

CMM PROC 3:2012

Registration of disinfectants and detergent-disinfectants

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Contents		Page
1	Scope	3
2	Normative references.....	3
3	Terms and definitions	4
4	Symbols and abbreviated terms	4
5	General requirements	5
	5.1 Communications.....	5
	5.2 Data.....	5
	5.3 Records.....	5
	5.4 Proof of compliance.....	5
	5.5 Technical files.....	5
6	Application for registration	6
7	Type-examination of disinfectants and detergent-disinfectants.....	8
8	Rejection of registration	9
9	REGISTRATION GRANTED.....	10
10	Extension of registration	12
11	Withdrawal of registration	16
12	Forms	17
	Annexure A: Arrangement of registration number.....	18
	Annexure B: REGISTRATION REJECTED.....	19
	Annexure C: NRCS form No. AA33.....	20
	Revision record.....	21
Attachments		
	<i>NRCS Inspection Report</i> for disinfectants and detergent-disinfectants	Attached
	<i>NRCS REGISTRATION GRANTED certificate</i> for disinfectants and detergent-disinfectants	Attached
	<i>NRCS REGISTRATION EXTENDED certificate</i> for disinfectants and detergent-disinfectants	Attached
	<i>NRCS REGISTRATION WITHDRAWN certificate</i> for disinfectants and detergent-disinfectants	Attached
Tables		
	Table 1 — Classes of disinfectants and detergent-disinfectants	11

1 Scope

This document sets out the procedures that shall be used by CMM for the registration of disinfectants and detergent-disinfectants in terms of VC8054:1999.

This document applies to the following:

- a) All staff members of CMM involved in the registration of disinfectants and detergent-disinfectants.
- b) All disinfectant and detergent-disinfectant formulations as covered by the scope of VC8054:1999.

This document covers the following:

- a) General requirements for the registration of disinfectants and detergent-disinfectants.
- b) Application for the registration of disinfectants and detergent-disinfectants.
- c) Type-examination of disinfectants and detergent-disinfectants.
- d) Refusal to register disinfectants and detergent-disinfectants.
- e) Registration of disinfectants and detergent-disinfectants.
- f) Extension of registration to cover changes to registered disinfectants and detergent-disinfectants.
- g) Withdrawal of registration of disinfectants and detergent-disinfectants.

2 Normative references

This document incorporates by 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 document only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Compulsory Specification for disinfectants and detergent-disinfectants (herein referred to as VC8054:1999) as published by Government Notice No. R. 529 (Government Gazette No. 19999) of 14 May 1999.

Corporate Policy No. NRCS-CPO 124: *'Records management policy'*

Departmental Procedure No. 5337 E008: *'Sanctions'*

National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008)

Regulations 2 and 12 relating to the payment of fees in the form of levies and the registration of manufacturers, builders, importers and service providers as published by Government Notice No. R. 924 (Government Gazette No. 33615) of 15 October 2010.

SANS 11014: *'Safety data sheet for chemical products — Content and order of sections'*

SANS 17025: *'General requirements for the competence of testing and calibration laboratories'*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

applicant

Manufacturer or importer who applies for the registration of a disinfectant or detergent-disinfectant formulation. The manufacturer or importer shall be established within the Republic of South Africa.

disinfectant or detergent-disinfectant formulation

A category of disinfectant or detergent-disinfectant that does not differ in chemical composition. However, the disinfectant or detergent-disinfectant formulation may include a range of product names, colour and perfume variants.

ILAC-accredited testing authority

A laboratory that has been accredited in accordance with SANS 17025 or equivalent standard, by an organization that is part of the ILAC Mutual Recognition Arrangement.

inspector

Staff member of CMM responsible for the type-examination and registration of disinfectants and detergent-disinfectants.

registration

Confirmation by the NRCS that a disinfectant or detergent-disinfectant formulation has satisfied the requirements of VC8054:1999.

4 Symbols and abbreviated terms

CMM

NRCS Chemicals, Mechanical & Materials Division

ILAC

International Laboratory Accreditation Co-operation

MSDS

material safety data sheet

NPP

Non-Perishable Products

5 General requirements

5.1 Communications

All communications may be verbally, telephonically, electronically or in writing, except where otherwise stated in this document.

5.2 Data

5.2.1 *Technical File Database / Technical File Database – Health related products* is stored on the NRCS computer network. The Manager: Approvals shall be responsible for the maintenance of the aforementioned database.

5.2.2 *Homologation Database / Registration Database Disinfectants & Detergent-disinfectants* is stored on the NRCS computer network and shall be maintained by the Manager: Approvals.

5.3 Records

5.3.1 All records pertaining to the registration of a disinfectant or detergent-disinfectant formulation shall be kept in the applicable type-examination file during the type-examination and registration process. Records shall be kept for all documentation generated and received during the execution of this procedure. The records to be kept are identified in this procedure.

5.3.2 Client files are kept in room C314A. The contents of the client files shall be kept for a period of at least three (3) years after which the Manager: Approvals may forward it to the NRCS Records Manager for disposal or archiving in accordance with Corporate Policy No. NRCS-CPO 124.

5.3.3 Certificate files for disinfectants/detergent-disinfectants shall be kept in room C331. The Manager: Approvals shall be responsible for the maintenance of these files.

5.4 Proof of compliance

5.4.1 *Criteria*

5.4.1.1 Disinfectants and detergent-disinfectants shall be examined for compliance with all the relevant requirements of paragraphs 4.2 and 7.2 of VC8054:1999.

5.4.2 *Evidence*

5.4.2.1 Only test reports from an ILAC accredited testing authority shall be accepted as proof of compliance with the requirements of paragraph 4.2 of VC8054:1999. Test reports shall not be older than two years on date of receipt and shall meet the requirements of SANS 17025.

