



agriculture, forestry & fisheries

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

GUIDELINES ON THE DATA AND DOCUMENTS REQUIRED FOR REGISTRATION OF AGRICULTURAL REMEDIES IN SOUTH AFRICA

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Republic of South Africa

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1. INTRODUCTION

The purpose of this document is to outline the data and documentation required by the Registrar of Act No. 36 of 1947 in connection with the registration of agricultural remedies. The requirements differ according to the type of registration that is being sought. Information normally required for the different categories of registration is set out in this document; however, the Act makes provision for the Registrar to call for any further information in order to determine whether a remedy is acceptable in the context of public interest, suitability and biological efficacy. It is important that only data with a direct bearing on the registration application are presented.

NOTE: If any of the data or documents called for in the paragraphs that follow are deemed by the applicant to be unnecessary or irrelevant, good scientific argument supporting this view should be presented in an application for a waiver of the requirement for such data or documentation. The application for waiver should be submitted before any tests/trials/studies are conducted and prior to the registration application being submitted to the office of the Registrar.

This document supersedes the Agricultural Remedies Registration Procedure Policy Document November 2000 (1) and all other similar documents that were previously published. This document must be read in conjunction with all other relevant guidelines related to pesticide registration requirements under Act No 36 of 1947. This document is effective as from the 1st June 2015.

2. NEW REGISTRATIONS

2.1 New Active Ingredient

This section applies to the registration of an agricultural remedy containing an active ingredient that has not yet been approved for use in South Africa.

The following are required:

- 2.1.1. Proof of payment of the prescribed application fee.
- 2.1.2. A covering letter outlining the purpose of the application.
- 2.1.3. Three copies of the "Application for the Registration of an Agricultural Remedy" form, obtainable from the DAFF website www.daff.gov.za fully completed. This must include all relevant information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II) of which one copy of each must be submitted.
- 2.1.4. Reports and summary on the pharmacology, toxicology and environmental impact studies of the active ingredient and its metabolites and/or degradation products according to OECD guidelines (2). These reports can be submitted on a compact disc (CD/DVD). If a remedy containing a new active ingredient is already registered by one or more of the registration authorities of the USA, EU, UK, Japan or Australia, toxicological risk assessment reports from the registration authorities concerned, together with a toxicological risk assessment, by an independent and accredited toxicologist, can be submitted in support of a provisional registration.
- 2.1.5. Reports and summary on formulation toxicity according to OECD guidelines (2). These reports can be submitted on a compact disc (CD/DVD).
- 2.1.6. Reports and summary on the Physical properties and Storage stability of the formulated product. Applicants should consult both
 - (a) the most recent edition of the "Manual on Development and use of FAO and WHO Specifications for Pesticides" (3), obtainable on the internet at http://whqlibdoc.who.int/publications/2006/9251048576_eng_update3.pdf and
 - (b) the FAO Specification for Agricultural Pesticides (4) for the active ingredient. Details can be found on the internet at <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/lpe/lpe-b/en/>.

Tests listed for the formulation type in either (a) or (b) above, whichever is the more recent, must be submitted. Should an applicant wish to apply for an extended shelf life for a product, this must be done according to the above-mentioned Manual, as well as the Croplife, 2009 Technical Monograph No 17: "Guidelines for specifying the shelf life of Plant Protection Products" (5).

- 2.1.7. Three copies of the proposed label. The label has to conform to the "Regulations relating to Agricultural Remedies" (Gov. Gaz. No 29225, 2006) (6) and the requirements of the "Guidelines for the RSA Classification Code of Agricultural and Stock Remedies and Associated Labelling Practices" (7). Where the remedy will also be marketed in a small pack for the home-garden market the proposed home-garden label should also be submitted. Refer to SANS Code 1268: "Labelling Practices for Agricultural Remedies and Fertilizers registered for Home and Home Garden Sector" issued by SABS, 22 November, 2013 (8).
- 2.1.8 Experimental data, plus a summary of the data, on the biological efficacy and, if specified in the relevant guidelines, phytotoxicity on the commodity or commodities concerned. Trials must have been conducted in important production areas of the crop(s) concerned in any SADC country, with at least two thirds of these being in South Africa. The trial localities chosen should represent a range of conditions including different bioclimatic regions, climate/weather, cultivars, agricultural practices and soil characteristics. See Appendix 1 for further details.
- 2.1.9 Residue data from relevant production areas as per the Agricultural Remedies Residue Trial and Data Requirements Document (9).
- 2.1.10 For fungicides applied in wine grapes, fermentation studies as specified in the relevant guidelines.
- 2.1.11 In case of tobacco, smoking studies for pesticides and fungicides specified in the "TISA Research Committee Protocol on Flue-cured Tobacco Smoke Trials" (10).
- 2.1.12 International or local bee toxicity studies for the formulated product as specified in the relevant guidelines.
- 2.1.13 A Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa.

2.2 New formulation type

This section applies to the registration of an agricultural remedy where the source of the active ingredient is identical to that of a registered product, but the type of formulation, (e.g., EC, FS, SC, SL, WP, etc.) differs from that of the registered product.

The following are required:

- 2.2.1 Proof of payment of the prescribed application fee.
- 2.2.2 A covering letter outlining the purpose of the application.
- 2.2.3 Three copies of the "Application for the Registration of an Agricultural Remedy" form, obtainable from the DAFF website www.daff.gov.za fully completed and including;
 - (a) one copy of the Active Ingredient Dossier Index (List I), completed, but without the supporting documentation/Annexures if these were submitted previously and
 - (b) one copy of all relevant information listed in the Formulated Product Dossier Index (List II) together with the supporting studies.
- 2.2.4 A letter from the formulator stating that the applicant will be supplied with the formulated product containing the technical material.
- 2.2.5 Formulation toxicity information. For all formulation types, it is required that formulation toxicity data, generated according to OECD Guidelines (2), be submitted for hazard

classification (11), or, if test data on formulation toxicity are not available, formulation toxicity can be calculated from the toxicity of the a.i./s and all relevant inert ingredients, using the GHS Acute Toxicity Estimate Procedure for Classification and Labelling of Chemicals (12). The actual calculation must be submitted. These calculations may be subject to further discussion.

