GN. R. 1375 GG3629 11 August 1972

REGULATIONS PERTAINING TO THE REGISTRATION AND SALE OF AGRICULTURAL REMEDIES

The Minister of Agriculture has, under the powers vested in him by section 23 of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), made the regulations set out in the Annexure hereto.

ANNEXURE

Definitions

1. In these regulations, unless inconsistent with the context-

the Act, means the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

agricultural remedy, means any chemical substance or biological remedy or any mixture or combination of any such substance or remedy intended or offered to be used-

- (a) for the destruction, control, repelling or prevention of any undesired virus, bacterium, alga, nematode, fungus, insect, plant, vertebrate, invertebrate or any product thereof, but excluding any chemical substance, biological remedy or other remedy in so far as it is controlled under the Medical, Dental and Pharmacy Act, 1928 (Act 13 of 1928), the Food, Drugs and Disinfectants Act, 1929 (Act 13 of 1929), or the Drugs Control Act, 1965 (Act 101 of 1965), or any preparation prescribed by a medical practitioner or veterinarian for a particular patient or group of patients; or
- (b) as plantgrowth regulator, defoliant, desiccant or legume inoculant;

antidote means any immediate practical treatment in case of poisoning and includes first-aid.

Registration

- 2.(1) Every application for the registration of an agricultural remedy shall be submitted in triplicate in the form prescribed in the Second Schedule hereto, to The Registering Officer of Agricultural Remedies, Department of Agricultural Technical Services, Private Bag X116, Pretoria, and shall be accompanied by-
- ¹(a) three typed copies of the label, advertisement and other literature used or intended to be used in connection with such agricultural remedy;

¹Note: It is recommended that three typed copies of every label and advertisement intended for use in connection with any agricultural remedy be submitted to the Registering Officer before it is printed.

- (b) two samples of the agricultural remedy (not less than 4 oz/fl oz each);
- (c) the registration fee as specified in the First Schedule hereto;
- ²(d) except when not required by the Registering Officer, experimental data on biological efficacy and residues obtained under South African conditions;
- ²Note: (i) Before commencement of experimentation in support of applications for registration of agricultural remedies, applicants must approach the Registering Officer submitting particulars regarding the nature and extent of envisaged experimentation. If possible officials of the Department will visit these experiments. Such officials must be free to inspect experiments at all times with the view to acquainting themselves with the final results.
 - (ii) Such tests must be undertaken either by the applicant or by some other independent body. The Department, however, reserves the right to, where possible and/or desirable, first conduct tests prior to registration.
- (e) full particulars on the pharmacology and toxicology of the agricultural remedy; and
- (f) method of analysis for determining the percentage of active ingredient/s.
- (2) No application will be considered unless it complies in all respects with the requirements prescribed, and unless the applicant furnishes the Registering Officer with such further information (including suitable samples of the agricultural remedy), as he may call for in order to determine whether the agricultural remedy is suitable and sufficiently effective for the purpose for which it is intended.
- (3) Registration will only be effected upon receipt of printed copies of the approved label.
- (4) Whenever an agricultural remedy is registered, the Registering Officer shall issue or cause to be issued to the applicant a registration certificate which shall be valid for a period not exceeding four years and which shall expire on 30 June 1974.
- (5) As from 1 July 1970, the registration of agricultural remedies shall only take place every fourth year, or part of four years, which period shall be calculated from 1 July 1970. Applications for registration shall be submitted on the forms prescribed by subregulation (1) of these regulations and shall be accompanied by the registration fees set out in the First Schedule hereto.
- (6) An existing registration will be regarded as a new registration in case of an amendment thereto which will affect its active ingredient/s by more than five percent.
- (7) An agricultural remedy may not be imported into the Republic of South Africa for the purpose of sale unless it has been registered, prior to the importation thereof by a representative resident or carrying on business within the Republic.
- (8)(a) Agricultural remedies may only be imported for private use with the written consent of the Registering Officer. Where, however, agricultural remedies are imported with the view to sale the Registering Officer shall have the right to issue a general permit subject to the annual submission of required information and in this case it will not be necessary for those concerned to apply for individual consignments.

