DEPARTMENT OF TRADE AND INDUSTRY

NO. 1119 **20 OCTOBER 2017**

NATIONAL REGULATOR FOR COMPULSORY SPECIFICATIONS ACT (Act 5 of 2008) AS AMENDED THROUGH THE LEGAL METROLOGY ACT (ACT 5 OF 2015)

THE AMENDMENT OF THE COMPULSORY SPECIFICATION FOR FOR CHEMICAL DISINFECTANTS – VC 8054

I, Dr Rob Davies, Minister of Trade and Industry, under Section 13 (1) of the National Regulator for Compulsory Specifications Act (Act 5 of 2008) hereby declare the Compulsory Specification for Chemical Disinfectants (VC 8054) as set out in the attached schedule; and withdraws the Compulsory Specification for Disinfectants and detergent – disinfectants (VC8054:1999) as Published by Government Notice No. R. 529 (Government Gazette No.19999) of 14 May 1999, with effect twenty-four (24) months from the date of publication of this notice.

Chemical disinfectants that are already registered by the National Regulator for Compulsory Specifications (NRCS) in accordance with VC 8054:1999, shall submit proof of compliance with this Compulsory Specification within 12 months after its effective date to re-affirm their registration.

Dr Rob Davies, MP
Minister of Trade and Industry

SCHEDULE

VC 8054

THE COMPULSORY SPECIFICATION FOR CHEMICAL DISINFECTANTS

1. SCOPE

1.1 This compulsory specification covers the requirements for chemical disinfectants used for disinfection purposes on inanimate surfaces in all areas of application.

1.2 The application of European Standards for *Chemical disinfectants and antiseptics* together with the relevant SANS listed in clause 3.2 of compulsory specification *shall* apply; with the exclusion of all references to disinfectants used as antiseptics, or in veterinary area as provided for in SANS 54885. Notwithstanding the exclusion of veterinary areas such as veterinary clinics, hospitals and consulting rooms; and those of breeding, husbandry, production, transport and disposal of animals where disinfectants may come into contact with live animal tissues but the scope includes use in associated facilities e.g. offices, toilets and others.

1.3 Treated articles and substances for use on hard surfaces are excluded from the scope of this compulsory specification, on the following conditions:

1.3.1 The incorporated chemical disinfectant for use in or on the article or substance is registered in accordance with this compulsory specification; and

1.3.2 The sole purpose of the treatment is to protect the article or substance itself not the hard surface it is used on.

Note:

It may also be necessary to register the disinfectant under Fertilizers, farm feeds, agricultural remedies and stock remedies Act of 1947 (Act no 36 of 1947) or Medicines and Related Substances Act of 1965, Act 101 of 1965 depending on the efficacy claims made and/or the purpose for application.

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2. DEFINITIONS

2.1 For the purposes of this compulsory specification, the definitions in **SANS 54885**, *the application of European Standards for Chemical disinfectants and antiseptics* together with the SANS listed in clause 3.2 of compulsory specification as may be relevant shall apply.

2.2 In addition, the following definitions shall apply:

2.2.1 Applicant

A manufacturer or importer of a chemical disinfectant formulation who is an established legal business entity within the Republic of South Africa.

2.2.2 Application of a chemical disinfectant

The method (s) used to apply the chemical disinfectant which may include but not limited to air-circulation, dipping, flooding, immersion, spraying, wiping, fogging and/or the combination of these methods.

2.2.3 Application areas

2.2.3.1 Disinfectants for application in a in food, industrial, domestic and institutional areas

Disinfectants that are used on inanimate surfaces in food, industrial, domestic and institutional areas excluding areas and situations where disinfection is medically indicated and products used on living tissues as provided for in clause 1.2 of this compulsory specification (refer to the scopes of SANS listed in clause 3.2, table 1).

2.2.3.2 Disinfectant for application in a medical area

A disinfectant used on inanimate surfaces within health institutions, health professional consulting room, clinics and other institutions for disinfecting instruments by immersion and application to areas and situations where disinfection is medically Indicated; excluding products used on living tissues as provided for in Clause 1.2 of this compulsory specification (refer to the scopes of SANS listed in Clause 3.2, table 2).

