GOVERNMENT NOTICES

DEPARTMENT OF AGRICULTURE

No. R. 956 **29 September 2006**

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

REGULATIONS REGARDING STOCK 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.

INDEX FOR PROPOSED STOCK REMEDIES REGULATIONS

SCHEDULE

1. Definitions

In these regulations, unless inconsistent with the context -

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

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

"label" means any written, printed or graphic representation attached to or included in a container of a stock 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 stock remedies;

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

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

"SANS" means South African National Standards;

"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.

"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 stock remedy from that of any other manufacturer but excludes the registered name of a stock remedy as intended in these regulations;

PART I

REGISTRATION

Application for registration

2. (1) An application in terms of section 3(1) of the Act, for the registration of a stock remedy, must be submitted in triplicate to the Registrar on a prescribed form as set out in Annexure A

(2) An application must only 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.

(3) An application shall be accompanied by:

(a) the prescribed application fee as set out in Annexure B, Table 1;

(b) three copies of a typed label, in English. If any other language is used the label shall also be submitted in triplicate with an affidavit from the sworn translator declaring the label to be a true translation of the English label;

(c) a copy of the required data that substantiate and support the safety, quality and efficacy of the stock remedy as outlined in the data requirements set out in Annexure C. Data on biological efficacy of the stock remedy concerned must be determined under South African conditions.

(4) the Registrar may request additional data or sample which may enable him to evaluate the application.

(5) In the case of a stock remedy of which the active ingredient and formulation is identical to that of a stock remedy which is registered in favour of another registration holder, further be accompanied by the declaration by such other registration holder that the stock remedy in respect of which the application for registration is made may be registered in favour of the applicant concerned.

Period of registration

3. Subject to the provisions of sections 3(4) (a) and 4A of the Act a registration will be valid for one year from the date of registration.

Suitability and efficacy of stock remedies

4 (1) The suitability and efficacy of a stock remedy shall be proved by results of trials by the applicant or on behalf of the applicant or by a competent body which is recognized for this purpose.

(2) The person or body referred to in sub-regulation (1) shall, prior to the commencement of a trial in the Republic, request approval from the Registrar in writing of the intention to conduct such a trial, and the Registrar may inspect the performance of such a trial.

(3) The Registrar may permit the use of an unregistered stock remedy for the purpose indicated in sub-regulation (1).

(4) The Registrar may permit the import of an unregistered stock remedy for the purpose indicated in sub-regulation (1).

(5) The Registrar may permit the use of a registered stock remedy contrary to label indications for the purpose indicated in sub-regulation (1).

Renewal of registration

5. (1) An application in terms of section 3(4) (a) of the Act for the renewal of a registration of a stock remedy, shall be submitted to the Registrar on a form which is obtainable from the Registrar for this purpose, or on a clearly legible facsimile thereof.

(2) Such application shall:

(a) be made by the registration holder;

(b) be submitted to the Registrar on or before the expiry date of the registration concerned but not more than three months prior to such expiry date;

(c) be accompanied by the prescribed renewal fee as outlined in Annexure B;

(d) be accompanied by the current approved printed or scanned label.

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

(a) is received by the Registrar after the expiry date, but not more than 30 days after such expiry date, shall be considered only if it is accompanied by the prescribed maintenance fee for a late maintenance referred to in Annexure B;

(b) which is received by the Registrar after the days of grace referred to in paragraph (a) expired, will 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 furnishes with such application in respect of the stock remedy concerned or of a label which is being used in connection therewith, do not deviate in any manner whatsoever from the congruent details which have already been registered or approved in relation to that stock remedy or label.

Conditions for renewal and registration amendments of certain registrations

6. A renewal of a registration and the registration amendment of a stock remedy under section 3 of the Act are granted on condition that during the period of registration, amendment or renewal of the registration:

(a) the formulation of the stock remedy concerned shall not deviate 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 stock remedy concerned, shall not be altered without the prior written approval of the Registrar;

(c) that the details of the manufacturer of the active ingredient/s and the manufactured product shall not differ from the approved details; and

(d) all conditions determined by the Registrar are met.

Application for amendment of certain registrations and approved labels

7. (1) If any person in whose name a stock remedy is registered, intends to amend any detail relating thereof; he shall apply for an amendment to the registration on a form set out in Annexure A or on a clearly legible facsimile thereof.

(2) An application for an amendment shall:

(a) be made by the current registration holder;

(b) be accompanied by the prescribed application fee as set out in Annexure B;

(c) be accompanied by a typed label in triplicate in English and any other official language with an affidavit from the sworn translator declaring the label to be a true translation of the English label, if the amendment will affect any change to the label;

(d) be accompanied by a certified copy of the current certificate of registration and an undertaking to deliver the original thereof to the Registrar immediately upon

the allowance of amendment, if the amendment will affect any changes to the certificate;

(e) be accompanied by the relevant data as stipulated in data requirements set out in Annexure C if the data has not previously been submitted to the Registrar.

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

(a) is in the public interest; or

(b) is effected by the Registrar.

Application for transfer of a registration

8. (1) An application for transfer of registration shall 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.