- (b) Agricultural remedies may only be imported for experimental purposes with the written consent of the Registering Officer. Applications for the importation of test consignments must be accompanied by a sample together with the following information:
- (i) the country of origin;
- (ii) the port entry;
- (iii) the quantity to be imported;
- (iv) the purpose for which the remedy will be used;
- (v) where the remedy will be tested;
- (vi) pharmacological and toxicological properties; and
- (vii) methods of analysis.

Appeals

- 3.(1) Whenever an application for registration is rejected, or a registration is made subject to conditions in terms of the provisions of section 3 (3) of the Act, or is cancelled in terms of the provisions of section 4 of the Act, the Registering Officer shall notify the applicant, in writing, of such rejection, imposition of conditions or cancellation, and the applicant may within 56 days of being notified of such rejection, imposition of conditions or cancellation appeal to the Minister, in writing, against such decision and shall simultaneously submit an explanation of the grounds on which the appeal is based.
- (2) After consideration of the appeal the Minister shall or cause the applicant to be advised. in writing, of his decision.

Trade Names and Brands

4. No agricultural remedy shall be registered, imported or sold under any trade name or brand which is used in connection with any other agricultural remedy, or which is not readily distinguishable from any trade name or brand used in connection with any other agricultural remedy.

Labelling of Containers

- 5.(1) No person shall sell any agricultural remedy, other than a legume inoculant, unless there is clearly and legibly marked or printed on the container in which it is sold or on a label affixed thereto-
- ¹(a) the trade name and brand (if any) of the agricultural remedy;
- ¹Note: The name must be descriptive and the generic name of the active ingredients must appear in brackets below the name of the agricultural remedy.
- (b) the net weight/volume of the substance in such container;
- (c) the percentage composition of the agricultural remedy, in a form approved by the Registering Officer;
- (d) in the case of an agricultural remedy which is liable to deterioration in storage, the last date on which it can still be effectively used, and the conditions under which it must be stored;

- (e) a declaration in a form approved by the Registering Officer specifying the properties and the purpose for which the agricultural remedy is intended;
- ²(f) the directions for use and precautionary measures (if any);
- ²Note: Precautionary measures or warning skates must appear more prominently on the label than the directions for use.
- (g) the name and address of the person responsible for the registration of the agricultural remedy;
- (h) the registration number and the act in terms of which the agricultural remedy is registered, e.g. Reg. No. L in terms of Act 36 of 1947, as amended;
- (i) the skull and cross bones in case of a very toxic agricultural remedy; here the requirements of the Medical, Dental and Pharmacy Act, 1928 (Act 13 of 1928), as amended, must be complied with;
- (j) in case of poisoning the symptoms;
- (k) the name of an effective antidote; and
- (l) any other requirements under the Food, Drugs and Disinfectants Act, 1929 (Act 13 of 1929).
- (2) No person shall sell any agricultural remedy which is a legume inoculant, unless there is clearly and legibly marked or printed on the container in which it is sold or on a label affixed thereto in addition to the requirements of items (a), (f), (g) and (h) of regulation 5 (1)-
- (a) the name and address of the manufacturer and distributor in South Africa;
- (b) the name of the specific legume(s) for which the inoculant is intended;
- (c) the quantity of seed (pounds, weight) that can be treated in respect of each kind of legume for which the inoculant is intended;
- (d) the pack number whereby the source of the inoculant in the process of manufacture can be traced,
- ³(e) the dates of manufacture and expiration;
- ³*Note: The time between these dates must not exceed six months.*
- (f) a warning in the case of transparent containers: "Store in cool (1 °C to 24 °C or 34 °F to 75 °F) dry and dark place"; in the case of non-translucent containers the word "dark" may be omitted.
- (3) Save as otherwise provided by these regulations or any other law, no words or markings, other than those provided for in subregulations (1) and (2) and the words "Registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (or Act 36 of 1947)", may appear on any container in which an agricultural remedy is sold, or on any label affixed thereto.