5.4.2.2 MSDSs shall satisfy the requirements of paragraph 5 of SANS 11014.

5.5 Technical files

5.5.1 An AA33 form shall be completed and issued to the applicant:

- a) On receipt of application documents or technical files from the applicant.
- b) When the applicant or his agent collects technical files and registration certificates from CMM.

A copy of the AA33 form shall be kept in the relevant client file.

6 Application for registration

6.1 The applicant may request the registration of a disinfectant or detergent-disinfectant formulation verbally, telephonically, electronically or in writing.

6.2 On receipt of a request, the inspector shall determine if the product is covered by the scope of VC8054:1999.

6.3 Product not covered by VC8054:1999

6.3.1 Should it be found that the product is not covered by the scope of VC8054:1999, the inspector shall inform the applicant accordingly (electronically or in writing). The inspector shall file the following in the relevant client file (see paragraph 5.3.2):

- a) A copy of the abovementioned communication to the applicant.
- b) Documented evidence (e.g. labelling of the product, MSDS, marketing material, etc.) that demonstrated that the product was not covered by the scope of VC8054:1999.

6.4 Product covered by VC8054:1999

When it is found that the product is covered by the scope of VC8054:1999, the inspector or Administration Officer: Approvals shall issue the following documents to the applicant:

- a) CMM FM 8054-1;
- b) CMM FM 8054-2;
- c) CMM FM 8054-3.

6.5 The applicant will submit the items as communicated to him by means of CMM FM 8054-1 to CMM for processing.

6.6 Preliminary examination of application

6.6.1 Upon receipt of the application by an inspector, the inspector shall do a preliminary examination of the application in order to determine whether the applicant has included the following items:

- a) Proof of payment of the non-refundable application fee for the registration of the disinfectant or detergent-disinfectant formulation.
- b) Completed and signed NRCS form No. CMM FM 8054-3.
- c) Label or information on the container for the disinfectant or detergent-disinfectant formulation.
- d) MSDS for the disinfectant or detergent-disinfectant formulation.
- e) List of raw materials for the disinfectant or detergent-disinfectant formulation.
- f) Test report/s.

6.6.2 *Incomplete application*

6.6.2.1 When it is determined that the applicant has not included one or more of the items as listed in paragraph 6.6.1, the inspector shall inform the applicant of the following:

- a) The item/s that was/were excluded from the application.
- b) The Division will proceed with the processing of the application, but the examination of the application can only be finalised once all outstanding items have been submitted.

6.6.3 The inspector shall forward the application to the Administration Officer: Approvals for registration and a financial check.

6.7 Registration of application

The Administration Officer: Approvals shall take the following actions:

- 6.7.1 The application shall be registered in the *Technical File Database – Health related products*.
- 6.7.2 A type-examination file shall be opened. The type-examination file and all relevant documentation in the technical file shall be marked with the allocated technical file number.

6.8 Financial check

6.8.1 The Administration Officer: Approvals shall ensure with the Finance Division of the NRCS that the applicant has been registered as a levy payer in terms of regulation 2 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.

6.8.2 The Administration Officer: Approvals shall check for the following:

- a) If the applicant has included proof of payment of the non-refundable application fee for the registration of the disinfectant or detergent-disinfectant formulation.
- b) If the applicant's levy return forms and payments are up to date (check with the Finance Division of the NRCS).
- c) If the applicant owes any other outstanding fees to the NRCS (check with the Finance Division of the NRCS).

6.9 When it is found that the applicant has not met his financial obligations towards the NRCS as set out in paragraph 6.8.2, the Administration Officer: Approvals shall take the following actions:

6.9.1 *Application without proof of payment*

The Administration Officer: Approvals shall request the Finance Division to invoice the applicant for the due application fee for registration. A copy of the invoice shall be filed in the type-examination file.

6.9.2 The applicant shall be informed electronically or in writing of the following:

- a) The application for registration will not be considered, because of the outstanding levy return forms and payments, or other outstanding fees, or that no proof of payment of the non-refundable application fee for the registration of the disinfectant or detergent-disinfectant formulation was included in the application.
- b) The application will be rejected if no proof of payment of the outstanding fee/s has been received within three (3) weeks from the date of notification.

The Administration Officer: Approvals shall file a copy of the notification in the relevant type-examination file.

6.9.3 The actions as set out in paragraph 8 may be taken when no proof of payment of the outstanding fee/s has been received within the three (3) week notification period.

6.10 When it is found that the applicant has met his financial obligations towards the NRCS, the Administration Officer: Approvals shall take the following actions:

6.10.1 The Administration Officer: Approvals shall request the Finance Division to invoice the applicant for the received proof of payment of the application fee. The Administration Officer: Approvals shall file a copy of the invoice indicating full payment of the application fee in the relevant type-examination file.

6.10.2 The Administration Officer: Approvals shall forward the type-examination file to the inspector who has been nominated by the Manager: Approvals to examine the application.

7 Type-examination of disinfectants and detergent-disinfectants

7.1 The application shall be examined to establish whether the applicant has submitted the items as communicated to him by means of CMM FM 8054-1.

The technical file and its contents shall be examined for completeness and correctness in accordance with the requirements of CMM FM 8054-2.

The technical file and its contents shall be examined to establish its suitability with respect to demonstrating compliance with paragraphs 4.2 and 7.2 of VC8054:1999.

The results of the examination shall be recorded in a *NRCS Inspection Report* for disinfectants and detergent-disinfectants as attached to this document.