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Note:

Disinfectants used on medical instruments and the inanimate surfaces in hospitals operating rooms, intensive care units (ICU), burn units, catheterisation laboratories, etc. are controlled as medical devices under the ambit of the Medicines & Related Substances Act, 1965 (Act 101 of 1965) as amended.

2.2.4 Certification body

Third-party conformity assessment body operating certification schemes.

2.2.5 Chemical disinfectant formulation

A formulation of a chemical disinfectant that is similar in characteristics, in particular to its composition, identity, method of manufacture or production and disinfection properties.

2.2.6 Claim

Any written, pictorial, visual or other descriptive matter or verbal statement, communication, representation or reference brought to the attention of the public in any manner including a trade name or brand name and referring to the characteristics of a product, in particular to its nature, identity, quality, or method of manufacture or production.

2.2.7 Conformity assessment body

A body that performs conformity assessment services and is formally recognised in terms of the Conformity Assessment Policy of the NRCS.

2.2.8 Conformity assessment

Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled

2.2.9 Equivalence of standards

Sufficiency of different conformity assessment results to provide the same level of assurance of conformity with regard to the same specified requirements.

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2.2.10 Expiry date

The date indicating the end of the period under the stated storage conditions as specified on the label by the manufacturer until which the product will retain any specific qualities for which implied or expressed claims have been made.

2.2.11 Public health claim

A statement, pictogram or implication that a chemical substance or article is expected to provide a biocidal or biostatic action against microorganisms of public health relevance if used as indicated or implied by the person placing the substance or article on the market. The use of brand names, which imply any of these claims shall be considered equivalent to such a claim.

Examples of such claims include but are not limited to the following:

- Antibacterial
- Antimicrobial
- Bactericidal
- Germicidal
- Fungicidal
- Antiviral
- Kills pathogenic bacteria.
- Effective against E. coli and Staphylococcus.
- Provides a germ-resistant surface.
- Provides a bacteria-resistant surface.
- Surface kills common gram positive and negative bacteria.
- Surface controls both gram-positive and negative bacteria.
- Surface minimizes the growth of both gram-positive and negative bacteria.
- Reduces risk of cross-contamination from bacteria.

2.2.12 Inanimate surfaces

Any solid surface other than live human, animal or plant tissue.

2.2.13 Label

Any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed upon, or permanently attached to a container of a disinfectant, including labelling for the purpose of promoting its sale or disposal.

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2.2.14 The Letter of Authority certificate

As defined in section 1 of the NRCS Act, (Act No. 5 of 2008).

2.2.15 NRCS

The National Regulator for Compulsory Specifications as established by the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008).

2.2.16 Packaging

A container, blister pack, bottle, can, cover, drum, sachet, strip pack, syringe, tube, vessel, vial, wrapper or other similar article that serves as an immediately receptacle of a chemical disinfectant including any other component or material necessary to perform containment and safety functions.

2.2.17 Registration

Confirmation by the NRCS that a formulation of a chemical disinfectant satisfies the requirements of in accordance with Annexure A of this compulsory specification

2.2.18 Sell

As defined in section 1 of the NRCS Act, Act No. 5 of 2008.

2.2.19 Treated articles and substances

A treated article is any substance or article which has been treated with, or intentionally incorporates, one or more disinfectant products to protect the substance or article itself not the hard surface it is used on.

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3. SPECIFIC REQUIREMENTS WITH REGARDS TO CHEMICAL DISINFECTANT EFFICACY CLAIMS

3.1 Chemical disinfectants within the scope of this compulsory specification shall comply with the relevant requirements of **SANS 54885** - *The application of European Standards for chemical disinfectants and antiseptics* and the relevant SANS listed in clause 3.2 of compulsory specification.