¹(4) The information marked or printed on a container in which an agricultural remedy is sold, shall appear on one label only. The use of separate "stickers" for additional information is not permitted.

¹Note: If a container is too small to carry a complete label, the necessary directions may appear on a loose leaflet which must be packed with the container and reference must appear on the container to the effect that the product may not be sold without the said leaflet.

Packing of Very Toxic Agricultural Remedies

- 6.(1) Very toxic agricultural remedies must be packed (where possible) according to the South African Bureau of Standard's specifications (SABS 601/614-1961) and in accordance with the requirements of the Medical, Dental and Pharmacy Act, 1928 (Act 13 of 1928), as amended, in order to eliminate the hazard of food contamination in the process of handling and storing.
- (2) No person selling a very toxic agricultural remedy, may repack such a remedy in smaller quantities than that supplied to him. If, however, the main container is made up in smaller quantities with the view of allowing the seller to dispose of it in smaller quantities, the requirements of regulation 5 (1) shall apply mutatis mutandis.

Advertisements

- 7.(1) No person shall in an advertisement of an agricultural remedy-
- (a) use any words or phrases (other than the phrase "Registered in terms of the Fertilizers, Farm Feeds and Remedies Act, 1947") which are calculated to lead a purchaser to believe that registration implies special approval or official guarantee of efficacy upon the part of the Department of Agricultural Technical Services., or
- (b) make any claim in respect of such agricultural remedy, other than those approved of in the certificate of registration of such agricultural remedy.
- (2) Every person who desires to issue an advertisement of an agricultural remedy shall, 14 days prior to the first publication thereof, submit a typed or printed copy thereof to the Registering Officer.

Samples

- 8.(1) The inspector or officer taking a sample of an agricultural remedy in terms of section 15 of the Act, shall extract from the bulk of which the sample is taken a quantity which can be divided into three parts, each being sufficiently large for the purpose of analysis. Before dividing the quantity thus extracted it shall be thoroughly mixed.
- (2) When the agricultural remedy is in a container the contents of which are not sufficient for analysis if divided as aforesaid, additional containers, similarly labelled and purporting to contain a similar agricultural remedy, shall be procured and the contents of two or more such containers shall then be thoroughly mixed before being divided into three parts.

- (3) Where an agricultural remedy in a container is of a perishable nature, or where for any reason the opening of the container would interfere with the analysis of the remedy, unless such analysis were effected at the time of opening or immediately thereafter, at least three containers, similarly labelled and purporting to contain a similar agricultural remedy, shall be procured. The containers thus procured shall be split up into three groups, each of which shall contain one or more unopened container and which shall further be dealt with as prescribed by subsection (2) of section 15 of the Act.
- (4) The certificate accompanying one part of the sample to the analyst, as required by subsection (2) of section 15 of the Act, and the certificate stating the result of the analysis or test of a sample, as required by subsection (3) of the said section, shall be in the forms prescribed in the Third and Fourth Schedules hereto respectively.

Offences and Penalties

9. Any person who contravenes or fails to comply with any provision or requirement of these regulations shall be guilty of an offence and risible to a fine not exceeding R200 or imprisonment for a period not exceeding 12 months, or to both such fine and such imprisonment.

Repeal of Regulations

10. The regulations published in Government Notice R. 944 on 17 June 1966, and as amended by Government Notices R. 945 on 17 June 1966 and R. 1437 on 20 August 1971, are hereby repealed.

FIRST ANNEXURE REGISTRATION FEES - AGRICULTURAL REMEDIES

- 1. Application for registration: R20.
- 2. Application for amendment of existing registrations: R10.