- 2.2.6 Reports and summary on the Physical properties and Storage stability of the formulated product – as for 2.1.6 above.
- 2.2.7 Three copies of the proposed label – as for 2.1.7 above.
- 2.2.8 Experimental data, plus a summary of the data, on the biological efficacy and, if specified in the relevant guidelines, phytotoxicity on the commodity or commodities concerned. Trials must have been conducted in important production areas of the crop(s) concerned in any SADC country, with at least two thirds of these being in South Africa. The trial localities chosen should represent a variety of conditions including different bioclimatic regions, climate/weather, cultivars, agricultural practices and soil characteristics. The phytotoxicity data should have been generated on known sensitive cultivars in which the candidate remedy was compared to a similar remedy on a commodity or commodities on which it is used extensively. Referring to the approved end uses on the label of the registered reference product, trials will have to be undertaken on one third of those end uses intended for inclusion on the label of the new formulation. By “one third of those end uses” is meant one third of the crops/pests/weeds to be listed on the label.” See Appendix 1 for further details. NOTE: In the case of changes in physical form, e.g. water soluble tablets, granules and powders where the ingredients remain the same (same loading or composition) and agricultural practices/usage pattern are the same, the experimental data requirements are the same as for minor formulation amendments (Refer section 3.3 and Appendix 1).
- 2.2.9 Residue data from relevant production areas as per the Agricultural Remedies Residue Trial and Data Requirements Document (9).
- 2.2.10 For fungicides applied in wine grapes, fermentation studies as specified in the relevant guidelines.
- 2.2.11 In case of tobacco, smoking studies for pesticides specified in the “TISA Research Committee Protocol on Flue-cured Tobacco Smoke Trials” (10).
- 2.2.12 International or local bee toxicity studies for the formulated product as specified in the relevant guidelines.
- 2.2.13 A Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa.

2.3 Generic active ingredient

This section applies to the registration of an agricultural remedy containing a generic active ingredient from a source other than that of a registered product.

The following are required:

- 2.3.1 Proof of payment of the prescribed application fee.
- 2.3.2 A covering letter outlining the purpose of the application.
- 2.3.3 Three copies of the “Application for the Registration of an Agricultural Remedy” form, obtainable from the DAFF website www.daff.gov.za fully completed. This must include one copy of all relevant information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II) together with the supporting studies.
- 2.3.4 A letter from the manufacturer of the technical material stating that the applicant will be supplied with the technical material.

- 2.3.5 A letter from the formulator stating that the applicant will be supplied with the formulated product containing the technical material.
- 2.3.6 Full details on the manufacture, identity and purity of the Technical Grade Active Ingredient (TGAI) and the identity and quantities of its impurities, as specified in the "Guidelines on Equivalence of Agricultural Remedies (Pesticides)" (13) issued by the Registrar, Act No. 36 of 1947. The above information must be substantiated by an analytical report on five different production batches of the TGAI by an ISO 17025 accredited, or certified GLP compliant laboratory. As from a date to be announced by the Registrar, Act No. 36 of 1947, only 5-batch analysis reports complying with the OECD principles on GLP will be accepted.

The Technical Grade Active Ingredient must conform to internationally recognised specifications or standards, if available e.g., FAO specifications (4), Australian Pesticides and Veterinary medicines Authority standards <http://www.apvma.gov.au/products/constituents/standards/index.php> (14) or the European Union listed standards in the EU Pesticides Database http://ec.europa.eu/sanco_pesticides/public/index.cfm (15).

If the results of the 5-batch analysis are inconclusive (i.e., the Registrar is unable to make a clear decision on chemical equivalence) he will request results of a test for mutagenicity (Ames test), done by a laboratory complying with the OECD principles on GLP.

In the case of a substance where the active ingredient does not have a known minimum percentage purity, a certificate of analysis from an ISO 17025 or GLP accredited laboratory will be accepted in place of a 5-Batch analysis. Some examples of products that fall into this category include a number of adjuvants, plant growth regulators, plant/botanical extracts, swimming pool products and biological remedies. Consult the Registrar's Technical Advisers for guidance in this regard.

- 2.3.7 Formulation toxicity information - as for 2.2.5 above.
- 2.3.8 Reports and summary on the Physical properties and Storage stability of the formulated product as - for 2.1.6 above.
- 2.3.9 Three copies of the proposed label – as for 2.1.7 above.
- 2.3.10 Experimental data, plus a summary of the data, on the biological efficacy and, if specified in the relevant guidelines, phytotoxicity on the commodity or commodities concerned as specified in Section 2.2.8. Refer to Appendix 4 for a list of generic active ingredients for which experimental data need not be submitted.
- 2.3.11 Residue data from relevant production areas as per the Agricultural Remedies Residue Trial and Data Requirements Document (9).
- 2.3.12 For fungicides applied in wine grapes, fermentation studies as specified in the relevant guidelines.
- 2.3.13 In case of tobacco, smoking studies for pesticides will be required as specified in the "TISA Research Committee Protocol on Flue-cured Tobacco Smoke Trials". Consult the TISA in case of uncertainty (10).
- 2.3.14 International or local bee toxicity studies for the formulated product as specified in the relevant guidelines.
- 2.3.15 A Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa.

2.4 Parallel and Daughter Registrations

This section applies to the registration of an agricultural remedy that is identical to a registered remedy, i.e., a particular remedy will be marketed under more than one trade name, each

having its own registration number. A parallel registration would be in the name of the same company that holds the original registration, whereas a daughter registration would be in the name of a different company.

