

GOVERNMENT NOTICE
GOEWERMENTSKENNISGEWING

DEPARTMENT OF AGRICULTURE
DEPARTEMENT VAN LANDBOU

No. R. 935

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**FERTILIZER, FARM FEEDS, AGRICULTURAL REMEDIES AND
STOCK REMEDIES ACT, 1947 (ACT No. 36 OF 1947)**

REGULATIONS RELATING TO AGRICULTURAL REMEDIES

I, Lulama Xingwana, acting under section 23 of the Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), made the regulations in the Annexure hereto.

L. Xingwana
Minister of Agriculture.

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SCHEDULE**Definitions**

1. Words and phrases in these regulations shall have the meaning assigned hereto and any other word or expression shall have the meaning assigned thereto in the Act, and unless the context otherwise indicates –

"applicant" means the person in whose name an application for the registration of an agricultural remedy has been filed;

"invoice" means an accompanying letter, delivery note or weighbridge ticket, receipt or receipt note;

"label" means any written, printed or graphic representation attached to or included in a container of an agricultural remedy

"manufacture" means make, compound, mix, formulate, process, package and label for purpose of sale and, "manufacturing" and "manufacturing process" have a similar meaning;

"manufacturer" means an individual or undertaking that manufactures agricultural remedies;

"mark" means a mark as defined in section 1 of the Trade Marks Act, 1993 (Act No. 194 of 1993);

"registered name" means the name approved by the registrar under which an agricultural remedy is registered and may be sold;

"registration holder" means the person to whom a certificate of registration in respect of a particular agricultural remedy has been issued;

"trademark" means a mark to which the holder of the registration has the right, either as owner or a registered user thereof, to distinguish his/her agricultural remedy from that of any other manufacturer but excludes the registered name of an agricultural remedy as intended in these regulations; and

"sworn translator" means a person admitted and enrolled by any division of the Supreme Court (High Court) in terms of Rule 59 of the Rules of Superior Court Practice.

PART I**REGISTRATION****Application for registration**

2. (1) An application in terms of section 3 (1) (a) of the Act for the registration of an agricultural remedy shall be submitted to the Registrar on a form as set out in Annexure 1.

(2) Such application shall:

- (a) be made by a person who is resident in the Republic or in the case of a juristic person, who has a registered office in the Republic;
- (b) signed by an approved person;
- (c) be accompanied by the fee specified in Table 1;
- (d) be accompanied by three copies, in English, of a typed version of the label. If any other language is used the label shall also be submitted in duplicate with an affidavit from the certified translator declaring the label to be a true translation of the English label.
- (e) further be accompanied by:

- (i) a copy of the experimental data on the biological/laboratory efficacy and residues of the agricultural remedy conducted under South African conditions; or any other data required by the Registrar. The Registrar may inspect the performance of such trials.
- (ii) experimental data relating to toxicology of the active ingredient/s concerned and to metabolites of such ingredient/s
- (iii) the method of analysis for the determination of the active ingredient concerned in the formulation and, where applicable, the method of analysis for the active ingredient and its toxic metabolites in residues; and
- (iv) the details of the effect, which the agricultural remedy may have on the environment.

(3) The Registrar may request any further data or sample which may enable him to evaluate the application.

(4) An agricultural remedy of which the active ingredient and formulation, is identical to that of an agricultural remedy which is registered in favour of another person, further be accompanied by the written permission of such other person that the agricultural remedy be registered.

Period of registration

3. (1) Subject to the provisions of sections 4 and 4A of the Act, a registration in terms of section 3 of the Act shall be valid until 31 March of the following year: Provided that if a registration is granted during a particular calendar year within six months prior to the applicable expiry date it shall be valid until the expiry date concerned in the following year.

Renewal of registration

4. (1) An application in terms of section 3 (4) (a) of the Act for the renewal of the registration shall be submitted to the Registrar on a form as prescribed by regulation.

(2) Such application shall be:

- (a) submitted to the Registrar not later than 30 days prior to the expiry date of the registration concerned but not more than six months prior to such expiry date;
- (b) accompanied by the application fee as prescribed by regulation.

(3) An application made in terms of sub - regulation (1) which is:

- (a) received by the Registrar after the expiry date of the registration concerned, but not more than 30 days after such expiry date, shall be considered only if it is accompanied by the applicable additional late application fee, or
- (b) received by the Registrar after the days of grace referred to in paragraph (a) expired, shall not be considered. A new application must be made in terms of regulation 2.

(4) Any person who applies in terms of this regulation for the renewal of a registration shall in an affidavit confirm that the details which he or she furnishes with such application in respect of the agricultural remedy concerned or of a label which is being used in connection therewith, do not deviate in any manner whatever from the congruent details which have already been registered or approved in relation to that agricultural remedy or label: Provided that only the original of each application must be sworn to or attested.

Conditions for certain registrations and renewal of certain registrations

5. A registration, amendment and maintenance of an agricultural remedy under section 3 of the Act is granted on condition that during the period of registration or renewal of the registration:

- (a) the formulation of the agricultural remedy concerned shall not deviate more than the permissible deviation from the formulation which is registered in respect thereof;
- (b) the details which are approved to be indicated on a label or container used in connection with the sale of the agricultural remedy concerned, shall not be altered without the prior written approval of the Registrar.

Application for amendment of certain registrations and approved labels

6. If any person in whose favour an agricultural remedy is registered, intends to alter the registered composition thereof or to effect any amendment to the details which are approved to be indicated on a label or container in connection with the sale and use thereof, such application shall be accompanied by prescribed documents and fee, and shall be accompanied by the applicable certificate of registration if it will be affected by the amendment;

Provided that the Registrar may grant exemption from the payment of the application fee concerned or submission of the application form if the alteration or amendment concerned:

- (a) is in the public interest;
- (b) is effected by the Registrar; and
- (c) is due to editorial changes to improve the label.

Suitability and efficacy of agricultural remedies

7. (1) The suitability and efficacy of an agricultural remedy stated in an application for the registration thereof shall, where applicable, be proved by results of trials which were carried out therewith, by the person who made such application or by a competent body which is recognized for this purpose by the Registrar.

