

Compulsory Specification for

Disinfectants and detergent-disinfectants

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**DEPARTMENT OF TRADE AND INDUSTRY
DEPARTEMENT VAN HANDEL EN NYWERHEID**

No. R. 529

14 May 1999

STANDARDS ACT, 1993

**COMPULSORY SPECIFICATION FOR
DISINFECTANTS AND DETERGENT-DISINFECTANTS**

I, Alexander Erwin, Minister of Trade and Industry, hereby under Section 22(1)(a)(I) of the Standards Act, 1993 (Act No. 29 of 1993), and on the recommendation of the Council of the South African Bureau of Standards, declare the specification for disinfectants and detergent-disinfectants as set out in the Schedule, to be compulsory with effect from the date 2 months after the date of publication of this notice.

ALEXANDER ERWIN
Minister of Trade and Industry

SCHEDULE

COMPULSORY SPECIFICATION FOR DISINFECTANTS AND DETERGENT-DISINFECTANTS

1 Scope

This specification covers requirements for disinfectants and detergent-disinfectants intended for use on inanimate surfaces.

NOTES

- 1 All disinfectants and detergent-disinfectants in the Republic of South Africa are covered by this compulsory specification. In addition to the requirements in this specification, the requirements promulgated by the Registrar, Agriculture Pests Act, 1983 (Act 36 of 1983), and those in respect of substances subject to the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), also apply. Biocides for use in water treatment are excluded.
- 2 As a result of specific applications or assertions made on the label or in the directions for use, it may be necessary also to register the disinfectants or detergent-disinfectants under Act 36 or Act 101, depending on the purpose for application.
- 3 Using the compulsory specification, it is not possible to determine the bactericidal activity of the undiluted product. Some dilution is always produced by the addition of inoculum, hard water or sterile skimmed milk.
- 4 Should virucidal efficacy be claimed with reference to this specification, reference may not be made to a specific virus, but a general reference thereto may be made on the label.
- 5 If a product complies with the requirements of this compulsory specification, it can be considered to be bactericidal or virucidal, but it should not necessarily be inferred that the product is a suitable disinfectant for a defined purpose.

2 Definitions

For the purposes of this specification, the following definitions apply:

2.1 acceptable: Acceptable to the authority administering this specification.

2.2 address: An address in the Republic of South Africa, which includes the street or road number (if a number has been allocated), the name of the street or road and the name of the suburb, village or town, and in the case of a farm, the name of the farm and of the magisterial district in which it is situated. In the case of imported disinfectants or detergent-disinfectants, "address" means the address of the manufacturer or supplier or importer.

2.3 bacteriophage; phage: A virus that infects bacteria.

NOTE – In this compulsory specification, phage is used as a model to assess general virucidal efficacy.

2.4 batch: That quantity of sealed containers of disinfectant or detergent-disinfectant that have been filled from one homogeneous blend or, in the case of continuous production processes, that have been filled from one day's production.

2.5 clean conditions: Conditions where surfaces are physically clean before the application of the disinfectant or detergent-disinfectant.

2.6 creaming: A phenomenon associated with a concentration of the dispersed phase in one portion

of an emulsion, at the expense of the dispersed phase in the remaining portion of the emulsion.

2.7 critical dilution: The highest dilution with water of a coal-tar type disinfectant or of the standard phenol, which, when tested in accordance with 5.9, permits growth of *Salmonella typhi* after exposure to it of 2,5 min and 5,0 min, but not after exposure of 7,5 min.

2.8 detergent-disinfectant: A product that cleans and disinfects simultaneously.

2.9 dirty conditions: Conditions where organic material is present on surfaces to such an extent that a higher than normal concentration of the disinfectant or detergent-disinfectant is needed to cancel the inactivating effect of the organic material and still ensure disinfection.

2.10 disinfectant: A chemical agent that kills most vegetative forms of pathogenic and other micro-organisms (but not necessarily all bacterial and fungal spores, mycobacteria, rickettsiae or viruses) on inanimate surfaces.

2.11 factory: Any premises in which the disinfectant or detergent-disinfectant is manufactured, produced or repacked or handled in such a way that the quality of the disinfectant or detergent-disinfectant could be affected by the activities.

2.12 inanimate surface: Any surface other than live human or live animal tissue.

2.13 plaque: A clear zone of lysis on a lawn of bacteria, that results from the lytic infection of one bacterium by one bacteriophage, and subsequent infection of surrounding bacteria by the offspring of that phage.

2.14 plaque count: The total number of plaques counted on a lawn of bacteria that develop on a plate of bacterial growth medium incubated at 37 °C.

3 General requirements for the factory and for employees

3.1 General

All the statutory requirements of the Occupational Health and Safety Act, 1993 (Act 85 of 1993), and the Health Act, 1977 (Act 63 of 1977), shall be complied with.

3.2 Factory construction, layout and conditions

3.2.1 The factory buildings shall be of sound construction, in good repair and large enough to prevent crowding of equipment and employees and to permit adequate cleaning and the maintenance of product quality. A system of control shall be maintained to keep the factory free from birds, rodents, insects and other vermin, and to ensure that the disinfectant or detergent-disinfectant is not contaminated and that the quality of the disinfectant or detergent-disinfectant is not compromised in any way.

3.2.2 Roof and ceilings

The roof shall be weatherproof and the ceiling (or underside of the roof if there is no ceiling) shall be smooth and reasonably dustproof.

3.2.3 Walls, floors and doors

Outer walls shall be weatherproof and impermeable to water. Doors and door frames shall be made from corrosion-resistant material or protected to prevent corrosion. Floors shall be constructed of concrete or other durable, impervious and non-slip material that is resistant to wear and corrosion and easy to clean. Provision shall be made for adequate drainage.