AFRICAN BIOLOGICALS ALLIANCE
For Africa. By Africa.

REGISTRATION · SOUTH AFRICA · AGRICULTURAL REMEDIES

Data for each type of new registration

What goes in the dossier depends on what you are registering. Find your route, then see what is asked.

5 routes to a new registration	**17** items compared across them
1/3 of the end uses need trials for a new formulation	**5** production batches analysed for a generic

FIND YOUR ROUTE

Five routes

New active ingredient

Never approved in South Africa.

New formulation type

Same active ingredient source as a registered product, a different formulation type (EC, SC, WP and so on).

Generic active ingredient

A source other than a registered product's.

Parallel or daughter

Identical to a registered remedy.
Parallel: same company.
Daughter: a different company.

Organic agriculture

Only for use in organic agriculture.

Biopesticides and minor use remedies need essentially the same data as conventional remedies. See the biological remedies guide for the specifics.

WHAT GOES IN

Seventeen items, five routes

● required ○ conditional or reduced

Item	New active ingredient	New formulation type	Generic active ingredient	Parallel or daughter	Organic agriculture
Proof of the fee	●	●	●	●	●
Covering letter	●	●	●	●	●
Application form	●	●	●	●	●
Active ingredient dossier (List I)	●	○	●		●
Formulated product dossier (List II)	●	●	●		●
Toxicology and environment of the active ingredient	●				○
Formulation toxicity	●	●	●		●
Physical properties and storage stability	●	●	●		●
Proposed label	●	●	●	●	●
Efficacy trials	●	○	○		○
Residue data	●	●	●		○
Bee toxicity studies	●	●	●		●
Safety data sheet	●	●	●	●	●
Letter from the formulator		●	●		●
Letter from the technical material manufacturer			●		
Identity and purity: five batches, or a certificate			●		○
Legal agreement between the parties				○	

Fungicides on wine grapes also need fermentation studies. Tobacco needs smoking studies. These apply to new active ingredients, new formulations, generics and organic remedies.

THE DETAILS THAT MATTER

Generics and new formulations

Generic: prove it is the same

Chemical equivalence

1. Details of manufacture, identity, purity and impurities
   Technical grade active ingredient.
2. Analysis of five production batches
   By an ISO 17025 accredited or GLP certified laboratory.
3. If inconclusive, an Ames test
   For mutagenicity, from a GLP laboratory.
4. No known minimum purity? A certificate of analysis
   For example adjuvants, plant extracts and biological remedies.

New formulation: trials on one third

Of the end uses on the reference label.



One third of the crops, pests or weeds to be listed on the new label. Phytotoxicity on known sensitive cultivars, compared with a similar remedy.

WHERE IT IS UNCLEAR

Ask before you rely on it

This 2015 guideline says	But
Three copies of the application form and of the label	The 2023 regulations say duplicate, and two printed label copies
The label follows the 2006 regulations	The 2023 regulations replace them
Forms come from the old department's website	Get current forms from the Registrar's office
Five-batch reports will later need to follow GLP, from a date to be announced	The date is not in our sources: ask

Trials and residue data follow the registrar's other guidelines. Ask the registrar's office, in writing, which version applies to your product.

Information, not legal advice. Facts as of 26 October 2026, from the Registrar's Guidelines on the data and documents required for registration of agricultural remedies in South Africa (2015). Later changes are not reflected. Guidelines page: https://www.nda.gov.za/index.php/publication/581-guidelines

Sources

Prepared by the African Biologicals Alliance from these documents. They belong to the department and remain subject to its own terms.

- Guidelines on the data and documents required for registration of agricultural remedies in South Africa. Issued by the Registrar of Act 36 of 1947, 2015. https://www.nda.gov.za/index.php/publication/581-guidelines

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