(2) The person or body referred to in sub - regulation (1) shall where applicable, prior to the commencement of a trial indicated in that sub - regulation, notify the Registrar of the intention to conduct such trial, and the Registrar may inspect the performance of such a trial.

Determination of toxicity and potential hazards of agricultural remedies

8. (1) The toxicity or potential hazards of the active or inert ingredients of an agricultural remedy shall, in accordance with the LD-50 values specified in Table 2 and with due observance of additional toxicological information relating to properties such as skin and/or eye irritancy, sensitization, systemic accumulation, chronic poisoning, carcinogenicity and teratogenicity of such active or inert ingredients, be determined on the oral or inhalation toxicity to the rat or the dermal toxicity to the rabbit or guinea pig, as the case may be.

(2) When the LD-50 values of an agricultural remedy were thus determined, such agricultural remedy shall be classified as the group indicated in column 1 of Table 2, opposite which the applicable LD-50 values are specified in columns 2 and 3 of the said Table 2.

Return of certificate of registration

9. A certificate of registration which is returned in terms of section 4 A (3) of the Act shall reach the Registrar:

- (a) within 14 days of the date on which the:

- (i) person to whom the certificate of registration in question was issued, was notified in terms of section 5 of the Act in writing of the reasons for the cancellation of such registration; or
 - (ii) registration of the agricultural remedy concerned has lapsed in terms of section 4A (2) of the Act, or
- (b) at least 30 days prior to the date on which the registration of an agricultural remedy, is to be transferred to another person: Provided that an application as contemplated in regulation for the registration of the agricultural remedy in question in favour of such other person, shall be submitted simultaneously.

PART II

LABELLING AND CONTAINERS

Containers of agricultural remedies

10. (1) Subject to the provisions of any other law relating to containers, a container in which a quantity of an agricultural remedy is packed for sale and a container in which a measured dosage of an agricultural remedy is packed (respectively referred to in these regulations as an immediate container and a sachet), shall at the time of packing be:

- (a) sound and clean;
- (b) closed or sealed in the manner permitted by the agricultural remedy concerned and the immediate container or sachet concerned.

(2) The design of an immediate container or sachet shall:

- (a) after the contents thereof has been used not be instrumental to the use of such empty container or sachet for any other purpose; and
- (b) in the case of a liquid agricultural remedy, prevent spillage when pouring out the contents thereof.

(3) An immediate container or sachet or an outer container or display container respectively referred to in regulation 10(1) shall not be labelled with any other marks or signs than the applicable details referred in regulation 10(1) on which shall appear in terms of a provision of any other law on such container or sachet, or which related to the contents of such container or sachet and which was approved by the Registrar.

(4) Containers and packaging material shall comply with South African National Standards 10229.

(5) No Group Ia and Group Ib may be sold in containers smaller than a mass of 1 kilogram or volume of 1 litre or as specified by the Registrar.

Labelling of containers of agricultural remedies

11. (1) An immediate container and, where applicable, a sachet referred to in regulation 12 (1) shall, except when it contains a legume inoculant, be labelled with:

- (a) the trade mark, if any, and the trade name which may be used by the person in whose favour the agricultural remedy concerned is registered;
- (b) the registration number of the agricultural remedy concerned together with a reference to the Act expressed as "Reg. No.Act No. 36 of 1947";
- (c) the applicable toxicity group to which the agricultural remedy concerned was classified in accordance with regulation 8 (2);

- (d) the type of formulation of the agricultural remedy and the purpose for which it is registered;
 - (e) the composition of the agricultural remedy concerned;
 - (f) the number of the batch from which the agricultural remedy in such container originates and the manufacturing date of that batch, provided that in the case of an agricultural remedy:
 - (i) of which the registered active ingredient contents will possibly diminish over a period of two years to below the applicable permissible deviation specified in regulation 19, the expiry date shall be indicated instead of the manufacturing date;
 - (ii) which is sold in an aerosol container, the batch number and manufacturing date may be marked on the bottom of such container provided an appropriate indication to that effect appears on the main panel referred to in sub - regulation (2) (a);
 - (g) subject to the provisions of the Trade Metrology Act, 1973 (Act No. 77 of 1973), the nett volume or mass, as the case may be, of the agricultural remedy in such container; and
 - (h) the name and address of the person and where applicable, the company registration number in whose favour the agricultural remedy concerned is registered.
- (2)
- (a) A label shall be divided into different panels and the applicable details referred to in sub - regulation (1) shall, in the order set out in that sub - regulation, be labelled on the main panel which shall not take up more than 40 percent of the total surface of the label concerned, together with any other details or indications which are to appear on such main panel in terms of the provision of any other law provided that the Registrar may approve alternative label layouts;
 - (b) The name of an active ingredient of an agricultural remedy, shall when it is included in the trade name or is labelled in accordance with the provisions of sub - regulation (2) (a), be the name as is accepted as a common name by International Organisation for Standards or be the chemical name of the common name of the active ingredient;
 - (c) The toxicity group to be labelled in accordance with sub - regulation (1) (c), shall in the case where the agricultural remedy concerned:
 - (i) was classified as group 1a (red colour band), consist of the expression "Very toxic" in letters at least half the size of the largest letter of the trade name and be in black with a red background with skull and crossbones and appropriate pictograms;
 - (ii) was classified as group 1b (red colour band), consist of the expression "Toxic" in letters at least half the size of the largest letter of the trade name and be in black with a red background and appropriate pictograms;
 - (iii) was classified as a group II (yellow colour band), consist of the expression "Harmful" with the Saint Andreas cross and appropriate pictograms;
 - (iv) was classified as group III (blue colour band, consist of the expression "Caution" and appropriate pictograms;
 - (v) was classified as group IV (green colour band), and appropriate pictograms.

Provided that if the sizes of letters and symbols as specified are impracticable on a particular label, the Registrar may approve practical sizes: Provided further that no particulars of toxicity group of an agricultural remedy which was classified as group IV must be labelled.