3.2 For purposes of this compulsory specification only the relevant requirements and tests specified in the tables below are applicable:

Table 1 - Requirements for chemical disinfectants used in food, industrial, domestic and institutional areas

Bactericidal Efficacy	Fungicidal/yeasticidal Efficacy	Sporicidal Efficacy	Virucidal Efficacy
SANS 51276 *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas — Test method and requirements (phase 2, step 1)*	**SANS 51650** *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of disinfectants and antiseptics used in food, industrial, domestic and institutional areas — Test method and requirements (phase 2, step 1)*	**SANS 53704** *Chemical disinfectants — Quantitative suspension test for the evaluation of sporicidal activity of disinfectants used in food, industrial, domestic and institutional areas — Test method and requirements (phase 2, step 1)*	**SANS 53610** *Chemical disinfectants- Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of disinfectants used in food and industrial areas - Test method and requirements (phase 2, step 1)*

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Table 2 - Requirements for chemical disinfectants used in a medical area

Bactericidal Efficacy	Fungicidal Efficacy	Virucidal Efficacy
SANS 53727 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area - Test method and requirements (phase 2, step 1)*	**SANS 53624** *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area - Test method and requirements (phase 2, step 1)*	**SANS 54476** *Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2, step 1)*

3.3 Chemical disinfectants shall have a Safety Data Sheet (SDS) that complies with **SANS 11014**, *Safety data sheet for chemical substances - content and order of sections.*

3.4 Each type of chemical disinfectant formulation shall be registered in accordance with the requirements of Annexure A of this compulsory specification before it is imported, sold or supplied in South Africa.

3.5 The NRCS registration number shall be legibly and indelibly marked on the packaging of a chemical disinfectant in the following format:

"NRCS Registration:" followed by the appropriate number "XXXXX."

3.6 Chemical disinfectants shall be so manufactured as to conform to the formulation registered under this compulsory specification.

3.7 The applicant shall inform the NRCS of any change (s) in the material composition affecting any mandatory requirement of this compulsory specification. In the event of such change(s) the NRCS may, at its discretion, demand the submission of new evidence of conformity or a new application for registration.

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3.8 Any chemical substance that makes any public health claims with regards to application on hard surfaces on its label, packaging or related promotional materials in any form of in-house or external media, shall comply with the requirements of this compulsory specification.

3.9 For treated substances or articles to qualify for the exemption from the requirements of this compulsory specification, conditions stated in clauses 1.3.1 and 1.3.2 of this compulsory specification shall be met. If both are not met, the article shall comply with this compulsory specification.

4 PACKAGING

4.1 Packaging for chemical disinfectants shall:

4.1.1 Be impervious to and incapable of reacting with its content.

4.1.2 Be sufficiently strong to prevent leakages arising from ordinary risks of handling, storage or transport.

4.1.3 Have sufficient excess capacity to prevent breakage of the container or leakage of the contents if contents are likely to expand during handling, storage or transport.

5 MARKINGS AND LABELLING

5.1 The nominal volume or mass (as appropriate) of the contents shall be marked in accordance with the applicable requirements of SANS 289, *Labelling requirements for prepackaged products (prepackages) and general requirements for the sale of goods subject to legal metrology control.*

5.2 The manufacturer or supplier shall provide on a label on or firmly attached to the packaging of a chemical disinfectant with at least the legible and indelible information specified in 5.2.1 to 5.2.14::

5.2.1 The spectrum of activity which is claimed e.g. bactericidal, fungicidal, sporicidal and virucidal.

5.2.2 Area of application in accordance with table 1 and 2 in clause 3.2.

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5.2.3 The registration number referred to in clause 3.5, the address of the manufacturer, producer, proprietor or controlling company or, in the case of bottles packed for any other person or organisation, the full name and address of that person or organisation.

5.2.4 The name (s) of the active ingredient and percentage (of each) in letters not less than 4 mm in height;

5.2.5 Batch identification and the production date of the batch;

5.2.6 Expiry date of the chemical disinfectant which shall not be more than 2 years from the date of manufacture unless evidence has been provided supporting a longer time period through stability tests conducted in accordance with clause 6.4 of **SANS 11607-1**, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems.