The following are required:

- 2.4.1 Proof of payment of the prescribed application fee.
- 2.4.2 A covering letter outlining the purpose of the application.
- 2.4.3 In the case of a daughter registration, the legal agreement signed by both parties, in which the holder of the primary registration grants permission for the formulation concerned to be registered in the name of the applicant.
- 2.4.4 Three copies of the “Application for the Registration of an Agricultural Remedy” form, obtainable from the DAFF website www.daff.gov.za fully completed, but excluding the information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II).
- 2.4.5 Three copies of the proposed label – as for 2.1.7 above.
- 2.4.6 A Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa.

2.5 Biopesticides and “Minor use” remedies

This section applies to the registration of Biopesticides and other agricultural remedies of biological origin as well as remedies for “Minor uses” or to be used on “Minor Crops”.

The data and documentation required for these are essentially the same as for conventional Agricultural Remedies. For more information on the test data and trial work that are needed for products of this type, refer to their specific registration guidelines (16, 19, 20).

2.6 Remedies For Organic Agriculture

This section applies to the registration of an agricultural remedy that is intended for use only in Organic Agriculture.

In most cases, these remedies have different properties from conventional chemical products, consequently separate guidelines have been, or are being prepared in connection with their registration.

The following are required: For other requirements, refer also to: “Guidelines for the registration of allowed inputs for organic agriculture” (17).

- 2.6.1 Proof of payment of the prescribed application fee.
- 2.6.2 A covering letter outlining the purpose of the application.
- 2.6.3 Three copies of the “Application for the Registration of an Agricultural Remedy” form, obtainable from the DAFF website www.daff.gov.za, fully completed. This must include one copy of all relevant information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II) If any particular section of the Active Ingredient Dossier Index (List I) data requirements is not considered relevant to a particular remedy, the applicant should provide a reason for its exclusion.
- 2.6.4 A letter from the formulator stating that the applicant will be supplied with the formulated product containing the technical material.
- 2.6.5 Full details on the identity and purity of the technical material and quantities of impurities present in the technical material, supported by a certificate of analysis.
- 2.6.6 For products containing a new active ingredient, refer to Section 2.1.4 above.
- 2.6.7 Formulation toxicity information as for 2.2.5 above.

- 2.6.8 Summary reports on the Physical properties and Storage stability of the formulated product – as for 2.1.6 above.
 - 2.6.9 Three copies of the proposed label – as for 2.1.7 above.
 - 2.6.10 Experimental data, plus a summary of the data, on the biological efficacy and, if specified in the relevant guidelines, phytotoxicity on the commodity or commodities concerned as specified in Section 2.2.8. Since trials data requirements for remedies in this category differ from those of conventional remedies, the guidelines mentioned above should also be consulted.
 - 2.6.11 If residues are likely to be present at harvesting, local residue data from relevant production areas as per the Agricultural Remedies Residue Trial and Data Requirements Document (9) have to be submitted.
 - 2.6.12 For fungicides applied in wine grapes, fermentation studies as specified in the relevant guidelines.
 - 2.6.13 In case of tobacco, smoking studies for pesticides specified in the “TISA Research Committee Protocol on Flue-cured Tobacco Smoke Trials” (10).
 - 2.6.14 International or local bee toxicity studies for the formulated product as specified in the relevant guidelines.
 - 2.6.15 A Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa.
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3 AMENDMENTS TO EXISTING REGISTRATIONS

3.1 New source of active ingredient.

This section applies where approval is sought for a change of source, or an additional source for the active ingredient of a registered agricultural remedy.

The following are required:

- 3.1.1 Proof of payment of the prescribed application fee.
 - 3.1.2 A covering letter outlining the purpose of the application.
 - 3.1.3 Three copies of the “Application for the Registration of an Agricultural Remedy” form, obtainable from the DAFF website www.daff.gov.za fully completed. This must include one copy of all relevant information listed in the Active Ingredient Dossier Index (List I), but excludes the Formulated Product Dossier Index (List II) if this was submitted previously.
 - 3.1.4 A letter from the manufacturer of the technical material stating that the applicant will be supplied with the technical material.
 - 3.1.5 Full details on the manufacture, identity and purity of the Technical Grade Active Ingredient (TGA) and the identity and quantities of its impurities. The requirements are exactly the same as in the case of a generic product, refer to 2.3.6 above.
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3.2 Major amendment to a registered formulation

This section applies where a major change is made to a registered formulation, but the formulation type remains the same. A change is regarded as major if more than 10% of the total content of the formulation is changed. A change of less than 10% would also be regarded as major if the classification of the formulation moved to a more hazardous class.

The following are required:

- 3.2.1 Proof of payment of the prescribed application fee.

- 3.2.2 A covering letter outlining the purpose of the application.
- 3.2.3 Three copies of the “Application for the Registration of an Agricultural Remedy” form, obtainable from the DAFF website www.daff.gov.za fully completed and including one copy of the Active Ingredient Dossier Index (List I), completed, but without the supporting documentation / Annexures if these were submitted previously and one copy of all relevant information listed in the Formulated Product Dossier Index (List II) together with the supporting studies.
- 3.2.4 A letter from the formulator stating that the applicant will be supplied with the formulated product containing the technical material.
- 3.2.5 Formulation toxicity information - as for 2.2.5 above.
- 3.2.6 Reports and summary on the Physical properties and Storage stability of the formulated product - as for 2.1.6 above.
- 3.2.7 Three copies of the proposed label – as for 2.1.7 above, if any of the details have changed.
- 3.2.8 Experimental data, plus a summary of the data – as for 2.3.10 above.
- 3.2.9 Residue data from relevant production areas as per the Agricultural Remedies Residue Trial and Data Requirements Document (9).
- 3.2.10 Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa, if any of the details in the SDS have changed.
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3.3 Minor amendment to a registered formulation

This section applies where a minor change is made to a registered formulation. Some examples of minor formulation changes are:

- change in substances added to preserve the formulation in the container or to improve safety to non-targets
- substitution of one inert for another with similar properties
- changes in substances used to identify the formulation, e.g., dyes
- in general, changes of not more than 10% in the total content of the formulation
- changes in the carrier or water content of GR and SC formulations.