- (d) The composition to be labelled in accordance with sub-regulation (1) (f) shall, with due observance of the provisions of paragraph (b) (i), consist of the common name or chemical name, as the case may be, of the active ingredient concerned and, if that ingredient has been classified in the list referred to in the said paragraph as a particular chemical group, the name of the chemical group concerned, followed by the nominal value of the contents of such active ingredient expressed:
- (i) in the case of a liquid agricultural remedy, as gram per litre at 20°C;
 - (ii) in the case of a dry agricultural remedy, as gram per kilogram, and
 - (iii) in the case of an agricultural remedy contained in an aerosol container, as gram per kilogram.

Provided that in the case of wood preservatives, such indication shall represent the minimum value of the active ingredient concerned.

- (e) The manufacturing date or expiry date, as the case may be, to be labelled in accordance with the provisions of sub - regulation (1) (g) shall be expressed separately from the batch number as a month and year: Provided that the requirement of this sub-regulation does not apply to remedies to be used in swimming pools.
- (3) (a) Warning statements and precautionary measures relating to the use of an agricultural remedy and in the case of a Group I or Group II agricultural remedy, the symptoms of poisoning, first aid and a note to the physician shall be indicated under those headings and in that sequence on a side panel of the label.
- (b) If a withholding period is required between the last application of an agricultural remedy and the harvesting, feeding, grazing or processing of a commodity which is treated with such agricultural remedy, the period which shall thus expire shall as the first statement appear in bold type face, or be underlined, immediately below the heading "Warning Statements".
- (4) (a) Directions for use and where applicable resistance warnings, use restrictions, waiting period for follow-up crops, compatibility statements, mixing instructions in the form of a table, the actual uses of the agricultural remedy concerned after such mixing shall be indicated under those headings and in that sequence on a side panel of the label and shall be clearly distinguishable from any other details to be indicated in accordance with sub - regulations (1) and (3).
- (b) If the efficacy of an agricultural remedy will be enhanced or the spectrum of use thereof will be broadened by adding to the final mixture of another agricultural remedy, the compatibility statement referred to in paragraph (a) shall furnish the trade name and registration number of the agricultural remedy of which it is known that it is compatible with the agricultural remedy concerned.
- (c) Directions for use of an agricultural remedy shall:
- (i) if applicable, state the method of mixing and the rate at which dilution shall be made;
 - (ii) indicate the method of application and the rate at which it shall be administered.

(5) In the case where the immediate container or sachet referred to in regulation 11 (1) is packed in an outer container in which it is sold, such outer container shall also be labelled with all the applicable details and in the manner referred to in sub - regulations (1), (2) (3) and (4).

- (6) (a) If such immediate or outer container is too small to be labelled with all the applicable details and in the manner referred to in sub - regulations (1), (2), (3) and (4), the container concerned may be labelled with those details only referred to in sub - regulation (1), together with the words "For full details see attached label" or the words "For full details see included label", as the case may be.
- (b) Such attached or included label shall, in addition to any other marks or indications relating to the agricultural remedy concerned, be labelled with the applicable details and in the manner referred to in sub - regulations (1) (a), (b), (c), (d), (e), (f) and (h), (2), (3) and (4).

(7) A sachet referred to in sub - regulation 11 (1) which is too small to be labelled with all the applicable details referred to in sub-regulations (1), (3) and (4) may be labelled with the details only referred to in sub - regulation (1) (a), (b), (c), (d) (f) and (h), in which case the outer container of such sachet shall be labelled with those details and in the manner referred to in sub-regulation (5) or (6), as the case may be.

(8) A label which is attached to a container in terms of sub - regulation (6) or where applicable, in terms of sub - regulation (7), shall not obliterate any details labelled in terms of the applicable sub - regulations on the container concerned.

(9) Herbicide labels must be indicated by a purple square in the top right hand corner.

(10) A label shall in relation to a legume inoculant be labelled with the:

- (a) applicable details and in the applicable manner referred to in sub-regulations (1) (a), (b), (c), (e), (g) and (h) (2), (4) (a), (5), (6), (7) and (8), on the panel specified in the sub-regulation concerned: Provided that the expiry date of the inoculant concerned shall not be more than six months of the date of manufacture; and
- (b) words "KEEP IN A COOL, DRY AND DARK PLACE" on the main panel referred to in sub - regulation 2(a): Provided that the word "dark" may be omitted if the container concerned is opaque.

(11) (a) If an immediate container or sachet referred to in regulation 11 (1) or an outer container referred to in sub - regulation (5) or (6) or in those sub - regulations as applied by sub - regulation (7) or (10), is packed in a display container, such display container shall in addition to any other particulars, marks or signs relating to the agricultural remedy concerned, be labelled with the details referred to in sub - regulations (1) (a), (c), (d), (g) and (h).

- (b) A casing in which a container or sachet referred to in paragraph (a) is packed for transport shall, in addition to any other details, marks or indications relating to the transportation of the agricultural remedy concerned, be labelled with the applicable details referred to in sub regulation (1) (a), (c), (d), (g) and (h).

(12) Unless otherwise provided for in these regulations, the applicable details referred to in regulations 11 shall be labelled with permanent ink, contrasting to the background in letters, figures and symbols of not less than one mm high.

(13) Containers and labels, which at the commencement of these regulations, do not comply with the requirements specified in this regulation shall only be used for the labelling of the agricultural remedy concerned until three months after the commencement of these regulations.

PART III
ADVERTISEMENTS

Details of advertisements

12. (1) An advertisement shall in addition to any other relevant details which the Registrar may approve to appear therein:

- (a) when published in a newspaper, magazine or other printed matter;
 - (i) furnish the trade mark, if any, and the trade name which may be used by the person in whose favour the agricultural remedy in question is registered;
 - (ii) where it is applicable furnish the toxicity group as which the agricultural remedy in question was classified and the name of the active ingredient which it contains, if such name is not already included in the trade name;
 - (iii) contain the registration number of the agricultural remedy in question together with a reference to the Act, expressed as "Reg. No....Act No. 36 of 1947", and
 - (iv) furnish the name and address of the person in whose favour the agricultural remedy in question is registered, or
- (b) when screened or broadcasted, at least furnish those details referred to in paragraph (a) (i), (ii), (iii) and (iv).