5.2.7 Recommended method (s) of application (use concentration (s), contact times (s), volume to be applied and application procedure, and, if applicable, suitable diluents (s) and usage temperature (s);

5.2.8 For treated substances or article, a statement that clarifies that it is the substance or article itself that is protected from micro-organisms, e.g.; "This article or substance has been treated with .....to protect it from (or resist) bacterial growth on its surface",

5.2.9 The conditions of soiling as defined in 3.3 of SANS 54885;

5.2.10 Instructions for the storage of the chemical disinfectant;

5.2.11 The PH value at the recommended dilution; where relevant to the efficacy of the product;

5.2.12 The first-aid measures to be taken, for different exposure routes, i.e. inhalation, skin contact, eye contact and ingestion, if necessary;

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5.2.13 The warnings that the chemical disinfectant is not intended for internal use (ingestion) and should be stored away from children and foodstuffs; and

5.2.14 Where applicable, warnings that:

5.2.14.1 The chemical disinfectant must be shaken before use;

5.2.14.2 The chemical disinfectant could stain certain porous materials and/or corrode certain metals.

5.2.14.3 Contact of the undiluted chemical disinfectant and /or its fumes with skin and eyes should be avoided.

5.2.14.4 The chemical disinfectant should not be mixed with other incompatible substances unless recommended by its manufacturer.

5.2.14.5 The efficacy of the chemical disinfectant could be compromised if surfaces are soiled.

5.2.14.6 Personal protective equipment should be worn when the chemical disinfectant is being handled.

5.2.14.7 All markings and instructions for use shall at least be in the English language.

5.3 If a chemical disinfectant is offered for sale to the user of the product in additional packaging, that packaging shall also bear the required information as listed in 5.2.

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6. REQUIREMENTS FOR GOOD MANUFACTURING PRACTICE AND CONFORMITY OF PRODUCTION

6.1 The production (manufacturing and packaging) operations shall comply with clause 7 of SANS 22716, Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices. (All references to cosmetics in SANS 22716 shall be replaced with Chemical disinfectant as defined by this compulsory specification).

6.2 Manufacturers or importers of chemical disinfectants applied in industrial, domestic and institutional areas (excluding medical and food areas as defined in this compulsory specification) shall control production and/or conduct routine testing in accordance with Annexure B.

6.3 The manufacturer or importer of chemical disinfectants applied in **food and medical areas** shall appoint a certification body recognised by the Regulator in terms of its conformity assessment policy to verify the initial compliance and ongoing conformity of the production of chemical disinfectants with the requirements of this compulsory specification.

6.4 Quality Management Systems (QMS) such as **SANS 1853,** *Disinfectants and detergent-disinfectants for use in the food industry*; **SANS 9001**, *Quality management systems - Requirements* and **SANS 13485**, *Medical devices - Quality management systems- Requirements for regulatory purposes;* may upon evaluation and to the satisfaction of the NRCS be deemed to satisfy the requirements of **Clause 6.3** of this compulsory specification.

6.5 The efficacy performance of the chemical disinfectant substance shall comply with the requirements of Table 1 and 2 in clause 3.2 of this compulsory specification in the cases where clause 6.4 is applied.

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7. GENERAL PROVISIONS

7.1 Reference to specific micro-organisms made on the labels or any related marketing materials of chemical disinfectants shall only be for those the chemical disinfectant was tested against in accordance with the relevant SANS listed in clause 3.2 of this compulsory specification.

7.2 No person shall advertise a chemical disinfectant in any manner, which contains any information, claim, reference or declaration not permitted on the label in accordance with this compulsory specification.

7.3 Chemical disinfectants shall not contain, as part of their composition, any chemical substances that are banned/ restricted by any SA legislation and/or international agreements that SA has ratified.

8. EQUIVALENCE OF STANDARDS

8.1 Standards issued by other standardisation bodies will only be accepted if it is proven, in the form of a declaration report from an accredited conformity assessment body, to be technically equivalent to the relevant South African National Standard.

8.2 The applicant shall be responsible for obtaining such a declaration report.

8.3 Proof of conformity with such a standard shall be accepted as conformity with the corresponding South African National Standard.

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9. CONFORMITY TO REFERENCED STANDARDS

9.1 For the purposes of this compulsory specification, a new edition of a referenced standard shall become effective six months from the date of publication as a South African National Standard.

9.2 When a new edition of a referenced standard is published, chemical disinfectants originally approved in accordance with the previous edition of that standard may have their registration extended for up to two (2) years from the effective date of the new standard, subject to the requirements of Annexure A, unless declared otherwise by the Minister.

9.3 Chemical disinfectants that are already registered by the National Regulator for Compulsory Specifications (NRCS) in accordance with VC 8054:1999, shall submit proof of compliance with this Compulsory Specification within 12 months after its effective date to re-affirm their registration.