7.2 Unacceptable technical file

The inspector shall take the following actions should the technical file and its contents not meet the criteria as set out in paragraph 7.1:

7.2.1 The inspector shall notify the applicant electronically or in writing of the following:

- a) The applicant shall be notified of the problems with the technical file and requested to resubmit a corrected file within four (4) months from the date of notification.
- b) The technical file must be collected at the NRCS premises for correction purposes.

7.2.2 The inspector shall file copies of the notification and technical file in the type-examination file.

7.3 The actions as set out in paragraph 8 shall be taken should the applicant fail to resubmit the corrected technical file within the four (4) month period.

7.4 The following actions shall be taken when it is found that the resubmitted technical file still did not meet the criteria as set out in paragraph 7.1:

7.4.1 One copy of the technical file shall be made and kept in the type-examination file.

7.4.2 The inspector shall invite the applicant to a meeting at the NRCS premises. The purpose of the meeting will be the following:

- a) Explanation of the findings on the technical file.
- b) The applicant shall be supplied with a copy of the findings.
- c) The inspector shall return the technical file to the applicant during the meeting for correction purposes.
- d) The applicant shall be requested to resubmit a corrected technical file within three (3) weeks from the date of the meeting.

7.4.3 The actions as set out in paragraph 8 shall be taken should:

- a) the applicant fail to resubmit the corrected technical file within the three (3) week period after the meeting date or;
- b) when it is found that the resubmitted technical file still did not meet the criteria as set out in paragraph 7.1.

7.5 Acceptable technical file

7.5.1 The actions as set out in paragraph 9 shall be taken when the technical file meets the criteria as set out in paragraph 7.1.

8 Rejection of registration

- 8.1** The inspector shall complete and sign the inspection report. The inspector shall include the inspection report in the type-examination file.
- 8.2** The inspector shall prepare a letter as set out in Annexure B and include it in the type-examination file.
- 8.3** The inspector shall forward the type-examination file to the Manager: Approvals for review.
- 8.4** Once satisfied with the contents of the inspection report and letter, the Manager: Approvals shall sign the aforementioned documents.
- 8.5** The inspector shall file copies of the following documents in the type-examination file:
- a) The signed letter in paragraph 8.4;
 - b) *NRCS Inspection Report*;
 - c) Technical file (when available).
- 8.6** The inspector shall ensure that the signed letter in paragraph 8.4 is forwarded to the applicant electronically or by mail.
- 8.7** The inspector shall file the type-examination file in the relevant client file.

9 REGISTRATION GRANTED

- 9.1** The inspector shall complete and sign the inspection report and include it in the type-examination file.
- 9.2** The inspector shall register the disinfectant or detergent-disinfectant formulation in the *Registration Database Disinfectants & Detergent-disinfectants*. A registration number shall be assigned to the disinfectant or detergent-disinfectant formulation. The registration number shall consist of the following digit groupings:

Act5GNR529	Customer Account No. that is obtainable from the Finance Division of the NRCS	Class of disinfectant or detergent-disinfectant in accordance with column 1 for the corresponding description in column 2 of Table 1	Sequential number
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NOTE See Annexure A for an example of a registration number.

Table 1 — Classes of disinfectants and detergent-disinfectants

1	2
Class	Description of active ingredient
010	Detergent-disinfectant
020	Medical instrument disinfectant
030	Organic halogen base
040	Quaternary ammonium compound
050	Aerosol
060	Polymeric biguanide hydrochloride base
070	Chlorine base
071	Ammonium chloride
072	Sodium hypochlorite / Sodium chlorite
080	Peracetic acid
081	Coal tar acid
082	Acetic acid
083	Sulphuric acid
090	Alcohol base
100	Iodine
110	Glutaraldehyde
120	Phenol disinfectant
130	Peroxygen disinfectant
140	Other
150	Dodecyl benzene
160	Sodium hydroxide

9.3 REGISTRATION GRANTED certificate

9.3.1 The inspector shall prepare a *NRCS REGISTRATION GRANTED certificate* for disinfectants and detergent-disinfectants as attached to this document.

9.3.2 The inspector shall mark the following documents with the allocated registration number and initial it:

- a) List of raw materials for the disinfectant or detergent-disinfectant formulation;
- b) Label or information on the container for the disinfectant or detergent-disinfectant formulation.

The documents shall be described in the *NRCS REGISTRATION GRANTED certificate* for disinfectants and detergent-disinfectants.

9.3.3 The inspector shall emboss the golden star on the certificate with the NRCS emblem embossment machine.

9.3.4 The inspector shall sign the prepared *NRCS REGISTRATION GRANTED certificate* and include it in the type-examination file.

9.4 The inspector shall forward the type-examination file to the Manager: Approvals for review.

9.5 Once satisfied with the contents of the inspection report and *NRCS REGISTRATION GRANTED certificate*, the Manager: Approvals shall sign the aforementioned documents.

9.6 The inspector shall compile the following:

<p>ORIGINAL <i>NRCS REGISTRATION GRANTED certificate</i></p> <p style="text-align: center;">↓</p> <p>Attach to ORIGINAL certificate: COPIES of marked documents in paragraph 9.3.2.</p> <p style="text-align: center;">↓</p> <p>Submit to applicant.</p>	<p>COPY of <i>NRCS REGISTRATION GRANTED certificate</i></p> <p style="text-align: center;">↓</p> <p>Attach to COPY of certificate: ORIGINAL marked documents in paragraph 9.3.2.</p> <p style="text-align: center;">↓</p> <p>File in <i>certificate files for disinfectants/detergent-disinfectants</i>.</p>
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9.7 The inspector shall file the copy of the *NRCS REGISTRATION GRANTED certificate* and attached documents in the *certificate files for disinfectants/detergent-disinfectants*.