SECOND SCHEDULE

DEPARTMENT OF AGRICULTURAL TECHNICAL SERVICES

FERTILIZERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947 (ACT 36 OF 1947), AS AMENDED

APPLICATION FOR THE REGISTRATION OF AN AGRICULTURAL REMEDY

DIRECTIONS FOR COMPLETION AND SUBMISSION OF APPLICATION

- 1. The application must be accompanied by-
- (a) three copies of every label, advertisement and other literature used or intended to be used in connection with the agricultural remedy;
- (b) the prescribed fee;
- (c) two suitable samples of the agricultural remedy;

- (d) experimental data on biological tests (including residues) in the Republic of South Africa;
- (e) pharmacological and toxicological data.
- 2.(a) Under "composition" (item 5 of application form) the name of every ingredient, together with the percentage in which such ingredient is present and the form in which it occurs, shall be stated.
- (b) The percentage specified shall be the minimum unless the maximum is specifically called for. In the case of poisons as defined by the Medical, Dental and Pharmacy Act, No. 13 of 1928, both the maximum and minimum percentage shall be stated.
- (c) In the case of both solid and liquid agricultural remedies the percentage shall be specified by weight.
- (d) Only the analytical or pharmaceutical terms in common use such as those contained in the U.S.P., N.F., U.S. Dispensatory, B.P., B.P.C., Martindale's Extra Pharmacopoeia, D.A.B. and addenda and supplements thereof may be employed in stating the composition.
- 3. Particulars which must be reflected on the application form must under no circumstances be submitted separately.
- 4. Applications for the registration of an agricultural remedy shall be submitted in triplicate to: The Registering Officer, Act 36 of 1947, Department of Agricultural Technical Services, Private Bag X116, Pretoria.

PART I

1.	Name of applicant
2.(a) (b)	Postal address of applicant Business address of applicant
3.	Is applicant responsible for the importation, manufacture or sale of the agricultural remedy/stock remedy?
4.(a) (b) (c)	Descriptive trade name
5.	Composition
6.	Toxicity:
(a) (b) (c)	Precautionary measures
7.	Directions for use
8.	What properties are claimed for the agricultural remedy?

9.	Packaging used
reme	hereby apply for the registration, in terms of Act 36 of 1947, as amended, of the agricultural dy of which particulars are given above and I do hereby certify that these particulars are to the of my knowledge true and correct.
Date	
	Signature of applicant
PAR (For	T II official use only)
	ΓΙFICATE OF REGISTRATION
I do l	nereby-
(a) (b)	certify that the agricultural remedy referred to in Part I has been registered; and approve of the labels, advertisement and other literature copies of which are attached hereto and which are to be used in connection with the said agricultural remedy.
condi	registration expires on
Date	Registering officer: Act 36/1947
ſ	THIRD SCHEDULE CERTIFICATE OF INSPECTOR OR OFFICER TAKING SAMPLE OF AN AGRICULTURAL REMEDY In terms of section 15 (2) of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947]
	eby certify that the accompanying is a sample of an agricultural remedy taken by me on
	in the presence of
The f	following further particulars are given in connection with the sample:
(1)	Trade name and brand of agricultural remedy
(2)	Marks or number on sample
(3)	Information given on container from which sample is taken
(4)	Estimated quantity of agricultural remedy represented by sample
(5)	Name and address of seller

(6)	Other particulars
	ctor or officer
	ature of witness
	······································
Note:	A copy of this certificate shall be handed or forwarded to the owner or seller of the agricultural remedy or to his agent. A third copy shall be retained by the inspector or officer.
	FOURTH SCHEDULE
CE	RTIFICATE BY ANALYST OF RESULT OF ANALYSIS OR TEST OF SAMPLE OF AGRICULTURAL REMEDY
[In terms of section 15 (3) of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947]
sectio	l name), a duly appointed analyst, in terms of on 14 of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947, by declare under oath-
(1)	that on
(2)	that the sample was labelled, sealed and marked ³
(3)	that I have analysed and/or tested the sample and found that (state details or result of analysis and/or test)
 Signa	uture of analyst
Swor	n to before me at this day of 19
The d	leponent acknowledges that he understands the contents of this document.
	missioner of Oaths
1	Fill in name of article as stated on the label. Fill in name of person who sent the sample and state whether it was delivered "by hand", "by post" or "by rail", as the case may be.

Insert distinguishing mark or number of sample.