

Technical file for chemical disinfectants

For an application for the registration of a chemical disinfectant formulation in terms of the Compulsory Specification for chemical disinfectants (herein referred to as VC8054:2017) as published by Government Notice No. 1119 (Government Gazette No. 41186) of 20 October 2017.

The technical file for each chemical disinfectant formulation shall consist of the following:

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1 Application form

Completed and signed NRCS form No. CMM FM 8054-3.

NOTE The applicant shall be the manufacturer or importer of the chemical disinfectant formulation. The manufacturer or importer shall be an established legal business entity within the Republic of South Africa.

2 Manufacturing plants and warehouses

Full name and physical address of each manufacturing plant where the chemical disinfectant formulation is produced or, in the case of an imported product, warehoused.

3 List of raw materials

A list of the raw materials and active ingredient(s) for the chemical disinfectant formulation. The list of raw materials shall state the concentration of each listed active ingredient.

4 Safety data sheet (SDS)

An SDS relevant to the chemical disinfectant formulation.

NOTE SDSs shall satisfy the requirements of paragraphs 5, A.2, A.4, A.5, A.8, A.9, A.10, A.11 and A.12 of the latest edition of SANS 11014.

5 Product label

A product label for the chemical disinfectant formulation as required by paragraph 5 of VC8054:2017.

NOTE 1 The product label for the chemical disinfectant formulation shall be supplied in a scale of 1:1. If the product label is not supplied in a scale of 1:1, it shall include an indication of the print size of the information on the label, e.g. by means of an indicated scale or measurements.

NOTE 2 When the statement of net quantity as required by paragraph 5.1 of VC8054:2017 is indicated on the packaging material of the chemical disinfectant formulation, then the details of such markings on the packaging material shall accompany the product label.

6 Proof of compliance

Copies of test reports demonstrating compliance with the applicable requirements of paragraphs 3.1 and 3.2 of VC8054:2017, and where applicable, with the requirement of paragraph 5.2.6 of VC8054:2017.

NOTE 1 In accordance with the requirement of paragraph 5.2.6 of VC8054:2017, the expiry date or shelf life of the chemical disinfectant formulation (which shall be not more than two (2) years from date of manufacture) shall be indicated on the product label. When an expiry date or shelf life of more than two (2) years from date of manufacture is indicated on the product label, the technical file shall include a test report demonstrating that the chemical disinfectant formulation still satisfied the applicable requirements of paragraphs 3.1 and 3.2 of VC8054:2017 after it was subjected to stability tests conducted in accordance with the requirements of paragraph 6.4 of the latest edition of SANS 11607-1.

NOTE 2 Only test reports from a conformity assessment body (CAB) that has been accredited in accordance with the latest edition of SANS 17025 by a signatory to the International Laboratory Accreditation Co-Operation's Mutual Recognition Agreement shall be accepted as proof of compliance with the applicable requirements of paragraphs 3.1 and 3.2 of VC8054:2017. No approval certificates or product certification certificates shall be accepted.

NOTE 3 Test reports shall satisfy the requirements of the latest edition of SANS 17025. See NRCS form No. CMM FM 8054-5 for guidance.

NOTE 4 Test reports shall not be older than five (5) years from the date of receipt.

7 Conformity of production and routine tests

7.1 Chemical disinfectant formulations for use in food and medical areas

7.1.1 A product certification document that was issued by a CAB in accordance with the requirements of the latest edition of SANS 17065, demonstrating that the chemical disinfectant formulation satisfies the requirements of the latest edition of SANS 1853, or the requirements of the latest edition of a relevant product specification standard as set out in paragraph 3.2 of VC8054:2017;

OR

A certification document that was issued by a CAB in accordance with the requirements of the latest edition of SANS 17021-1, demonstrating that the management system applied by the manufacturer or importer satisfies the requirements of the latest edition of either SANS 9001 or SANS 13485.

NOTE 1 Only product certification documents from a CAB that has been accredited by a signatory to the International Accreditation Forum's Mutual Recognition Agreement (IAF MRA) in accordance with the latest edition of SANS 17065 shall be acceptable.

NOTE 2 Product certification documents shall satisfy the requirements of the latest edition of SANS 17065 and shall still be valid on the date of receipt.

NOTE 3 Only management system certification documents from a CAB that has been accredited by a signatory to the IAF MRA in accordance with the latest edition of SANS 17021-1 shall be acceptable.

NOTE 4 Management system certification documents shall satisfy the requirements of the latest edition of SANS 17021-1 and shall still be valid on the date of receipt.

7.1.2 Completed NRCS form No. CMM FM 8054-6.

7.2 Chemical disinfectant formulations for use in industrial, domestic and institutional areas

Completed NRCS form No. CMM FM 8054-6.

8 Other

Any other materials that the applicant may wish to include in the technical file in order to support the application for registration, e.g. marketing materials.