(2) Any reference in an advertisement to the:

- (a) ingredient or active ingredient as the case may be;
- (b) instructions for use, application or administration; and
- (c) registration of the agricultural remedy in question

shall be restricted to those details which are approved to be indicated on a label or container used in connection with the sale of that agricultural remedy.

(3) All advertisements must comply with the prescriptions for advertising of the Advertising Standards Authority of South Africa.

Publication or distribution of false or misleading advertisements

13. (1) No person shall publish or distribute any false or misleading advertisement relating to an agricultural remedy.

(2) It shall be a sufficient defence for any person, other than the person selling the agricultural remedy to which the false or misleading advertisement relates, who is charged with a contravention of sub regulation 13(1), if he or she proves to the satisfaction of the court that he/she did not know and could not reasonably be expected to have known that the advertisement was false or misleading in any respect, unless it is proved that the accused failed on demand by the registrar or a police official to furnish the name and address of the person at whose instance the advertisement was published or distributed.

PART IV**MANUFACTURING ESTABLISHMENT*****Practices to be followed at establishments***

14. (1) The practices in respect of the operation of the undertaking at an establishment and which relates to the manufacture, control, packing, marking or labelling of an agricultural remedy for the purpose of sale, shall be in conformance with quality documented management systems and be such that the composition and efficacy of the agricultural remedy in question comply with the details registered in respect thereof, and that it possesses all the chemical, physical and other properties thus registered.

(2) Raw materials used for the manufacture of an agricultural remedy, and the agricultural remedy manufactured therefrom, shall be handled and stored at the premises of an establishment in such a manner that:

- (a) it is protected against damage, contamination and deterioration;
- (b) access to the different raw materials and agricultural remedies can readily be obtained.

(3) Chemical or physical quality checks shall be made on each consignment of all raw materials used for the manufacture of an agricultural remedy and on the agricultural remedy manufactured from such raw materials by the person in whose favour an agricultural remedy is registered or by a competent body in the Republic which is recognised for this purpose by the Registrar.

(4) The person managing the undertaking at an establishment shall keep samples (at least 300 ml/300g) in respect of each batch of different agricultural remedies manufactured for a period of at least 2 years from the date of manufacturing.

(5) The names of the raw materials to be used for the manufacture of an agricultural remedy shall be marked clearly and legibly on the containers thereof. Provided that if such raw materials are stored in bulk, the names of such raw materials shall be shown on the containers in or the places at which they are thus stored.

(6) If an agricultural remedy is not packed and labelled immediately after manufacture, the name thereof shall be shown on the containers in or places at which it is stored.

Requirements for establishments

15. (1) An establishment where an agricultural remedy is manufactured, controlled, packed or labelled for the purpose of sale must conform to the requirements of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).

(2) The premises of such establishment shall be kept orderly and clean.

(3) The area at such establishment which is used for the performance of a particular function in connection with the manufacture, control packing or labelling of an agricultural remedy shall be adequate for the proper carrying out of that function.

(4) Facilities and equipment which shall ensure that an agricultural remedy shall be manufactured, packed and labelled in the manner determined in these regulations and that the composition and efficacy of the agricultural remedy concerned complies with the requirements registered in respect thereof, and that it possessed the chemical physical and other properties registered, shall be available at the establishment concerned.

(5) An employee at an establishment who is responsible for the manufacture, control, packing, marking or labelling of an agricultural remedy shall have the knowledge of the practices to be followed in the operation of the undertaking at such establishment and of the provisions of the Act which, in the opinion of the Registrar, is sufficient for the performance of the duty imposed upon such employee.

Maintenance and care of facilities

16. (1) All facilities and equipment used in the manufacture, control packing or labelling of an agriculture remedy shall be maintained in a sound condition and be cleaned at regular intervals.

(2) Where the same facilities and equipment are used for the manufacture, control, packing of labelling of different agricultural remedies, such facilities and equipment shall be cleaned properly before it is used in connections with another agricultural remedy.

Records at establishments

17. (1) A person managing the undertaking at an establishment shall, in respect of each batch of the different agricultural remedies manufactured, controlled, packed or labelled there, keep comprehensive record of:

- (a) the results of quality checks which were made in terms of regulation 14(3) of the raw materials used for the manufacture of the agricultural remedy comprising such batch and of such agricultural remedy;
- (b) the total quantity of the agricultural remedy comprising such batch and if packed, the number of containers in which it is packed;
- (c) the records indicating the source of raw materials and processing;
- (d) the names and addresses of the persons to whom the agricultural remedy was sold, and the quantity thereof which is sold to each such person; and
- (e) complaints which were received in connection with the composition or efficacy of the agricultural remedy comprising such batch, or the chemical, physical or other properties thereof.

(2) The records to be kept at an establishment in terms of sub - regulations (1) as well as the formula for formulating a batch of an agricultural remedy there, shall be preserved at such establishment or such other place as may on application be approved by the Registrar, for at least two years after the date on which the batch concerned were sold: Provided that if a complaint referred to in sub - regulation (1) (e) was received, the records in respect of the batch in question shall not be destroyed within two years after the date of such complaint.

(3) The records must always be kept at an establishment and made available when required by the authority.

PART V**SAMPLING AND PERMISSIBLE DEVIATIONS IN ACTIVE INGREDIENT CONTENT****Representative samples of agricultural remedies**

18. (1) (a) An agricultural remedy which is sold in containers shall be sampled by selecting at different places from the batch of a particular agricultural remedy the number of containers required to obtain a sufficient quantity for a sample of such agricultural remedy.
- (b) Such containers shall be similarly labelled and the agricultural remedy therein shall originate from the same batch.
- (c) If a sample is composed of the contents of more than one container, such sample shall be thoroughly mixed before being divided in terms of section 15 (3) (c) of the Act.