Note: The classification of the formulation must not change to a more hazardous class as a result of the minor change. In cases where the changes result in the classification changing to a more hazardous class, the registration requirements for major formulation changes will apply. The following are required:

- 3.3.1 Proof of payment of the prescribed application fee.
- 3.3.2 A covering letter outlining the purpose of the application.
- 3.3.3 Three copies of the “Application for the Registration of an Agricultural Remedy” form, obtainable from the DAFF website www.daff.gov.za fully completed and including one copy of the Active Ingredient Dossier Index (List I), completed, but without the supporting documentation / Annexures if these were submitted previously and one copy of all relevant information listed in the Formulated Product Dossier Index (List II).
- 3.3.4 A letter from the formulator stating that the applicant will be supplied with the formulated product containing the technical material.
- 3.3.5 In the case of the substitution of an inert with another, a SDS for this new inert should be provided.
- 3.3.6 Three copies of the proposed label – as for 2.1.7 above, if any of the details have changed.

- 3.3.7 Experimental data on selectivity, phytotoxicity and residues are not required in the case of a minor amendment to a registered formulation.
- 3.3.8 A Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa, if any of the details in the SDS have changed.
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3.4 Label extension.

This section applies to new end uses or other additional claims to be added to the label, altered recommendations, etc.

The following are required:

- 3.4.1 Proof of payment of the prescribed application fee.
- 3.4.2 A covering letter outlining the purpose of the application.
- 3.4.3 Three copies of the “Application for the Registration of an Agricultural Remedy” form, obtainable from the DAFF website www.daff.gov.za, fully completed but excluding the information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II) if these were submitted previously.
- 3.4.4 Three copies of the proposed label – as for 2.1.7 above.
- 3.4.5 Experimental data, plus a summary of the data, on the biological efficacy and, if specified in the relevant guidelines, phytotoxicity on the commodity or commodities concerned as per Section 2.1.8.
- 3.4.6 Residue data from relevant production areas as per the Agricultural Remedies Residue Trial and Data Requirements Document (9).
- 3.4.7 For fungicides applied in wine grapes, fermentation studies will be required as specified in the relevant guidelines.
- 3.4.8 In case of tobacco, smoking studies for pesticides specified in the “TISA Research Committee Protocol on Flue-cured Tobacco Smoke Trials” (10).
- 3.4.9 In cases where international or local bee toxicity studies have previously been submitted, bee toxicity data will not be required.
- 3.4.10 Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa, if any of the details in the SDS have changed.
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3.5 Administrative amendment

This section deals with various types of administrative amendment.

Some examples are:

- Changes in a Registration holder’s name and/or contact details, where the Company Registration Number remains the same.
- Minor changes in label wording
- Addition of any voluntary restrictions to the label.
- Removal of end uses from the label.
- Change of Trade name

The following are required:

- 3.5.1 Proof of payment of the prescribed application fee.
- 3.5.2 A covering letter outlining the purpose of the application.

- 3.5.3 Three copies of the “Application for the Registration of an Agricultural Remedy” form, obtainable from the DAFF website www.daff.gov.za fully completed, but excluding the information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II).
- 3.5.4 Three copies of the proposed label – as for 2.1.7 above.
- 3.5.5 A Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa, if any of the details have changed.
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3.6 Transfer of a Registration

This section applies in the case of a registration being transferred from one registration holder to another, where the Registration holder’s name and/or contact details and Company Registration Number change.

The following are required:

- 3.6.1 Proof of payment of the prescribed application fee.
- 3.6.2 A legal document confirming the transfer of the registration.
- 3.6.3 A covering letter outlining the purpose of the application.
- 3.6.4 Three copies of the “Application for the Registration of an Agricultural Remedy” form, obtainable from the DAFF website www.daff.gov.za fully completed, but excluding the information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II).
- 3.6.5 An affidavit confirming that the supplier of technical material, formulation, formulator, label and any other relevant data have not changed (or indicating any changes if applicable), also confirming that the new owner takes over responsibility for the product from the previous owner.
- 3.6.6 A letter from the manufacturer of the technical material stating that the new owner will be supplied with the technical material. In the event that the source of technical material changes, an application for a new source will be required (refer section 3.1).
- 3.6.7 A letter from the formulator stating that the applicant will be supplied with the formulated product containing the already approved technical material.
- 3.6.8 Three copies of the proposed label – as for 2.1.7 above.
- 3.6.9 A Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa.
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3.7 Renewal of registrations

This section applies where a product is reaching the end of the 3-year registration cycle and must be renewed.

The following are required:

- 3.7.1 Proof of payment of the prescribed application fee.
- 3.7.2 Renewal application forms.
- 3.7.3 Signed declaration that accompanies the renewal application
- 3.7.4 In the case of a Daughter registration being renewed, a newly signed legal agreement.

Note that Agricultural Remedy registrations should be renewed before 31st May. Refer to Regulations relating to Agricultural Remedies document (6).

3.8 New formulator

This section applies where a formulator/formulation site is changed or added.
The following are required:

- 3.8.1 Proof of payment of the prescribed application fee.
 - 3.8.2 A covering letter outlining the purpose of the application.
 - 3.8.3 Three copies of the “Application for the Registration of an Agricultural Remedy” form, obtainable from the DAFF website www.daff.gov.za fully completed, but excluding the information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II).
 - 3.8.4 A letter from the formulator stating that the applicant will be supplied with the formulated product.
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3.9 Reinstatement of registration

This section applies where an application is made for the reinstatement of a lapsed registration.
The following are required:

- 3.9.1 Proof of payment of the prescribed application fee.
 - 3.9.2 A covering letter outlining the purpose of the application.
 - 3.9.3 Three copies of the “Application for the Registration of an Agricultural Remedy” form, obtainable from the DAFF website www.daff.gov.za fully completed, including the information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II).
 - 3.9.4 A letter from the manufacturer of the technical material stating that the applicant will be supplied with the technical material. In the event that the source of technical material changes, an application for a change of source will be required (refer to section 3.1).
 - 3.9.5 A letter from the formulator stating that the applicant will be supplied with the formulated product containing the already approved technical material.
 - 3.9.6 Three copies of the proposed label – as for 2.1.7 above.
 - 3.9.7 A Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa.
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3.10 Cancellation of registration

This section applies where a product registration is to be cancelled.
The following are required:

- 3.10.1 No fees payable
- 3.10.2 A covering letter outlining the purpose of the application. Alternatively, if the cancellation is timed to coincide with the normal registration renewal date, two copies of Form B of the renewal forms.
- 3.10.3 Original Agricultural Remedy Registration Certificate which must be returned in terms of Section 4 A of the Act.