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ANNEX A - REGISTRATION OF DISINFECTANTS (NORMATIVE)

A.1 APPLICATION FOR REGISTRATION

The applicant shall apply to the NRCS for registration of every chemical disinfectant formulation. The application shall be accompanied by the following:

A.1.1 A list of raw materials for the chemical disinfectant formulation.

A.1.2 Details of the manufacturing plant/s where the chemical disinfectant is produced or warehoused in the case of imported products;

A.1.3 Evidence of conformity to prove compliance with all the relevant requirements of this compulsory specification including:

A.1.3.1 A completed and signed application form

A.1.3.2 Efficacy requirements including valid test reports issued by an accredited microbiological laboratory recognised in terms of the NRCS's Conformity Assessment Policy. For chemical disinfectants, a test report issued not more than-five (5) years before the date of submission to the NRCS;

A.1.3.3 A safety data sheet (SDS) that complies with clause 3.3 of this compulsory specification;

A.1.3.4 A product label that complies with Section 5 of this compulsory specification;

A.1.3.5 A sample of packaging material and a bill of materials used in the construction of the packaging material;

A.1.3.6 A Quality Management System (QMS) certificate as may be applicable in terms of clause 6.4 of this compulsory specification.

A.1.3.7 The NRCS may require additional information to clarify the above.

A.1.4 For chemical disinfectants used in **household and commercial areas**, a quality manual in accordance with clause 7 of SANS 22716, Cosmetics —

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Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices and information with regards to the control of production in accordance with Annexure B of this compulsory specification.

A.1.5 For **chemical disinfectants a applied in food and medical areas,** a copy of the Certification Agreement entered between the Applicant and the Certification Body in accordance with SANS 17065, *Conformity assessment — Requirements for bodies certifying products, processes and services*, indicating the following information as a minimum:

a) The name of the certification body.
b) The name and address of the manufacturing facility.
c) The scope of the certification granted, which shall include a statement that the chemical disinfectant complies with the requirements of the relevant national standard (s) as set out in clause 3.2 of this compulsory specification.
d) The schedule for control of conformity, which shall include at least the following information:

Lot size	Sample for inspection/testing	
	Sample size	Inspections/tests to be conducted
Number of units in a lot.	Number of units in the sample for inspection/testing.	Identification of the inspections/tests to be conducted in accordance with the relevant product standard.

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A.2 THE ISSUANCE OF REGISTRATION

A.2.1 The NRCS shall assess the evidence of conformity supplied by the applicant and shall grant registration if all requirements of this Compulsory specification are met.

A.2.2 The NRCS shall assign a unique registration number to each type of chemical disinfectant formulation approved.

A.2.3 The NRCS shall confirm that registration has been granted to the applicant by means of a registration certificate bearing the registration number referred to in clause 3.4 of this compulsory specification

A.2.4 The registration granted with respect to chemical disinfectants pursuant to this compulsory specification may be withdrawn by the NRCS, at any time, after the applicant has been notified in writing, if the requirements have not been met or maintained.

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ANNEXURE B
(Normative)

CONFORMITY OF PRODUCTION AND ROUTINE TESTS FOR CHEMICAL DISINFECTANTS USED IN INDUSTRIAL, DOMESTIC AND INSTITUTIONAL AREAS (EXCLUDING MEDICAL AND FOOD AREAS AS DEFINED IN THIS COMPULSORY SPECIFICATION)

B.1 The responsibilities of the applicant, particularly to the conformity of production:

B.1.1 The applicant or a conformity assessment body appointed by the applicant shall undertake the control of conformity of production.

B.1.2 Ensure that the routine test results are recorded and that the records remain available for a time period of 3 years after test.

B.1.3 Analyse the routine test results of each type of test to verify and ensure the conformity of production of the chemical disinfectant, making allowances for the variations of industrial production.

B.1.4 Ensure that at least the tests prescribed in paragraph B.3 are carried out routinely for each chemical disinfectant.

B.1.5 Ensure that when any samples show non-conformity with the test concerned, further samples are taken and tested. All the necessary steps must be taken to restore conformity of the corresponding production and prevent the sale of non-compliant products.