- (d) Notwithstanding the provisions of paragraph (a) at least three sealed containers in which an agricultural remedy is sold, may also be taken as the sample of such agricultural remedy and the containers comprising such sample shall without being opened, be divided in terms of section 15 (3) of the Act.
- (2) (a) An agricultural remedy which is not sold in a container shall be sampled by taking small quantities at different places from the stock of such agricultural remedy to obtain a sufficient quantity for a sample.
- (b) Such sample shall be thoroughly mixed before being divided in terms of section 15 (3) (c) of the Act.
- (3) The provisions of sub - regulation (2) shall *mutatis mutandis* apply to the sampling of an agricultural remedy referred to in sub - regulation (1) prior to the packing thereof in containers, and to the sampling of an active ingredient used in the manufacture of an agricultural remedy.
- (4) A certificate in respect of taking samples of an agricultural remedy shall be as indicated in Annexure 3.
- (5) A certificate on which the result of a test, examination or analysis of a sample of an agricultural remedy is to be recorded in terms of section 15 (4) (b) of the Act shall be as indicated in Annexure 4.
- (6) That part of a sample of an agricultural remedy which is referred to in section 15 (4) (c) of the Act:
- (a) shall, if a certificate referred to in sub - regulation (5) indicates that such sample does not possess the chemical, physical or other properties specified in the application for registration of the agricultural requirements referred to in these regulations, be retained until the action arising from such certificate is concluded.

Permissible deviations in active ingredient contents

19. Notwithstanding anything to the contrary contained in these regulations, an agricultural remedy shall not be deemed to deviate in its registered active ingredient contents if a certificate referred to in regulation 18(5) in relation to the analysis of a sample of such agricultural remedy indicates that it nominally contains:

- (a) less than 25 g of the active ingredient concerned per kilogram or litre, it deviates by not more than 15 per cent;
- (b) 25 g or more, but less than 100g of the active ingredient concerned per kilogram or litre, it deviates by not more than 10 per cent;
- (c) 100 g or more, but less than 250 g of the active ingredient concerned per kilogram or litre, it deviates by not more than six per cent;
- (d) 250 g or more, but less than 500 g of the active ingredient concerned per kilogram or litre, it deviates by not more than five per cent; and
- (e) 500 g or more of the active ingredient concerned per kilogram or litre; it deviates by not more than 2,5 per cent.

PART VI

INVOICES

Invoices for agricultural remedies

20. (1) An invoice given or sent in terms of section 9 of the Act by a person who sells any agricultural remedy not in a container, shall furnish all the applicable details referred to in regulation 12 in

the applicable manner specified in that regulation: Provided that such details may be omitted from the invoice if a label relating to the agricultural remedy concerned is given or sent with such invoice.

(2) A copy of an invoice referred to in sub - regulation (1) shall be preserved by the seller of that agricultural remedy for at least two years after the date on which such agricultural remedy was thus sold.

PART VII

SALES

Minimum requirements of a person selling group 1 agricultural remedies

21. (1) Any person in control of an establishment selling, supplying or making available group I agricultural remedies, must be licensed in terms of the regulations promulgated in terms of the Hazardous Substances Act, 1973 (Act No. 15 of 1973), comply with the conditions of sale or supply of Group I hazardous substances and keep such records as required.

Handling, storage and disposal

22. All handling, storage and disposal requirements of the South African National Standards must be complied with.

PART XIII

IMPORTS

Harbours and places through which imports may be made

23. (1) Agricultural remedies may only be imported through the ports of entry as set out in Annexure 2.

(2) A container in which an imported agricultural remedy is packed not for sale in South Africa shall be marked clearly with the wording "For export only".

(3) No unregistered agricultural remedy may be imported into South Africa unless such a remedy complies with the requirements as stipulated in section 16 of the Act.

PART IX

APPEALS

Submission of appeals

24. (1) An appeal in terms of section 6 of the Act shall be submitted to the Minister within 60 days of the date on which the reasons for the decision against which is appealed, were furnished in terms of section 5 of the Act.

(2) Such appeal shall:

- (a) be in the form of a written affidavit;
- (b) state the reference number and date of the documents by means of which such applicant or person was given notice of that decision;
- (c) state the grounds on which the appeal is based;
- (d) be accompanied by the documents relating to the subject of the appeal; and
- (e) be accompanied by the fee as prescribed in the regulation.

(3) If such appeal is submitted by a person other than the person in respect of whom the decision concerned was furnished, the appeal concerned shall be accompanied by a statement in which the person concerned discloses his interest in that decision or action.

(4) The amount referred to in sub - regulation (2) (e) shall be paid by cheque, postal order or money order made out in favour of the Director-General: Department of Agriculture: Provided that if the appeal concerned is delivered by hand, such amount may be paid in cash.

Address for submission of appeals

25. An appeal referred to in regulation 28(1) shall:

- (a) when forwarded by post, be addressed to the Director-General, Department of Agriculture, Private Bag X250, Pretoria, 0001; and
- (b) when delivered by hand, be delivered to the Director-General, Department of Agriculture, Agriculture Building, 20 Beatrix Street, Agriculture Place, Arcadia, Pretoria.

PART X

GENERAL

Offences and penalties

26. Any person who refuses or fails to comply with the provisions of these regulations shall be guilty of an offence and liable on conviction to a fine or imprisonment or to both a fine and imprisonment.

Payment of fees

27. (1) The postage on delivery costs of any application or document submitted in terms of these regulations, as well as on or of anything else pertaining thereto, shall be paid by the consignee.

(2) Any fee payable in terms of these regulations shall be paid by means of a cheque postal order or money order made out in favour of the Director-General Agriculture: Provided that if such a fee is delivered by hand, it may be paid in cash.

(3) Fees which are paid in terms of these regulations shall subject to section 6 of the Act and not be refundable.

Address for submission of documents

28. Any application or document or anything else pertaining thereto which is required in terms of these regulations to be submitted to the Registrar shall:

- (a) when forwarded by post be addressed to:
The Registrar: Act No. 36 of 1947, Private Bag X343, Pretoria, 0001; and
- (b) when forwarded by rail or delivered by hand, be addressed or delivered to:
The Registrar: Act No. 36 of 1947, Agriculture Place, 20 Beatrix Street, Arcadia, Pretoria.