9.8 The inspector shall notify the applicant in writing or by e-mail that the approved *NRCS REGISTRATION GRANTED certificate* must be collected at the NRCS premises. The inspector shall file a copy of the aforementioned notification in the type-examination file.

9.9 The inspector shall file the type-examination file in the relevant client file.

10 Extension of registration

10.1 Notification

10.1.1 In accordance with the terms and conditions of issue of a *NRCS REGISTRATION GRANTED certificate* for disinfectants and detergent-disinfectants the holder of the registration shall notify CMM of any modifications that will be made to the disinfectant or detergent-disinfectant formulation itself, or its label or information on the container.

10.1.2 The inspector shall establish the nature of the changes that will be made to the disinfectant or detergent-disinfectant formulation, and request in writing or electronically the following from the applicant:

- a) A letter from the holder of the registration indicating the modifications that will be made to the registered disinfectant or detergent-disinfectant formulation.
- b) Documented evidence as per NRCS form No. VC8054-C indicating such changes.
- c) Proof of payment of the current non-refundable application fee for the extension of registration of a disinfectant or detergent-disinfectant formulation as published in the Government Gazette in terms of section 14(3)(b) of Act No. 5 of 2008.

10.2 Registration of application

On receipt of the requested items as per paragraph 10.1.2, the Administration Officer: Approvals shall take the following actions:

10.2.1 The application shall be registered in the *Technical File Database – Health related products*.

10.2.2 A type-examination file shall be opened. The type-examination file and all relevant documentation in the technical file shall be marked with the allocated technical file number.

10.3 Financial check

10.3.1 The Administration Officer: Approvals shall check for the following:

- a) If the applicant's levy return forms and payments are up to date (check with the Finance Division of the NRCS).
- b) If the applicant owes any other outstanding fees to the NRCS (check with the Finance Division of the NRCS).
- c) If the applicant has included proof of payment of the non-refundable application fee for the extension of registration of the disinfectant or detergent-disinfectant formulation.

10.4 When it is found that the applicant has not met his financial obligations towards the NRCS as set out in paragraph 10.3.1, the Administration Officer: Approvals shall take the following actions:

10.4.1 ***Application without proof of payment***

The Administration Officer: Approvals shall request the Finance Division to invoice the applicant for the due application fee for extension of registration. A copy of the invoice shall be filed in the type-examination file.

10.4.2 The applicant shall be informed electronically or in writing of the following:

- a) The application for the extension of registration of the disinfectant or detergent-disinfectant formulation will not be considered, because of the outstanding levy return forms and payments, or other outstanding fees, or that no proof of payment of the non-refundable application fee for the extension of registration was included in the application.
- b) The application will be rejected if no proof of payment of the outstanding fee/s has been received within three (3) weeks from the date of notification.

The Administration Officer: Approvals shall file a copy of the notification in the relevant type-examination file.

10.4.3 The actions as set out in paragraph 8 may be taken when no proof of payment of the outstanding fee/s has been received within the three (3) week notification period.

10.5 When it is found that the applicant has met his financial obligations towards the NRCS, the Administration Officer: Approvals shall take the following actions:

10.5.1 The Administration Officer: Approvals shall request the Finance Division to invoice the applicant for the received proof of payment of the application fee. The Administration Officer: Approvals shall file a copy of the invoice indicating full payment of the application fee in the relevant type-examination file.

10.5.2 The Administration Officer: Approvals shall forward the type-examination file to the inspector who has been nominated by the Manager: Approvals to examine the application.

10.6 Examination of technical file

10.6.1 The inspector shall examine the technical file and its contents to establish its suitability with respect to demonstrating the following:

- a) The modifications made to the disinfectant or detergent-disinfectant formulation itself, or its label or information on the container.
- b) Compliance with VC8054:1999 as a result of the modifications made.

The results of the examination shall be recorded in a *NRCS Inspection Report* for disinfectants and detergent-disinfectants as attached to this document.

10.7 Unacceptable technical file

The inspector shall take the following actions should the technical file and its contents not meet the criteria as set out in paragraph 10.6.1:

10.7.1 The inspector shall notify the applicant electronically or in writing of the following:

- a) The applicant shall be notified of the problems with the technical file and requested to resubmit a corrected file within four (4) months from the date of notification.
- b) The technical file must be collected at the NRCS premises for correction purposes.

10.7.2 The inspector shall file copies of the notification and technical file in the type-examination file.

10.7.3 The actions as set out in paragraph 8 shall be taken should the applicant fail to resubmit the corrected technical file within the four (4) month period.

10.7.4 The following actions shall be taken when it is found that the resubmitted technical file still did not meet the criteria as set out in paragraph 10.6.1:

10.7.4.1 One copy of the technical file shall be made and kept in the type-examination file.

10.7.4.2 The inspector shall invite the applicant to a meeting at the NRCS premises. The purpose of the meeting will be the following:

- a) Explanation of the identified non-conformances on the technical file.
- b) The applicant shall be supplied with a copy of the identified non-conformances.
- c) The inspector shall return the technical file to the applicant during the meeting for correction purposes.
- d) The applicant shall be requested to resubmit a corrected technical file within three (3) weeks from the date of the meeting.

10.7.4.3 The actions as set out in paragraph 8 shall be taken should:

- a) the applicant fail to resubmit the corrected technical file within the three (3) weeks period after the meeting date or;
- b) when it is found that the resubmitted technical file still did not meet the criteria as set out in paragraph 10.6.1.

10.8 Acceptable technical file

10.8.1 The actions as set out in paragraph 10.9 shall be taken when the technical file meets the criteria as set out in paragraph 10.6.1.