3.11 New package size and/or packaging material

This section applies in the event of an addition to or change in packaging material or package size.

The following are required:

- 3.11.1 Proof of payment of the prescribed application fee.
- 3.11.2 A covering letter outlining the purpose of the application.
- 3.11.3 Three copies of the "Application for the Registration of an Agricultural Remedy" form, obtainable from the DAFF website www.daff.gov.za fully completed, but excluding the information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II).

3.12 New Company contact person

This section applies where a registration holder has appointed a new or additional contact person.

The following are required:

- 3.12.1 No fees payable
- 3.12.2 A covering letter outlining the purpose of the application
- 3.12.3 Company/ CC Registration Certificate (if applicable)

4 REQUEST FOR DATA WAIVER OR PROTOCOL APPROVAL

4.1 Request for Data Waiver

This section applies when any of the data or documents called for in this document are deemed by an applicant to be unnecessary or irrelevant.

The following are required:

- 4.1.1 Proof of payment of the prescribed application fee
- 4.1.2 An explanatory note sent by e-mail to the relevant Technical Adviser, with the request for a waiver of the data requirement attached.
- 4.1.3 This should contain a good scientific argument supporting the view that the data requirement should be waived.

4.2 Request for Protocol Approval

This section applies in the case when an applicant requests approval for a trial protocol prior to the application process.

The following are required:

- 4.2.1 Proof of payment of the prescribed application fee.
 - 4.2.2 Detailed protocol.
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5 REFERENCES

- (1) Agricultural Remedies Registration Procedure Policy Document November 2000 (Registrar, Act No. 36 of 1947).
- (2) Guidelines published by the Organization of Economic Co-operation and Development (OECD) <http://www.oecd.org/env/chemicalsandbiosafety/testingofchemicals/>
- (3) Manual on Development and use of FAO and WHO Specifications for Pesticides, November 2010. http://whqlibdoc.who.int/publications/2006/9251048576_eng_update3.pdf
- (4) FAO Specifications for Agricultural Pesticides <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/lpe/lpe-b/en/>
- (5) Guidelines for specifying the Shelf Life of Plant Protection Products, CropLife International, 2009 Technical Monograph No 17.
- (6) Regulations relating to Agricultural Remedies (Gov. Gaz. No. 29225, 22 Sept 2006).
- (7) Guidelines for the RSA Classification Code of Agricultural and Stock Remedies and Associated Labelling Practices (Dept. of Agriculture & AVCASA, 1991).
- (8) SANS Code 1268: Labelling Practices for Agricultural Remedies and Fertilizers registered for Home and Home Garden Sector Nov 2013 (SABS).
- (9) Agricultural Remedies Residue Trial and Data Requirements Document, 2015 (Registrar, Act No. 36 of 1947).
- (10) TISA Research Committee Protocol on Flue-Cured Tobacco Smoke Trials.
- (11) The WHO recommended classification of pesticides by hazard and guidelines to classification: 2009 (World Health Organisation, 2010).
- (12) United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS); Part 3: Health Hazards, Chapter 3.1.3 – Classification Criteria for Mixtures.
- (13) Guidelines on Equivalence of Agricultural Remedies (Pesticides) (Registrar, Act No. 36 of 1947, November 2000).
- (14) Australian Pesticides and Veterinary medicines Authority standards <http://www.apvma.gov.au/products/constituents/standards/index.php>.
- (15) EU Pesticides Database http://ec.europa.eu/sanco_pesticides/public/index.cfm
- (16) Guidelines for the registration of Biopesticides, (DAFF, November 2010)
- (17) Guidelines for the registration of allowed inputs for organic agriculture (Not yet issued)
- (18) Organic Standard SANS 1369:201x for use in Organic agriculture (not yet finalised)
- (19) Guidelines for the registration requirements of Botanical Pesticides (Departments of Agriculture and Health, 2003)
- (20) Registration Guidelines for Minor Uses (Minor Crops) in South Africa, (DAFF, 2010)
- (21) EPPO standard series PP1 (efficacy evaluation of plant protection products) (EPPO: <http://pp1.epo.org/>).

APPENDIX 1:

GENERAL GUIDELINES FOR THE TESTING OF AGRICULTURAL REMEDIES FOR BIOLOGICAL EFFICACY, PHYTOTOXICITY AND RESIDUES / BIOLOGICAL EFFICACY AND PHYTOTOXICITY

1. INTRODUCTION

The purpose of this document is to outline the general requirements for field trials for the registration of agricultural remedies for pest control in conventional agricultural crops and forestry. (The word “pest” is used in its broad sense, meaning insect or other animal pest species, plant pathogen or weed). The information is relevant to most crop/pest situations, but other situations, where the requirements differ in some or other way, include the following:

- Household and home garden pest control
- Industrial pest control
- Disease vector control, e.g., malaria
- Control of unwanted trees, shrubs and invasive plant species
- Biopesticides
- Inputs for Organic Agriculture
- Inoculants
- Plant Growth Regulants
- Seed treatment products
- Adjuvants
- Minor uses of Agricultural Remedies
- Attractants and mating disruptors
- Swimming pool remedies
- Residue studies
- Wine fermentation tests
- Tobacco smoking tests

Separate guidelines exist for most of the above types of registration, or are being developed. This document must be read in conjunction with all other relevant guidelines related to pesticide registration requirements under Act No 36 of 1947.