Repeal of regulations

29. The following regulations are hereby repealed.

- (a) Government Notice R. 2296 of 11 November 1977.
- (b) Government Notice R. 2042 of 03 October 1980.
- (c) Government Notice R. 2561 of 27 November 1981.

ANNEXURE 1



agriculture

Department:
Agriculture
REPUBLIC OF SOUTH AFRICA

Republic of South Africa
Registrar: Act 36/1947
Private Bag X343
0001 Pretoria

**FERTILIZERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947
(ACT No. 36 OF 1947), AS AMENDED**

APPLICATION FOR THE REGISTRATION OF AN AGRICULTURAL REMEDY

INFORMATION FOR APPLICANTS

1. The application form must be duly completed in all respects. Where applicable, the requested information can be submitted as separate numbered attachments.
2. The application and draft label must be submitted in triplicate with an explanatory covering letter.
3. The application must be submitted to the Registrar: Act 36 of 1947, Private Bag X343, Pretoria, 0001.
4. Every application must be accompanied by the prescribed registration fee.
5. Only one copy is required of supportive studies (e.g., toxicological data, efficacy data, residue data, physical specifications, and any other relevant studies.) See Lists I and II as well as the "Agricultural Remedies Registration Procedure Document", "Guidelines for the Toxicological Evaluation of Microbial Pest Control Agents", "Agricultural Remedies Residue Trial Data Requirements Document" and "Guidelines on Equivalence of Agricultural Remedies".
6. Lists I and II are supplied as check lists and an index to ensure that the applicant has provided all relevant data.
7. For further information visit our website at <http://www.nda.agric.za/act36/main.htm>

Indicate as appropriate:

Agricultural Remedies containing a new active ingredient			
Agricultural Remedies where source of active ingredient and/or formulation is not identical to a registered product.			
Registration transfer:			
Amendments to an existing registration:			
Other:			
Will product be marketed under own label:	YES:		NO:
Proposed date of marketing:			

1. APPLICANT		
Identification:	Name of applicant/Corporate name of company, and company registration number:	Name of agent/Importer (List of agents/Importers attached):
Status (Importer/formulator/distributor):		
Physical address:		
Postal address (and postal code):		

Telephone (and area code)		
Fax (and area code)		
e-mail:		

2. PRODUCT			
Designation: (Description of product)	Trade name		
	Trade mark holder		
Function of product (e.g., insecticide, herbicide, plant growth regulator, etc)			
Intended use (e.g., public health, industrial, agriculture, forestry)			
Target pest(s) and host(s)			
Method, dosage rates and frequency of application			
Type of formulation:		Crop life in days (approx.)	
Existing reg. no. (if relevant)		Customs tariff code (Brussels Convention)	
Registration in SEARCH** country/ies (please indicate)			
Registration in other country/ies (please indicate)			
Is the product registered in country of manufacture and formulation	If yes, submit evidence		If not, why not?

3. ACTIVE INGREDIENT(S) (Technical grade) (may be attached in sealed envelope)			
Active ingredient(s) (Common name/s)	Manufacturer (Name and address)		

4. FORMULATION (may be attached in sealed envelope)	
Formulator (Name):	Address:

Toxicity (formulated product)			
Route and Method (LD ₅₀)	Concentration	g/l	mg

Toxicity (formulated product)			
	Acute Oral (LD ₅₀ mg/kg)	Acute Dermal (LD ₅₀ mg/kg)	
		Experimental	Experimental
	Calculated	Calculated	Calculated
Skin Irritation		Eye Irritation	
	None	Mild	Moderate
	Severe		
	Ia	Ib	II
			III

Summary of other mammalian toxicological studies:

Toxicity to bees:

Toxicity to fish and other aquatic organisms:

Toxicity to birds:

Toxicity to earthworms and soil micro-organisms:

Toxicity to other non-target organisms:

Persistence in environment:

Other effects:

6. PACKAGING
Packaging material / container (e.g., plastic jug, glass bottle, etc.):
Pack size(s):
Disposal of empty container(s):

7. DECLARATION BY APPLICANT OR THE DULY APPOINTED REPRESENTATIVE	
Trade name of product: _____	
For and on behalf of _____ I hereby certify that the abovementioned information and data provided in support of this application are to the best of my knowledge true, correct and complete.	
..... Name in full (printed) Signature
..... Date Official Title
Official Stamp of Applicant / Company	FOR OFFICIAL USE Registration is: Recommended <input type="checkbox"/> Not Recommended <input type="checkbox"/> Technical Adviser:
 Date

NOTES:

* CropLife International = formerly GCPF (Global Crop Protection Federation), formerly GIFAP (International Group of National Association of Manufacturers of Agrochemical Products).

** SEARCH = Southern and East Africa Regulatory Committee for Harmonization of Pesticide Registrations.

ACTIVE INGREDIENT: DOSSIER INDEX

LIST I

The dossier accompanying the application must provide full details (as applicable) of the information requested in the lists, i.e. details on the methods used, summaries of methods and results used in toxicology and ecotoxicology studies, method of analyses, etc. Applicants are advised to use CIPAC methods for physical and chemical properties. Numbering used in the dossier must correspond to that used in the application form. If the product contains more than one active ingredient, compile a separate dossier for each active ingredient.