10.9 REGISTRATION EXTENDED

10.9.1 The inspector shall complete and sign the inspection report. The inspection report shall be filed in the type-examination file.

10.9.2 The inspector shall register the extension of registration of the disinfectant or detergent-disinfectant formulation in the *Registration Database Disinfectants & Detergent-disinfectants* and shall assign a sequential "Extension No." for such an extension. The Extension Number shall be in Roman numerals, e.g. I, II, III, etc.

10.10 REGISTRATION EXTENDED certificate

10.10.1 The inspector shall compile a *NRCS REGISTRATION EXTENDED certificate* as attached to this document.

10.10.2 The inspector shall mark the following documents with the appropriate registration number and initial it:

- a) When relevant, the list of raw materials demonstrating the modifications made to the disinfectant or detergent-disinfectant formulation;
- b) When relevant, details of the modifications made to the label or information on the container for the disinfectant or detergent-disinfectant formulation.

The relevant documents and alterations shall be described in the *NRCS REGISTRATION EXTENDED certificate*.

10.10.3 The inspector shall emboss the golden star on the *NRCS REGISTRATION EXTENDED certificate* with the NRCS emblem embossment machine.

10.10.4 The inspector shall sign the prepared *NRCS REGISTRATION EXTENDED certificate* and include it in the type-examination file.

10.11 The inspector shall forward the type-examination file to the Manager: Approvals for review.

10.12 Once satisfied with the contents of the inspection report and *NRCS REGISTRATION EXTENDED certificate*, the Manager: Approvals shall sign the aforementioned documents.

10.13 The inspector shall compile the following:

<p>ORIGINAL <i>NRCS REGISTRATION EXTENDED certificate</i></p> <p style="text-align: center;">↓</p> <p>Attach to ORIGINAL certificate: COPIES of marked documents in paragraph 10.10.2.</p> <p style="text-align: center;">↓</p> <p>Submit to applicant.</p>	<p>COPY of <i>NRCS REGISTRATION EXTENDED certificate</i></p> <p style="text-align: center;">↓</p> <p>Attach to COPY of certificate: ORIGINAL marked documents in paragraph 10.10.2.</p> <p style="text-align: center;">↓</p> <p>File in <i>certificate files for disinfectants/detergent-disinfectants</i>.</p>
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- 10.14** The inspector shall file the copy of the *NRCS REGISTRATION EXTENDED certificate* and attached documents in the *certificate files for disinfectants/detergent-disinfectants*.
- 10.15** The inspector shall notify the applicant in writing or by e-mail that the approved *NRCS REGISTRATION EXTENDED certificate* must be collected at the NRCS premises. The inspector shall file a copy of the aforementioned notification in the type-examination file.
- 10.16** The inspector shall file the type-examination file in the relevant client file.

11 Withdrawal of registration

When a written request has been received for the withdrawal of the registration for a disinfectant or detergent-disinfectant formulation in accordance with Departmental Procedure No. 5337 E008, the Manager: Approvals shall ensure the following.

- 11.1 The registration number and related product information shall be deleted from the *Registration Database Disinfectants & Detergent-disinfectants*.
- 11.2 The copy/copies of the NRCS REGISTRATION GRANTED/EXTENDED certificate/s that was/were issued for the disinfectant or detergent-disinfectant formulation shall be removed from the certificate files for disinfectants/detergent-disinfectants.
- 11.3 **REGISTRATION WITHDRAWN certificate**
- 11.3.1 A *NRCS REGISTRATION WITHDRAWN certificate* as attached to this document shall be compiled.
- 11.3.2 The red star on the *NRCS REGISTRATION WITHDRAWN certificate* shall be embossed with the NRCS emblem embossment machine.
- 11.3.3 The Manager: Approvals shall sign the *NRCS REGISTRATION WITHDRAWN certificate*.
- 11.4 The following shall be submitted to the holder of the registration:
- 11.4.1 A **copy** of the *NRCS REGISTRATION WITHDRAWN certificate*;
- 11.4.2 An electronic or written notification containing the following information as a minimum:
- The registration of the disinfectant or detergent-disinfectant formulation pursuant to the Compulsory Specification for disinfectants and detergent-disinfectants as published by Government Notice No. R. 529 (Government Gazette No. 19999) of 14 May 1999 has been withdrawn.
 - The reasons for the withdrawal of the registration.
 - It will be an offence in terms of the requirements of sections 14(1) and (2) of the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008) to import, sell or supply the disinfectant or detergent-disinfectant formulation as identified in the notification.
- 11.5 The following shall be bonded together and filed in the appropriate client file:
- The **original** *NRCS REGISTRATION WITHDRAWN certificate*.
 - The copy/copies of the NRCS REGISTRATION GRANTED/EXTENDED certificate/s that was/were issued for the disinfectant or detergent-disinfectant formulation.
 - The written request for the withdrawal of the registration for the disinfectant or detergent-disinfectant formulation.
 - A copy of the notification as set out in paragraph 11.4.2.

12 Forms

The following forms are available at the following network location:

<L:\REGULAT\Electro LOA correspondance\HEPS\Controlled documents\Forms>

CMM FM 8054-1: *'Application for the registration of disinfectants and detergent-disinfectants – Items required'*

CMM FM 8054-2: *'Technical file for disinfectants & detergent-disinfectants'*

CMM FM 8054-3: *'Application for the registration of a disinfectant or detergent-disinfectant formulation'*

Annexure A

Arrangement of registration number

Example of the arrangement of a registration number for a disinfectant or detergent-disinfectant formulation:

Act5GNR529/205585/040/0229

The above registration mark affixed to the container or label of a disinfectant or detergent-disinfectant shows that the disinfectant or detergent-disinfectant formulation concerned has been registered under registration number Act5GNR529/205585/040/0229. The registration number shows that this registration was granted to Deluxe Chemicals (who's Customer Account No. with the NRCS Finance Division is 205585) for a quaternary ammonium compound based disinfectant (see Table 1).