In the absence of guidelines to conduct efficacy trials on any specific crop in South Africa, the use of EPPO standard series PP1 (efficacy evaluation of plant protection products) is recommended (EPPO:<http://pp1.epo.org/>) (21).

Trial sites must be available for inspection by officials of Act 36 at any time following commencement of such trials.

Trials must be conducted under conditions of Good Agricultural Practices (GAP). It should be noted that agricultural practices change from time to time, and researchers should familiarize themselves with the latest trends and changes in application technology and agricultural practices.

Data must be generated using sound scientific principles and experimental design and analysed using appropriate statistical methods. Applicants must be able to demonstrate that when their product is used according to label directions, it is effective for the purpose claimed and that its application to the target plant will not cause any unintended effects. It is the responsibility of the applicant to present adequate data to support any claims made on the product's proposed label.

Data should demonstrate that:

- the remedy applied is effective
- its side effects on the treated crop are negligible and manageable
- its effects (in the case of herbicides and some other remedies) on subsequent crops are negligible and manageable
- its effects on non-target organisms such as beneficial insects and pollinators are negligible and manageable.

2. GENERAL TRIAL REQUIREMENTS

2.1 TRIAL MATERIAL

The test substance or formulation used in trials should be the same product for which registration is sought.

Sample material used in registration trials must be no more than two years old when the trials are conducted.

2.2 NUMBERS AND LOCALITIES OF TRIALS

2.2.1 Efficacy Trials

A minimum of three successful field trials must be done for each end use (crop/pest species) to demonstrate the efficacy of the product. In order to prove consistency of activity over a range of environmental conditions, the trials should be located in a variety of locations, spanning the bioclimatic regions, where relevant (refer to Appendix 2), and taking into account seasonal variation i.e. weather/climate, irrigation practices cultivars and soil characteristics in which the crop/pest combination are found and for which registration is sought.

For new active ingredients, the trials must be conducted over a minimum of two seasons or cropping cycles and under a range of environmental conditions relevant to the crop/pest as mentioned above.

In the case of new formulations of registered active ingredients, or products containing equivalent active ingredients from generic manufacturers, one season's trial work will suffice provided that the trials are conducted under a range of environmental conditions relevant to the crop/pest as mentioned above. Alternatively, trials should also be conducted in different growing seasons if the crop occurs in one geographic area or bioclimatic zone. For soil acting pesticides/biopesticides, physical soil analysis reports done by an AgriLasa/GLP/ISO17025 accredited laboratory should be submitted. Such reports should be from soil samples taken not more than five years before or after the trial was initiated.

2.2.2 Phytotoxicity / Selectivity Trials / Yield Trials

In most cases, a minimum of three successful field trials must be done on each crop or group of related crops to demonstrate the crop safety of the product. The trials should be located in the same or a similar range of locations to the efficacy trials. Efficacy trials can also be used for visual phytotoxicity evaluations, provided that the appropriate treatments are included in these trials. The use of different cultivars is highly recommended.

For new active ingredients, the trials must be conducted over a minimum of two seasons or cropping cycles, on different cultivars and, in the case of soil-applied remedies, on soils with different physical characteristics. For herbicides applied in agronomic (field) crops, yield trials must be conducted on a range of different cultivars and, where relevant, under irrigated or dryland conditions and on different soil types, including soils on which phytotoxicity is more likely to occur.

In the case of new formulations of registered active ingredients, or generic products, a minimum of three trials in one or more season will be required provided that the trials are conducted under a range of environmental conditions relevant to the crop as mentioned above, including, if relevant, soil types on which phytotoxicity is more likely to occur. If the crop occurs in one geographic area or bioclimatic zone then trials should be conducted in more than one growing season.

2.2.3 Residue Trials - refer also to the Residue Guidelines

The numbers of trials required are stipulated in the Residue Guideline Document (9) . The trials should be located in the same or a similar range of locations to the efficacy trials. Efficacy and phytotoxicity trials can also be used for residue sampling, provided that the appropriate treatments are included in these trials and that the plot size allows for this. One season's trial work will suffice provided that the trials are conducted under a range of environmental conditions, relevant to the crop/pest as mentioned above. Alternatively, trials should be conducted in different growing seasons if the crop occurs in one geographic area or bioclimatic zone.

2.3 EXPERIMENTAL DESIGN

Efficacy and phytotoxicity trials should be designed and laid out in such a way as to permit a statistical evaluation. Usually a randomised block design is adequate. It is essential to ensure adequate pest pressure, evenly distributed through the trial site for trials to give meaningful efficacy data.

Treatments must be replicated at least four times, however, in order to allow for meaningful statistical analysis, the Error Degrees of Freedom should be 12 or more and thus the replicate number should be adjusted according to the Error Degrees of Freedom. For example, if you have one product at two rates plus an untreated control and a reference product in the trial you need to have 5 replicates in order to have 12 Error Degrees of Freedom.

The design must include an untreated Control treatment. In the case of herbicide efficacy trials, this can be in the form of an untreated control strip alongside each treated plot.

The remedy being tested must be compared to an appropriate reference product. This could be another remedy having the same or similar active ingredient, one with a pest control spectrum similar to that of the remedy being tested, or one that is commonly used in the specific crop or situation concerned.

Experiments with a new remedy (new active ingredient) should include a range of dosages in order to determine the optimum rate(s) for effective pest control without significant crop damage. Once optimum rates have been determined for different crop/pest combinations, further trials should be done using these rates. The selected optimal rate(s) should provide consistent results on the targeted pest species.

Efficacy trials with new formulations or generic remedies must include the optimum rate(s) of active ingredient as determined above and these rates should reflect the proposed commercial rate(s).