ACTIVE INGREDIENT (a.i.) (Technical Grade)	Annex. No. in dossier if study included	Official use only
1. DESIGNATION		
a. Common name (ISO)		
b. Manufacturer or development code		
c. Chemical name (IUPAC)		
d. Chemical group		
e. Structural formula		
f. Empirical formula		
g. Patent status		
Is the a.i. under patent?		
Who is patent holder?		
Expiry date		

2. PHYSICAL AND CHEMICAL PROPERTIES (Active ingredient – technical grade)		
a. Physical state		
b. Colour		
c. Odour		
d. Density at 20°C		
e. Vapour pressure at 20/25°C		
f. Volatility		
g. Hydrolysis DT ₅₀ Days.....°C.....pH		
h. Photolysis		
i. Solubility in water.....°C.....pH		
j. Solubility organic solvents		
k. n-octanol/water partition coefficient		
l. Boiling point °C		
m. Melting point °C		
n. Decomposition temperature °C		
o. Method of analysis and impurities		

3. TOXICOLOGY (Active ingredient – technical grade)		
a. ADI		
b. Acute oral LD ₅₀ mg/kg rat/rabbit		
c. Acute dermal LD ₅₀ mg/kg rat		
d. Inhalation LC ₅₀ mg/l /hour (rat)		
e. Skin irritation (rabbit)		
f. Eye irritation (rabbit)		
g. Sensitization (guinea pig)		
h. Reproduction (specify species)		
i. Subchronic toxicity 90 day NOEL mg/kg/day		
j. Chronic toxicity NOEL mg./kg/day		
k. Carcinogenicity (life time) NOEL mg/kg/day		
l. Neurotoxicity NOEL mg/kg/day		
m. Teratogenicity NOEL mg/kg/day		
n. Mutagenicity / Genotoxicity		
o. Metabolism (rat)		
p. Other studies		

LIST I

ACTIVE INGREDIENT (Technical Grade)		Annex. No. in dossier if study included	Official use only
4. ECOTOXICOLOGY (Active ingredient – technical grade)			
a. Birds (2 species)	LD ₅₀ mg/kg		
	NOEL		
	LD ₅₀ mg/kg		
	NOEL		
	Reproduction		
b. Fish (2 species)	LD ₅₀ mg/kg		
	NOEL		
	LD ₅₀ mg/kg		
	NOEL		
	Reproduction		
c. Daphnia	LC ₅₀ mg/l		
	NOEL		
d. Algae	LC ₅₀ mg/l		
	NOEL		
e. Bees	LD ₅₀ µg/bees		
	NOEL		
f. Earthworms	LC ₅₀ mg/kg		
g. Soil micro-organisms	EC/LC ₅₀ mg/kg		
5. BEHAVIOUR IN ENVIRONMENT (Active ingredient – technical grade)			
Behaviour, ways of degradation, degradation products in soil:			
a. Major metabolites			
b. DT ₅₀ (days)			
c. Mobility			
d. Absorption			
e. Mobility of metabolites			
Behaviour, ways of degradation, degradation products in water:			
f. Major Metabolites			
g. DT ₅₀ (days)			
h. Surface			
i. Ground			
6. MODE OF ACTION			
7. PLANT RESIDUES			
a. Major metabolites			
b. Metabolism			
c. Behaviour of residues			
d. Crop			
e. MRL codex			
f. MRL country			
g. PHI & MRL proposed			
h. Method of residue analysis			
8. COUNTRY SPECIFIC REQUIREMENTS			
a.			
b.			
c.			
d.			
e.			
f.			

FORMULATED PRODUCT: DOSSIER INDEX

LIST II

The dossier accompanying the application must provide full details (as applicable) of the information requested in the lists i.e., details on the methods used, summaries of methods and results used in toxicology and ecotoxicology studies, methods of analysis, etc. Applicants are advised to use CIPAC methods for physical and chemical properties. Numbering used in the dossier must correspond to that used in the application form. If the product contains more than one active ingredient, compile a separate dossier for each active ingredient.

FORMULATED PRODUCT	Annex. No. in dossier if study included	Official use only
1. PHYSICAL AND CHEMICAL PROPERTIES		
a. Physical state / formulation type		
b. Colour		
c. Odour		
d. Storage stability		
e. Shelf life		
f. Density		
g. Bulk density		
h. Flammability		
i. Flash Point		
j. Compatibility with other pesticides		
k. pH		
l. pH of 1% aqueous dilution		
m. Oxidizing properties		
n. Corrosiveness		
o. Water content		
p. Wettability		
q. Solubility in water		
r. Foaming		
s. Particle size		
t. Suspensibility / emulsifiability		
u. Emulsion stability		
v. Volatility		
w. Viscosity		
x. Other properties (where applicable)		
y. Method of Analysis		
2. TOXICOLOGY		
a. Rat Acute oral LD ₅₀ mg/kg		
b. Acute dermal LD ₅₀ mg/kg		
c. Inhalation LC ₅₀ mg/l /hour		
d. Rabbit Skin irritation		
e. Eye irritation		
f. Sensitisation in guinea pig		
g. WHO classification		
h. Other studies		
3. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING		
a. Symptoms of human poisoning		
b. First aid treatment		
c. Skin contact		
d. Eye contact		
e. Inhalation		
f. Ingestion		
g. Antidote		
h. Note to physician		

LIST II

FORMULATED PRODUCT	Annex. No. in dossier if study included	Official use only
4. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE		
a. Fire fighting measures		
b. Procedures in case of spillage		
5. USES (New label claims with this application)		
a. Crop/area of use		
b. Target organism		
c. Rate		
d. Stage of treatment		
e. Directions for use		
f. Residue data and pre-harvest interval		
g. Phytotoxicity		
h. Contraindications		
6. MINIMUM LABEL REQUIREMENTS		
a. Product identification		
b. Warnings and use restrictions		
c. Safety precautions		
d. First aid/note to physician (as applicable)		
e. Pictograms (if applicable)		
f. FAO colour code (if applicable)/group		
g. Directions for use		
7. COUNTRY SPECIFIC REQUIREMENTS		
a.		
b.		
c.		
d.		
e.		
f.		