Annexure B

REGISTRATION REJECTED



Your ref.:

Our ref: **REGISTRATION
REJECTED.DOC**

Enquiries:



Technical file No.:

Date: 08/11/2010

Page: 1 of 1

«Company»
Attention: «Title» «First» «Last»
«Address»
«City»
«ZipPostal_Code»
«Country»

Dear Sir/Madam

REGISTRATION REJECTED

You are hereby notified that the application for the registration of the following disinfectant or detergent-disinfectant formulation has been rejected:

Disinfectant or detergent-disinfectant formulation: [Full name of manufacturer, proprietor, controlling company or trade mark holder] [Product name] [Type of disinfectant or detergent-disinfectant] [disinfectant or detergent-disinfectant formulation]

Please refer to the following NRCS Inspection Report for the type-examination results:

NRCS Inspection Report No. XXXX

The NRCS Inspection Report must be collected at the following premises:

NRCS Head Office
SABS Campus
1 Dr. Lategan Road
Groenkloof
Pretoria

The NRCS Inspection Report will be disposed of if not collected within six (6) months from the date of this notification.

Yours faithfully,

T. Magolego (Mrs.)
MANAGER: APPROVALS
NRCS Chemicals, Mechanical & Materials Division

NRCS Chemicals, Mechanical & Materials Division
SABS Campus 1 Dr. Lategan Road Groenkloof Pretoria
Private Bag X25 BROOKLYN 0075
Tel. +27 12 428-6377 • Fax. +27 12 428-6513
www.nrcs.co.za

Disinfectant / Detergent-Disinfectant Formulation

"Protecting health, Safety, the Environment and ensuring Fair Trade"

Annexure C

NRCS form No. AA33

National Regulator for Compulsory Specifications Private Bag X25 Brooklyn 0075	 No: 0282
Protecting Health, Safety, the Environment and ensuring Fair Trade	
GOODS DISPATCH AND RECEIPT NOTE	
Date: _____	
To: _____ _____	
Please acknowledge receipt of the following goods by signing and returning one copy of this voucher.	
GOODS _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	
_____ Recipient	_____ Date
<small>AA33 REV.1 2002-08/02 NORT. H.C.</small>	

Revision record

Page/Paragraph/ Annexure/Appendix/ Figure/Table	Nature of revision
-	-

No.:

Date: 10/11/2011

Page: 1 of 6

1. Product information on container or label

Full name of manufacturer, proprietor, controlling company or trade mark holder: _____

Product name: _____

Type of disinfectant or detergent-disinfectant: _____

Disinfectant

Detergent-disinfectant

2. General

2.1 Inspection method

- Type-examination of an application for the registration of a disinfectant or detergent-disinfectant formulation in accordance with the latest edition of Divisional Procedure No. CMM PROC 3.
- Type-examination of an application for the extension of registration of a disinfectant or detergent-disinfectant formulation in accordance with the latest edition of Divisional Procedure No. CMM PROC 3.
- Type-examination of an application for a Sales Permit for a disinfectant or detergent-disinfectant formulation in accordance with Divisional Procedure No. REG 003.

2.2 Items required

	Included		Acceptable	
	Yes	No	Yes	No
<u>Application for registration</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Applicant has submitted the items as communicated to him by means of NRCS form No. CMM FM 8054-1.

Remarks:

3. Technical file

No.: _____

Inspection date/s: _____

3.1 Completeness and correctness of technical file in accordance with NRCS form No. CMM FM 8054-2

	Included		Acceptable	
	Yes	No	Yes	No
C.1 Application form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Application for registration</u>				
NRCS form No. CMM FM 8054-3.				
<i>Note: The applicant shall be the manufacturer or importer of the disinfectant or detergent-disinfectant formulation. The manufacturer or importer shall be established within the Republic of South Africa.</i>				
<u>Application for a Sales Permit</u>				
Application form as set out in Divisional Procedure No. REG 003.				
Remarks:				
C.2 Label	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Label or information on the container for the disinfectant or detergent-disinfectant formulation.				
Remarks:				
C.3 MSDS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Material safety data sheet (MSDS) relevant to the disinfectant or detergent-disinfectant formulation.				
<i>NOTE: MSDSs shall satisfy the requirements of paragraph 5 of the latest edition of SANS 11014.</i>				
Remarks:				
C.4 List of raw materials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
List of raw materials for the disinfectant or detergent-disinfectant formulation.				
Remarks:				
C.5 Proof of compliance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Copies of test reports demonstrating compliance with all relevant requirements of paragraphs 4.2 and 7.2 of VC8054:1999.				
<i>Note 1: Only test reports from a testing authority 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 requirements of VC8054:1999. No approval certificates or product certification certificates will be accepted.</i>				
<i>Note 2: Test reports shall not be older than two years from date of receipt and shall satisfy the requirements of the latest edition of SANS 17025.</i>				
Testing authority:	_____		Test Report No.:	_____
Testing authority:	_____		Test Report No.:	_____
Testing authority:	_____		Test Report No.:	_____
Remarks:				

C.6 Other

Any other materials that the applicant has included in the technical file and that were examined during the type-examination process.

Remarks:

3.2 Suitability of technical file with respect to demonstrating compliance with paragraphs 4.2 and 7.2 of the Compulsory Specification for disinfectants and detergent-disinfectants (herein referred to as VC8054:1999) as published by Government Notice No. R. 529 (Government Gazette No. 19999) of 14 May 1999

This part of the inspection report should be read in conjunction with VC8054:1999.