Phytotoxicity trials must contain at least a single (1x) and double (2x) dosage to demonstrate crop safety.

If the remedy is to be applied in mixtures then the trials must be designed so as to demonstrate the properties of these combinations such as synergism, additive effect, antagonism, incompatibility, crop safety/phytotoxicity, and residues etc. In cases where an adjuvant/fertilizer/botanical extract is added in the spray mixture efficacy, phytotoxicity and residue data will be needed – refer to the Adjuvant Registration Guidelines and residue guidelines.

If the proposed rate of any product in a tank mixture differs from the recommended rate when the component products are applied alone, the trials must be designed so as to demonstrate the effectiveness and crop safety of the mixture with these rates of the different components. Similarly, if any pest claimed to be controlled by a tank mixture is in addition to pests controlled by the components individually at equivalent rates, then supporting data is needed for the new pest claim.

2.4 APPLICATION METHOD AND WATER VOLUME

All application equipment used in trials must be properly calibrated.

The application pattern should be similar to that used in commercial practice, both in particle size and distribution and in deposition on the treated surfaces.

The method(s) of application should be similar to the method(s) which will be recommended on the product label and these should reflect the current application technology and good agricultural practices.

Optimum spray volumes must be determined for the product concerned for each application method. A range of spray volumes should be tested if it is expected that different spray volumes will result in different levels of performance of the product.

The spray volume and the carrier or diluents should be similar to those that are, or will be recommended for commercial use. If it is intended to recommend more than one, or a range of application volumes, e.g., ground and aerial application, trial data must be generated to support such recommendations. Efficacy should be demonstrated on one or more of the target species in at least one trial at each of the application volumes. Similarly, at least one selectivity trial should be done at each application volume to prove that the reduced water volume and increased concentration of the pesticide do not cause any phytotoxicity to the target crop. This can be done simultaneously with the efficacy trials mentioned above.

2.5 DATA REQUIREMENTS

The following should be recorded and reported in the Trial Report:

Trial Sponsor: Details of Company seeking registration

Trial Objective: The reason for doing the trial

Person Responsible for the Trial: Name & contact details of the person who established and evaluated the trial.

Locality of Trial site: Town/City, Farm name and GPS coordinates.

Trial Co-operator: Name & contact details

Crop details: Common and scientific names of crop; Cultivar name, planting date (or age).

Pest details: Common and scientific names of pest(s). If codes or abbreviations are used these must be clearly explained.

Products evaluated: For each product included in the trial, give Trade name and/or Code name, Active ingredient, a.i. content, Formulation type, Registration number (if registered) and name of supplier or registration holder

Date of Trial Establishment: Normally date of first treatment

Trial Design: Trial layout, number of replicates, statistical design.

Plot size: Length x breadth (area) or number of trees or vines or crop rows

Row width, Plant spacing & Plant population/ha: For soil applied herbicides or seed treatment trials, also give planting depth

Planting Method: Method & type of planting equipment if relevant

Soil Analysis: Trials with soil-applied products & seed treatments, for example, the soil analysis reports should be from soil samples taken not more than five years before or after the trial was initiated. The reports should include: % clay, silt, sand, organic matter and soil classification.

Application Equipment: Make and type of equipment, including spray nozzle type if relevant.

Spray Pressure: If relevant, in bar or kPa

Spray volume applied: Volume in ℓ /ha or ℓ /tree at each application

Application dates: Date and time of each application

Crop and pest stages of growth at each application: e.g., Zadock, BBCH: These must agree with crop and pest stages to be claimed on the label.

Environmental conditions at application: Air temperature, humidity, cloud cover, wind strength & direction, soil moisture if relevant.

Topography of Trial Site: degree and direction of slope

Precipitation: Time and amount of first rainfall or irrigation after application and, if possible, weekly or monthly precipitation for the duration of the trial.

Good Agricultural Practices: List standard practices applied in the husbandry of the crop concerned, including fertilisation, standard pesticide treatments, etc.

Timing of evaluations: Date and number of days after treatment (DAT) for each evaluation.

Evaluation Methods: Describe methods used to assess efficacy & phytotoxicity; describe any rating system used.

Crop and pest stages of growth at each evaluation: e.g., Zadoks, BBCH

Assessment sampling: Describe sampling area or sample size used when doing assessments.