B.1.6 The applicant shall ensure that the body as agreed to by the NRCS in paragraph B.1.1 carries out conformity control on a statistical basis and by random sampling.

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B.2 The duties of the NRCS, particularly to the assessment of conformity of production:

B.2.1 The NRCS may at any time assess the effectiveness of the conformity of production.

B.2.2 The NRCS inspector may select samples to be sent to a conformity assessment body, when non-conformance is suspected in terms of control of production.

B.3 REQUIREMENTS FOR SAMPLING

B.3.1 Samples shall be taken in accordance with Table 1 in B.3.3

B.3.2 Samples should be selected by some rationalized criteria to ensure that they are truly representative of the lot, i.e. taken at random, evenly and throughout.

B.3.3 For the production to be considered to conform, the routine tests shall meet the following requirements:

Table 1- Sampling requirements

Lot size	Sample for inspection/testing	
	Sample size	Inspections/tests to be conducted
Number of units in a lot.	Number of units in the sample for inspection and testing.	Identification of the inspections and tests to be conducted in accordance with the relevant product standard.

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ANNEXURE C

NORMATIVE REFERENCES

This compulsory specification incorporates dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text. For dated references, subsequent amendments to or revisions of any of these publications apply to this specification only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to apply.

National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008) as amended through the Legal Metrology Act (Act No. 9 of 2014)

Regulation relating to the payment of fees in the form of levies as published by Government Notice No. R. 924 (Government Gazette No. 33615) of 15 October 2010.

SANS 54885, the *application of European Standards for Chemical disinfectants and antiseptics*

SANS 51276,*Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas —Test method and requirements (phase 2, step 1.*

SANS 51650, Chemical *disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of disinfectants and antiseptics used in food, industrial, domestic and institutional areas — Test method and requirements (phase 2, step 1).*

SANS 53704, *Chemical disinfectants — Quantitative suspension test for the evaluation of sporicidal activity of disinfectants used in food, industrial, domestic and institutional areas — Test method and requirements (phase 2, step 1).*

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SANS 53610, *Chemical disinfectants- Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of disinfectants used in food and industrial areas - Test method and requirements (phase 2, step 1).*

SANS 53727, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area - Test method and requirements (phase 2, step 1)*

SANS 53624, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area - Test method and requirements (phase 2, step 1).*

SANS 54476, *Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2, step 1).*

SANS 11014, *Safety data sheet for chemical substances - content and order of sections.*

***SANS 289**, Labelling requirements for prepackaged products (prepackages) and general requirements for the sale of goods subject to legal metrology control.*

SANS 22716, *Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices.*

***SANS 1853**, Disinfectants and detergent-disinfectants for use in the food industry.*

***SANS 9001**, Quality management systems – Requirements.*

***SANS 13485**, Medical devices -Quality management systems- Requirements for regulatory purposes.*

SANS 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems.*

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ANNEXURE D

LIST OF ACTIVE INGREDIENTS USED IN CHEMICAL DISINFECTANT FORMULATIONS

(Informative)

D.1 The list provided below is non-exhaustive but is provided for use as a guideline.

D.2 The active ingredient may be formulated in combination with other compatible actives.

1. Quaternary Ammonium Compounds (QACs)

- alkyltrimethyl ammonium bromide
- dialkyldimethyl ammonium chloride
- domiphen bromide
- benzethonium chloride
- cetylpyridinium chloride
- alkyl(dichlorophenyl)methyldimethyl chloride
- polymeric quaternary ammonium compound

2. Phenols (Clear soluble, white and black fluid) and chlorinated phenols

- Phenol
- Cresol
- Xylenol
- Ethylphenol
- Phenylphenol
- Chlorometaxylenol
- Dichlorometaxylenol
- Chloro-o-phenylphenol
- Benzylchlorophenol
- Benzylchlorophenol
- Parachlorometaxylenol

3. Halogen-releasing compounds

- Sodium hypochlorite
- Potassium hypochlorite
- Lithium hypochlorite
- Calcium hypochlorite
- Trichloroisocyanuric acid
- Sodium dichloroisocyanurate

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- Dichlorodimethylhydantoin
- Chloramine-T,
- Halozone,
- N-chlorosuccinimide
- Chlorinated trisodium phosphate
- Chlorine dioxide
- Bromine releasing products
    - Bromochlorodimethylhydantoin
    - Sodium bromide

4. Aldehydes

- Formaldehyde
- Glutaraldehyde
- Glyoxaldehyde
- Glycidaldehyde
- Succindialdeyhyde

5. Biguanides and polymeric biguanides

- Alexidine,
- Chlorhexidine
- Polymeric Biguanides.

