AFRICAN BIOLOGICALS ALLIANCE

For Africa. By Africa.

REGISTRATION · SOUTH AFRICA · BENEFICIAL INSECTS, NEMATODES AND MITES

Registering a macrobial product

Living predators, parasitoids and nematodes sold as agricultural remedies. What the registrar asks for, and what it does not.

22 items in the application	**5** batches analysed, on five measures
0 residue, limit or phytotoxicity data usually needed	**4** permit outcomes, by origin and where reared

WHAT GOES IN

The application, in seven groups

July 2026 guideline, section 3.

The paperwork

Fee, service request form, completeness checklist, covering letter, and the application form with an index to the macro-organism information. 3.1 to 3.5.

Access and supply

Letters from the rearing facility and from the formulator to the applicant. 3.6.

What it is

Class, genus, species, distribution, origin, identity, mode of action, metabolites, status elsewhere. 3.7.

Deposit and rearing

A voucher in a South African national collection, the rearing and quality control process, any genetic modification, history of use. 3.8 to 3.11.

Safety

A risk assessment by literature review, GHS calculation or a statement that insects alone cannot be classified, a safety data sheet, and a declaration. 3.13, 3.20 to 3.22.

Quality

Five-batch analysis, a shelf-life study and co-formulant details. 3.16 to 3.18.

Claims and label

Efficacy evidence, only if you go beyond the known science, and the label. 3.14, 3.19.

PERMITS

Which permits does it need?

It depends on whether the organism is indigenous or naturalised in South Africa, and where it is reared. Bioprospecting and Nagoya Protocol compliance also apply.

	Reared in South Africa	Reared outside South Africa
Indigenous or naturalised	**No permits** No import permit, no mass release permit.	**Import permit** Exempt from a mass release permit.
Not naturalised and non-indigenous	**Mass release permit** And a manufacture permit if applicable. May need a pest risk analysis by Plant Health.	**Import and mass release permits**

EVIDENCE

What you need to show, and what you may skip

Usually not needed

For macro-organisms.

X **Residue data**
No residues, no maximum residue limit. The residue guideline keeps an exception if residues are suspected.

X **Phytotoxicity data**
The organism does not cause phytotoxic symptoms.

X **Efficacy trials**
If claims stay within what peer reviewed literature supports.

If you go beyond the science

Claims outside the known scope.

1 **Efficacy data**
As the biological remedies data guideline sets out.

2 **By Codex crop group**

3 **To Good Efficacy Practice**

The risk assessment

a literature review signed off by a SACNASP-registered person. Use the first source you have, in this order

FIRST

Toxicity data

If available.

THEN

Overseas assessments

Toxicological assessments by overseas regulators.

THEN

A full literature review

With the articles included, not only references.

LAST

Expert opinion

Or extrapolation from a related species, with written justification.

Humans Consumers and operators.	**Plants**	**Non-target effects** Including bees and other pollinators.
Other beneficials	**Rearing method**	**Persistence** Biodegradability and persistence in the environment.

QUALITY

Five batches, five measures

Five distinct production batches, signed off by a SACNASP-registered person. OECD GLP accreditation is not required. Certificates of analysis are accepted.

01

Viability

Proportion alive after packaging.

02

Morphological integrity

Share free from deformities.

03

Stage uniformity

Consistent age or maturity stage.

04

Contaminants

For nematodes only: presence of bacteria.

05

Longevity

Survival after standard storage.

On the label, count in the right unit per container

Nematodes Infective juveniles	**Parasitoid wasps** Parasitised eggs or mummies
Predatory mites Adults or larvae	**Predatory insects** Adults or larvae

A shelf-life study in representative packaging, signed off by a SACNASP-registered person. Changing the container material or design needs a new study.

LABEL AND IMPORTS

The label, and bringing in unregistered product

The label carries

Annexure 10 checklist.

1. Registration number, product name, genus and species
2. Remedy type and formulation type
3. READ THE LABEL BEFORE USE, storage, disposal, directions for use
4. Content in macrobial units
5. GHS elements, or a statement that it is not hazardous; UN number or a not-regulated statement
6. Batch number and dates, holder details, emergency numbers
7. Aerial directions and an aerial risk assessment, if aerial application is claimed

Import permit

For trials, laboratory work or export.

1. Covering letter and protocol
2. Species and intended use
3. Quantity, origin, port of entry or exit
4. Safety data sheet
5. Re-export documents, if relevant
6. A Plant Health permit and proof of the fee

WHERE IT IS UNCLEAR

Ask before you rely on it

This guideline says	But
Macro-organisms need no residue data	The residue guideline keeps an exception where residues are suspected
The pest risk analysis definition cites the Plant Health Act as Act 35 of 2004	Its reference list gives Act 35 of 2024
Flowcharts in the annexures help decide permits, identification, risk and history of use	They are images that our summary does not reproduce

Ask the registrar's office, in writing, which requirements apply 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 the registration of macrobial remedies in South Africa (July 2026). Later changes are not reflected, and the guideline's flowchart annexures are not reproduced. 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 the registration of macrobial remedies in South Africa. Issued by the Registrar of Act 36 of 1947, July 2026. https://www.nda.gov.za/index.php/publication/581-guidelines

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