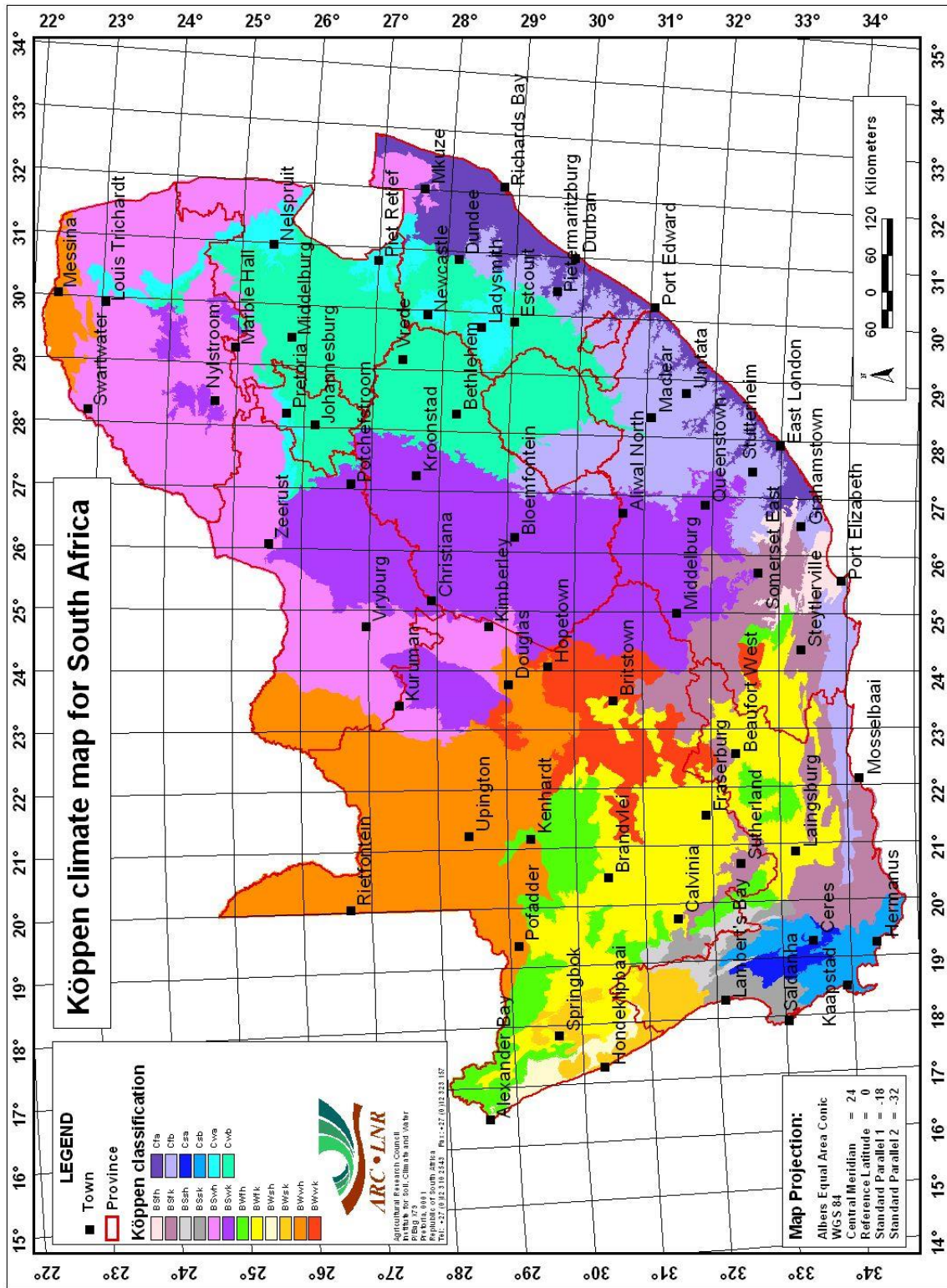
Results – Efficacy: Present data in table format; graphs or photographs may also be used to illustrate treatment effects. Data from counts, ratings, etc. should preferably be converted, where possible, into % control. Appropriate statistical analyses should be performed on the data.

Results – Phytotoxicity: Describe any symptoms seen. The number of evaluations would depend on the nature of the product and duration of symptoms being present. Data should be presented in table format. Even if there were no symptoms seen, tables should be presented to indicate that the levels of damage dropped to zero or were at zero since application. In the case of phytotoxicity trials in agronomic crops with herbicides containing new active ingredients, crop yield (kg/ha) must be recorded and analysed statistically.

Discussion and Conclusions: A discussion of the factual evidence from the trial and an accurate interpretation of the results, but do not include recommendations based on the results of one trial only.

APPENDIX 2:

BIOCLIMATIC REGIONS IN SOUTH AFRICA



APPENDIX 3:

INERT INGREDIENTS NOT PERMITTED

Inert ingredients (otherwise known as formulants) used in formulations must be toxicologically and environmentally acceptable. Inert ingredients that are no longer permitted for use in South Africa are:

Nonylphenol and nonylphenol ethoxylate
Octylphenol and octylphenol ethoxylate

(This list will be updated from time to time)

APPENDIX 4:

GENERIC COMPOUNDS EXEMPT FROM THE SUBMISSION OF EXPERIMENTAL DATA.

In the case of the following active ingredients, with formulations similar to currently registered formulations of the same active ingredients, no experimental efficacy, or phytotoxicity data need to be submitted for uses/claims that are already registered, except that phytotoxicity data will be needed for compounds preceded by (*p). These compounds are "general knowledge" products which have been in use for many years and should not be subjected to sophisticated assessment protocols for current uses if they meet the necessary specifications. Residue data will however be required on one third of those commodities listed on the label where the withholding period is 7 days or less.

If new formulations are developed data will be required for efficacy, phytotoxicity, and residues. This does not however, exempt those active ingredients listed in Table A below from being evaluated for equivalence as laid down in par. 2.3.5. For those listed in Table B, a Certificate of Analysis will be required.

TABLE A: Active ingredients for which a 5-batch analysis is required

Captab (=captan)	Metaldehyde
2,4-D	Metam-sodium (= metham sodium)
Dinocap	PCP (pentachlorophenol)
Folpet	PCP/zinc naphthanate
(*p) Mancozeb	Thiram
MCPA	Zineb
Mercaptothion (= malathion)	

TABLE B: Active ingredients for which a Certificate of Analysis is required (no 5-batch analysis).

Aluminium phosphide	Magnesium phosphide
Ammonium sulphate	N-alkyl dimethyl benzyl ammonium chloride
Arsenic/chromium/copper	Naphthalene
Borax/PCP	Poly(2-hydroxyethylene-dimethyliminio-2-hydroxypropylene-dimethyliminio-methylene) dichloride
Boric acid	Sodium fluosilicate
Calcium arsenate	Sodium hypochlorite
Calcium hydroxide/copper sulfate (=Bordeaux mixture)	Sulfur (= sulphur)
Calcium hypochlorite	Tartar emetic
Calcium polysulfide (=Lime sulfur)	Trichloroisocyanuric acid
Carbon dioxide	Zinc phosphide
Copper hydroxide	
Copper oxide (=Cuprous oxide)	(Refer also to the note in par. 2.3.6 regarding substances where the active ingredient does not have a known minimum percentage purity),
Copper oxychloride	
Copper sulphate	
Copper sulphate (basic)	
Creosote	
Creosote/coal tar	
Dichlorocyanurate	
Didecyl dimethyl ammonium chloride	