VC8054:1999 Requirements	REQUIREMENTS	EXAMINATION OF TECHNICAL FILE	ACCEPTABLE	
			Yes	No
4.2	Disinfecting efficacy When the disinfectant or detergent-disinfectant is tested in accordance with the relevant test procedures given in 5.6 to 5.13 and 6.4 (see table 1), at the prescribed concentration, the claims made in regard to the efficacy of the disinfectant or detergent-disinfectant on the package, in the package leaflet or on the label attached to the package (see 7.2(f)) or in product support information, shall be regarded as the disinfecting efficacy requirement for the disinfectant or detergent-disinfectant.		<input type="checkbox"/>	<input type="checkbox"/>
7.2	Marking The following information shall appear on each container, or on a label securely attached to each container, in prominent, legible and indelible marking in type of such size and presentation as is prescribed by regulations promulgated under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), and the Trade Metrology Act, 1973 (Act 77 of 1973):			
	a) The registration number and full name and address of the manufacturer, producer, proprietor, or controlling company or, in the case of bottles packed for any other person or organization, the full name and address of that person or organization;		<input type="checkbox"/>	<input type="checkbox"/>
	b) Words indicating the type of disinfectant or detergent-disinfectant and its active disinfecting ingredient (see table 1) and whether it is suitable for use for cleaning-in-place operations;		<input type="checkbox"/>	<input type="checkbox"/>

VC8054:1999 Requirements	REQUIREMENTS	EXAMINATION OF TECHNICAL FILE	ACCEPTABLE	
			Yes	No
	c) The nominal volume or mass (as appropriate) of the contents, in plain type and in a colour that affords a distinct contrast to the colour of the container or label;		<input type="checkbox"/>	<input type="checkbox"/>
	d) The batch identification; or e) The production date of the batch (or both);		<input type="checkbox"/>	<input type="checkbox"/>
	f) General instructions for use for the various purposes for which the disinfectant or detergent-disinfectant is suitable, including the recommended dilutions that allow the product to comply with the requirements of 4.2 (disinfecting efficacy), for the exposure period and test organism stated in the test method for each purpose;		<input type="checkbox"/>	<input type="checkbox"/>
	g) Where applicable, the pH value at the recommended dilution (see (f) above);		<input type="checkbox"/>	<input type="checkbox"/>
	h) The first-aid treatment and the name of any antidote that may be used;		<input type="checkbox"/>	<input type="checkbox"/>
	i) Where applicable, warnings that: <ol style="list-style-type: none"> 1) The disinfectant or detergent-disinfectant should be stored in closed bottles in a dry place at a temperature not exceeding 30°C, protected from intense light and apart from flammable materials, food products and packaging material; 2) Contact of the undiluted disinfectant or detergent-disinfectant and its fumes with skin and eyes should be avoided; 3) Rubber gloves and where necessary, goggles, should be worn when the disinfectant or detergent-disinfectant is being handled; 4) Unless recommended by the manufacturer, the disinfectant or detergent-disinfectant should not be mixed with other incompatible substances (such as soap and other anionic detergents) where relevant; 5) Some disinfectants, such as iodophors, could stain certain porous materials (such as plastics) and corrode certain metals (such as copper, iron, silver alloys and aluminium); and 6) The efficacy of the disinfectant could be compromised if surfaces are soiled; 		<input type="checkbox"/>	<input type="checkbox"/>

VC8054:1999 Requirements	REQUIREMENTS	EXAMINATION OF TECHNICAL FILE	ACCEPTABLE	
			Yes	No
	j) The storage period or shelf life of the diluted disinfectant or detergent-disinfectant, when diluted to the lowest recommended concentration (highest use dilution);		<input type="checkbox"/>	<input type="checkbox"/>
	k) The expiry date of the disinfectant or detergent-disinfectant;		<input type="checkbox"/>	<input type="checkbox"/>
	l) If, in the case of disinfectants based on glutaraldehyde, the disinfectant or detergent-disinfectant is supplied in the form of a homogeneous liquid and an activator, a statement that the liquid and the activator shall be mixed before use as a disinfectant;		<input type="checkbox"/>	<input type="checkbox"/>
	m) The strength designation and, in the case of coal-tar type disinfectants, the nominal Rideal-Walker coefficient (see 5.9.5);		<input type="checkbox"/>	<input type="checkbox"/>
	n) In the case of bottles for black coal-tar type disinfectants, the following statement: "Black coal-tar type disinfectant liquid is not recommended for use with exceptionally hard water";		<input type="checkbox"/>	<input type="checkbox"/>
	o) A substantiation of specific virucidal claims;		<input type="checkbox"/>	<input type="checkbox"/>
	p) The product name (which shall not be misleading to the consumer); and		<input type="checkbox"/>	<input type="checkbox"/>
	q) Where applicable, a statement that the disinfectant or detergent-disinfectant has to be shaken before use.		<input type="checkbox"/>	<input type="checkbox"/>

4. Remarks

-

5. Conclusion

	Yes	No	N/A ¹
Technical file complete and correct in accordance with NRCS form No. CMM FM 8054-2:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Technical file satisfied the requirements of paragraphs 4.2 and 7.2 of VC8054:1999:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks:

¹ Not applicable

	Yes	No	N/A ¹
Disinfectant or detergent-disinfectant formulation recommended for registration in terms of VC8054:1999:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Disinfectant or detergent-disinfectant formulation recommended for an extension of registration in terms of VC8054:1999:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Disinfectant or detergent-disinfectant formulation recommended for a Sales Permit in terms of section 14(4) of the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks:

Inspected by:

Name: _____

Designation: Inspector
NRCS CMM Division

Signature: _____

Reviewed by:

Name: T. Magolego (Mrs.)