Annexure 2**PORTS OF ENTRY**

Land boarder posts	International Airports	International harbours	Inland
Beitbridge	Cape Town	Cape Town	Johannesburg
Caledonspoort	Durban	Durban	Kimberly
Ficksburg	Gateway (Pietersburg)	East London	Pretoria
Golela	Johannesburg	Mossel Bay	Mmabatho
Groblersburg	Lanseria	Port Elizabeth	Pietermaritzburg
Kapfontein	Port Elizabeth	Richards Bay	Upington
Jeppesreef	Richards bay	Saldanha Bay	Bloemfontein
Lebombo	Upington		Stellenbosch
Mahamba	Bloemfontein		Germiston
Mananga	Mafikeng		
Maseru bridge			
Nakop			
Nerston			
Oshoek			
Qachas' Nek			
Ramatlabana			
Skilpadshek			
Van Rooyenshek			
Violsdrif			

ANNEXURE 3



agriculture

Department:
Agriculture
REPUBLIC OF SOUTH AFRICA

Department of Agriculture
Private Bag X 250
Pretoria
0001

**CERTIFICATE IN RESPECT OF THE TAKING OF SAMPLES
IN TERMS OF SECTION 15 OF ACT No. 36 OF 1947**

Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)
(To be completed in duplicate)

I hereby certify that the accompanying sample of Agricultural Remedy identified by the above serial number, was taken by me on _____ day of _____ 20____
At _____ in the presence of _____
*(Name of owner/person in charge of stocks/witness)
from the stock of _____
(Name and address of seller)

PARTICULARS OF AGRICULTURAL REMEDY FROM WHICH SAMPLE WAS TAKEN

1. Name of registration holder _____
2. Trade name† _____
3. Name of product‡ _____
4. Registration number‡ _____ Act 36/1947
5. Manufacturer details _____
6. Composition of Agricultural Remedy‡
 - 6.1 Chemical composition _____
(List chemicals which appear on the label)
 - 6.2 Physical properties _____
7. Conditions of container from which sample was taken _____
8. Estimated quantity of Agricultural Remedy from which sample was taken:
 - 8.1 Number of containers _____
 - 8.2 Capacity of containers _____
9. Remarks _____

Signature of witness

Registrar

Notes

- * Delete which ever is applicable.
- † Shall be particulars as indicated on the affixed label to the containers from which the sample was taken or as it is marked on such containers, or if the Agricultural Remedy which is sampled, is not sold in containers, as it appears on the invoice which is supplied together with that Agricultural Remedy.
- ‡ One copy shall accompany each of the three parts of the sample and the forth copy shall be kept by the officer who took the sample.

ANNEXURE 4

Analyst address

.....

**CERTIFICATE OF RESULTS OF ANALYSES OR TEST OF A SAMPLE OF AGRICULTURAL
 REMEDIES BY ANALYST**
Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)
(To be completed in duplicate)

I (full name) _____

of _____
 a duly appointed analyst in terms of section 14 of the Fertilizer, Farm Feeds, Agricultural Remedies and
 Stock remedies Act, 1947 (Act 36 of 1947) do hereby make oath and state:

(a) that on _____ I received a sample of ^(a) _____
 from _____ by _____ ^(b) for analyses and/or test;

(b) that the sample was labelled, sealed and marked ^(c) _____

(c) that I have analysed and/or tested the said sample and as a result of the analyses and/or test I
 found it to be constituted as follows:

Pure active ingredient^(d)

	g/kg
(a) _____	_____ / _____
(b) _____	_____ / _____
(c) _____	_____ / _____

Other ingredients (if required)

(a) _____	_____ / _____
(b) _____	_____ / _____
(c) _____	_____ / _____

Remarks _____

 Signature of analyst

DECLARATION TO BE MADE IN THE PRESENCE OF JUSTICE OF PEACE/COMMISSIONER OF OATHS.

TEL NO.....

DATE

INITIALS AND SURNAME

.....
SIGNATURE OF THE DEPONENT

I certify that the deponent has acknowledged that he/she know and understands the contents of this declaration which was sworn to/affirmed before me and the dependents' signature/thumb print/mark was placed thereon in my presence.

.....
JUSTICE OF PEACE/ COMMISSIONER OF OATHS

Full first name and surname:.....
(BLOCK LETTERS)

Designation (rank):..... **Ex Officio Republic of South Africa**.....

Business address:.....
(street address must be stated)

Date:.....

Place:.....

Notes

- (a) State name of Agricultural Remedy as specified on label/insert name of person supplying the sample and state whether it was "by hand", "by post" or by courier.
- (b) Insert distinguishing mark or number of sample.
- (c) State names of particular chemical constituents and physical properties.
- (d) State the common name of the active ingredient

TABLE 1

FEES PAYABLE

PURPOSE		AMOUNT PAYABLE PER APPLICATION
A.	Application for the registration of:	
(a)	a fertilizer, Agricultural Remedy or sterilizing plant	R1 100
(b)	an agricultural remedy or a stock remedy	R2 250
(c)	a pest control operator	R 480
B.	Application for the renewal of the registration of:	
(a)	a fertilizer, Agricultural Remedy or sterilizing plant	R 600
(b)	an agricultural remedy or a stock remedy	R1 100
(c)	a pest control operator	R 330
C.	Payment in addition to that specified in paragraph B, in the case of a late application for the renewal of the registration of:	
(a)	a fertilizer, Agricultural Remedy or sterilizing plant	R 450
(b)	an agricultural remedy or a stock remedy	R 800
(c)	a pest control operator	R 145
D.	An appeal in terms of section 6 of the Act	R3 600
E.	Payment for information and documentation:	
(a)	Application form and instructions	R45,00 per package
(b)	Certificate of free sale	R15,00 per certificate
(c)	Import permit	R10,00 per permit
(d)	Documents from own product files as requested by registration holders	R45,00 per request plus 50c per page

TABLE 2

WORLD HEALTH ORGANIZATION TOXICITY CLASSIFICATION

Group	LD ₅₀ for the rat (mg/kg body mass)			
	Oral		Dermal	
	Solids	Liquids	Solids	Liquids
Ia Extremely hazardous	≤ 5	≤ 20	≤ 10	≤ 40
Ib Highly hazardous	5 - 50	20 - 200	10 - 100	40 - 400
II Moderately hazardous	50 - 500	200 - 2000	100 - 1000	400 - 4000
III Slightly hazardous	≥ 501	≥ 2001	≥ 1001	≥ 4001
IV Acute hazard unlikely in normal use	≥ 2000	≥ 3000	-	-

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