6. Amphoterics

- Amphoteric compounds formulated with either anionic or cationic substances.

7. Iodine-based compounds

- Iodophors stabilised with either acids or acidic buffers.

8. Alcohols

- Ethyl alcohol
- Isopropyl alcohol
- M-propyl alcohol
- Terpene alcohols
- Phenoxyethanol
- Phenylethyl alcohol

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9. Acids

- Organic acids e.g. formic, citric, lactic, mallic, glutaric and propionic acids
- Inorganic acids e.g. nitric, hydrochloric, sulphuric, phosphoric and sulphamic acids

10. Peroxygen-based compounds

- Hydrogen peroxide
- Peracetic acid
- Sodium and potassium monopersulphates
- Sodium metaperiodate

11. Alkalis

- Sodium and potassium hydroxide
- Quicklime (calcium oxide)
- Sodium carbonate
- sodium metasilicate

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ANNEXURE E
CHEMICALS CONTROLLED BY INTERNATIONAL CONVENTIONS
(Informative)

E.1 The Stockholm Convention (Persistent Organic Pollutants)

E.1.1 List of identified POPs and their management measures

Chemical	Intentional production and use - Pesticide	Intentional production and use - industrial chemical	Un-intentional production	Annex and Management measure
Aldrin	✓			Annex A – Elimination for production, limited used as local ectoparasiticide
Chlordane	✓			Annex A – exemption for production in countries registering exemptions, limited use
Dieldrin	✓			Annex A – Elimination for production, limited use in agricultural operations
Endrin	✓			Annex A – Elimination
Heptachlor	✓			Annex A – Elimination for production, limited use
Hexachlorobenzene	✓		✓	Annex A – exemption for production in countries registering exemptions, limited use Annex C - Implement measures to reduce or eliminate released from unintentional production
Mirex	✓			Annex A – exemption for production in countries registering exemptions, limited use
Toxaphene	✓			Annex A – Elimination
Polychlorinated Biphenyls		✓	✓	Annex A – Elimination for production, elimination for use by 2025
DDT	✓			Annex B – Restricted use for malaria vector control and under exemption for use as an intermediate in the production of dicofol
Dioxins (polychlorinated dibenzo-p-dioxins)			✓	Annex C - Implement measures to reduce or eliminate released from unintentional production
Furans (polychlorinated dibenzofurans)			✓	Annex C - Implement measures to reduce or eliminate released from unintentional production
POPs listed by COP 4 2009				

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Chlordecone	✓			Annex A – Elimination
Hexabromobiphenyl		✓		Annex A – Elimination
Hexabromodiphenyl ether and heptabromodipheny l ether		✓		Annex A – Elimination for production, exemption for use as articles containing these chemicals for recycling
Alpha hexachlorocyclohex ane	✓		✓	Annex A – Elimination Annex C – manage unintentionally production
Beta hexachlorocyclohex ane	✓		✓	Annex A – Elimination Annex C – manage unintentionally production
Lindane	✓			Annex A – exemption for production in countries registering exemptions for use as a human health pharmaceutical
Pentachlorobenzen e (PeCB)	✓	✓	✓	Annex A – Elimination Annex C – manage unintentionally produced
Perfluorooctane sulfonic acid (PFOS) its salts & perfluorooctane sulfonyl fluoride (PFOS-F)		✓		Annex B – phase out with acceptable purpose and specific exemptions
Tetrabromodiphenyl ether and penta-bromodiphenyl ether		✓		Annex A – Elimination for production, exemption for use as articles containing these chemicals for recycling
Source: SA's National Implementation Plan for the Stockholm Convention (2011)				

E.2 Information on other international conventions on controlled chemicals may be found on:

https://www.thedti.gov.za/industrial_development/chemicals.jsp

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