Designation: Manager: Approvals
NRCS CMM Division

Signature: _____

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Concerning: **REGISTRATION GRANTED**

of a disinfectant or detergent-disinfectant formulation pursuant to the Compulsory Specification for disinfectants and detergent-disinfectants as published by Government Notice No. R. 529 (Government Gazette No. 19999) of 14 May 1999.

Registration No.: **Act5GNR529/**

Extension No.: **-**

1. Disinfectant or detergent-disinfectant formulation

Full name of manufacturer, proprietor, controlling company or trade mark holder:

Product name:

Product description:

Strength designation: **%**

Rideal-Walker coefficient (coal-tar type):

Colour variants:

Perfume variants:

2. Holder of the registration

Name:

Address:

3. Terms and conditions of issue

- 3.1 This registration certificate is applicable only to the disinfectant or detergent-disinfectant formulation as identified in it.
- 3.2 The holder of the registration shall maintain compliance of the disinfectant or detergent-disinfectant formulation with the requirements of the appropriate compulsory specification.
- 3.3 No modifications shall be made to the disinfectant or detergent-disinfectant formulation itself, its composition and information that shall appear on each container or on a label securely attached to each container as required by the appropriate compulsory specification, without prior notification of the NRCS.
- 3.4 This registration certificate remains the property of the NRCS and may be withdrawn if any of the conditions attached to its issue are not complied with.

4. Registration granted

Place: **Pretoria**

Date: **19/01/2012**

T. Magolego (Mrs.)
Manager: Approvals
NRCS CMM Division

Inspector
NRCS CMM Division



Head Office

SABS Campus 1 Dr Lategan Road Groenkloof Pretoria

✉ NRCS Private Bag X25, Brooklyn 0075

☎ Tel +27 12 428 5000 • Sharecall 0860 722 700 • Fax +27 12 428 5199

@ Web www.nrcs.org.za

5. Manufacturer

Name:

Address:

6. Reference documents

The following documents, bearing the registration number shown below, are attached to this registration certificate:

- **List of raw materials for the disinfectant or detergent-disinfectant formulation.**
- **Label or information on the container for the disinfectant or detergent-disinfectant formulation.**

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Page: **1 of 2**

Concerning: **REGISTRATION EXTENDED**

of a disinfectant or detergent-disinfectant formulation pursuant to the Compulsory Specification for disinfectants and detergent-disinfectants as published by Government Notice No. R. 529 (Government Gazette No. 19999) of 14 May 1999.

Registration No.: **Act5G NR529/**

Extension No.: _____

1. Disinfectant or detergent-disinfectant formulation

Full name of manufacturer, proprietor, controlling company or trade mark holder:

Product name:

Product description:

Strength designation: %

Rideal-Walker coefficient (coal-tar type):

Colour variants:

Perfume variants:

2. Holder of the registration

Name:

Address:

3. Terms and conditions of issue

- 3.1 This registration certificate is applicable only to the disinfectant or detergent-disinfectant formulation as identified in it.
- 3.2 The holder of the registration shall maintain compliance of the disinfectant or detergent-disinfectant formulation with the requirements of the appropriate compulsory specification.
- 3.3 No modifications shall be made to the disinfectant or detergent-disinfectant formulation itself, its composition and information that shall appear on each container or on a label securely attached to each container as required by the appropriate compulsory specification, without prior notification of the NRCS.
- 3.4 This registration certificate remains the property of the NRCS and may be withdrawn if any of the conditions attached to its issue are not complied with.

4. Registration extended

Place: **Pretoria**

Date: **19/01/2012**

**Manager: Approvals
NRCS CMM Division**

**Inspector
NRCS CMM Division**



Head Office

SABS Campus 1 Dr Lategan Road Groenkloof Pretoria

✉ NRCS Private Bag X25, Brooklyn 0075

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@ Web www.nrcs.org.za

5. **Manufacturer**

Name:

Address:

6. **Reference documents**

The following documents, bearing the registration number shown below, are attached to this registration certificate:

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Page: **1 of 2**

Concerning: **REGISTRATION WITHDRAWN**

of a disinfectant or detergent-disinfectant formulation pursuant to the Compulsory Specification for disinfectants and detergent-disinfectants as published by Government Notice No. R. 529 (Government Gazette No. 19999) of 14 May 1999.

Registration No.: **Act5GNR529/**

Extension No.: **-**

1 Disinfectant or detergent-disinfectant formulation

Full name of manufacturer, proprietor, controlling company or trade mark holder:

Product name:

Product description:

Strength designation: **%**

Rideal-Walker coefficient (coal-tar type):

Colour variants:

Perfume variants:

2 Holder of the registration

Name:

Address:

3 Terms and conditions of issue

3.1 This registration certificate is applicable only to the disinfectant or detergent-disinfectant formulation as identified herein.

3.2 It will be an offence in terms of the requirements of sections 14(1) and (2) of the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008) to import, sell or supply the disinfectant or detergent-disinfectant formulation as identified in this registration certificate.

4 Registration withdrawn

Place: **Pretoria**

Date: **19/01/2012**

**Manager: Approvals
NRCS CMM Division**

REGISTRATION WITHDRAWN



Head Office

SABS Campus 1 Dr Lategan Road Groenkloof Pretoria

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@ Web www.nrcs.org.za

5 **Manufacturer**

Name:

Address:

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REGISTRATION WITHDRAWN

Manager Approval
NRCS CMM Division

