to identify the appropriate regulatory pathway of these products. This risk based approach, summarised in Table 1 below, recognises:

- the application surface either as human skin or an inanimate surface;
- the place of use
 - Home
 - Public venues e.g. schools, toilets at train stations, toilets at taxi ranks, restaurants;
 - Health institutions, Health professional consulting rooms, clinics, and
 - Operating room; Burn ward; Intensive Care Unit (ICU); and
- the intended use / claim – anti-bacterial / antiseptic / germicide / disinfectant.

Table 1. Identification of regulatory ambit based on risk

Relative Level of Risk		Where? Place of use		Applied to:	
1	Low	A	Home	H	Human skin
2	Moderate	B	Public venues e.g. school, train station, taxi rank, restaurants	S	Inanimate surface
3	High	C	Health institution, Health professional consulting room		
4	Very High	D	Operating room, Burn ward, ICU		



1. All disinfectants, antiseptics and germicides such as hand sanitisers and hand rubs, used on both animate and inanimate surfaces which are used in the home and public venues such as schools, restaurants and ablution facilities at taxi ranks, airports, bus and train stations, will be controlled under the ambit of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) as amended, and managed by the Directorate: Environmental Health;
2. Disinfectants and germicides used on inanimate surfaces in low risk areas within health institutions and health professional consulting rooms and clinics will be controlled under the ambit of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) as amended, and managed by the Directorate: Environmental Health;
3. Antiseptics and germicides used on inanimate surfaces in areas of high risk in hospital operating rooms, intensive care units (ICU), burn units, Cath Labs, etc. will be controlled as medical devices under the ambit of the Medicines & Related Substances Act, 1965 (Act 101 of 1965) as amended;
4. Disinfectants used to clean medical instruments and the inanimate surfaces in hospitals operating rooms, intensive care units (ICU), burn units, Cath Labs, etc. will be controlled as medical devices under the ambit of the Medicines & Related Substances Act, 1965 (Act 101 of 1965) as amended;
5. Antiseptic and anti-bacterial agents used on human skin in hospitals' operating rooms, intensive care units (ICU), burn units, Cath Labs, etc. will be controlled as medicines under the ambit of the Medicines & Related Substances Act, 1965 (Act 101 of 1965) as amended;
6. Where the intended use / claim for a product is in both a low risk area and a high risk area, the product will fall under the regulatory ambit of the Medicines & Related Substances Act, 1965 (Act 101 of 1965) as amended;
7. The standards as set by the National Regulatory Compulsory Specifications (NRCS) will continue to address minimum performance standards required for these products.

DR JC GOUWS

REGISTRAR OF MEDICINES