(2) Such application shall be accompanied by:

(a) the prescribed application/registration fee as set out in Annexure B;

(b) the copy of the current registration certificate of the stock remedy to be transferred, if it has not already been submitted;

(c) a written consent from the current registration holder of the stock remedy authorizing the transfer of the registration;

(d) a declaration from the applicant confirming that the particulars furnished in the application and the label in connection therewith, remains identical to those of the registered or approved stock remedy except the details of the registration holder.

Return of certificate of registration

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

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

(i) the 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) the registration of the stock remedy, concerned has lapsed in terms of section 4A (2) of the Act, as the case may be; or

(b) at least 30 days prior to the date on which the registration of stock remedy is to be transferred to another person: Provided that an application as contemplated in the regulation for the registration of the stock remedy in question in favour of such other person, shall be submitted simultaneously.

PART II

LABELLING AND CONTAINERS

Containers of stock remedies

10. (1) Subject to the provisions of any other law relating to containers, a container in which a quantity of a stock remedy is packed for sale, shall at the time of packing:

(a) be sound and clean;

(b) be closed or sealed in the manner permitted by the stock remedy

(2) The design of the container 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;

(b) in the case of a liquid stock remedy, prevent spillage when pouring out the contents thereof.

(3) A stock remedy shall not be sold in a container/packaging which was not approved by the Registrar and if appropriate approved in terms of a provision of any other law.

Labelling of containers

11. (1) No person may sell any stock remedy without an approved label.

(2) A container of a stock remedy shall not be labelled with any marks or signs other than the prescribed details in the labelling requirements, or in terms of a provision of any other law, or and which was approved by the Registrar.

(3) Despite the labelling requirements in annexure D and regulations (10), and subject to the provisions of any other law, no words or marks may appear on the container in which a registered stock remedy is sold, or on a label and/or pamphlet affixed thereto without prior approval of the Registrar.

(4) Only recognized chemical, analytical and pharmaceutical expressions or terms or those expressions or terms which, for reasons of clarity, have been approved by the Registrar, may be marked or printed on a container in which a registered stock remedy is sold, or on a label affixed thereto, for the purpose of explaining the composition of such remedy.

(5) Approval of labelling by Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, (Act No. 36 of 1947) does not absolve the company from the obligations of complying with the South African National Standards 289 or any other relevant legislation.

PART III

ADVERTISEMENTS

Publication or distribution of false or misleading advertisements

12. No person shall publish or distribute any false or misleading advertisement relating to a stock remedy.

Details of advertisements

13. (1) An advertisement shall when published in a newspaper, magazine or other printed matter:

(a) furnish the trade mark, if any, and the trade name of the stock remedy;

(b) where it is applicable furnish the hazard statement;

(c) indicate the name of the active ingredient which it contains;

(d) contain the registration number of the stock remedy in question together with a reference to the Act, expressed as "Reg. No. ..... Act 36/1947"; and

(e) furnish the name and address of the registration holder.

(2) An advertisement shall, when screened or broadcast, at least furnish those details referred to in sub-regulation (1) (a) and (d).

(3) Any reference in an advertisement to:

(a) an active ingredient;

(b) the instructions for use, claims, application or administration; and

(c) the registration, of the stock remedy in question shall:

correspond to those details approved on the label or be based on the data filed in support of the application for registration of the stock remedy being advertised.

(4) Any statements made in an advertisement must be scientifically verifiable and on request of the Registrar such verification must be provided to the Registrar.

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

Approval of advertisements

14. (1) No advertisement shall be published screened or broadcast without prior approval of the Registrar.

(2) Approval of advertisements by Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, (Act No. 36 of 1947) is based on the Stock Remedies Regulations of Act No. 36 of 1947 and therefore does not absolve the company from the obligations of complying with the prescriptions for Advertising Standards Authority of South Africa or any other relevant legislation.

PART IV

MANUFACTURING ESTABLISHMENTS

Manufacturing Facilities

15. (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 a stock remedy for the purpose of sale, shall be in conformance with quality document management system and be such that the composition and efficacy of the stock remedy in question complies 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 a stock remedy, and the stock remedy manufactured there from, shall be handled and stored at the premises of an establishment in such manner that--

(a) it is protected against damage, contamination and deterioration; and

(b) access to the different raw materials and stock 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 a stock remedy and on the stock remedy manufactured from such raw materials by the person in whose favour a stock remedy is registered or by a competent body which is recognized for this purpose.

(4) An employee at an establishment who is responsible for the manufacture, control, packing, marking or labelling of a stock remedy shall have the knowledge of the practices to be followed in the operation of the undertaking of 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.

(5) The names of the raw materials to be used for the manufacture of a stock 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 a stock 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

16. (1) An establishment where a stock remedy is manufactured, controlled, packed or labelled for the purpose of sale, shall be registered under the Factories, Machinery and Building Work Act, 1941 (Act No. 22 of 1941) and 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 or a particular function in connection with the manufacture, control, packing or labelling of a stock remedy shall be adequate for the proper carrying out of that function.

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

(5) The Registrar may publish additional guidelines for the requirements of establishments in the Government Gazette that must be adhered to.

Records at establishments

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

(a) the results of quality checks which were made in terms of regulation 18(3) of the raw materials used for the manufacture of the stock remedy, comprising such batch, and of such stock remedy;

(b) the total quantity of the stock remedy comprising such batch and if packed, the number of containers in which it is packed;

(c) the names and addresses of the persons to whom the stock remedy was sold, and the quantity thereof which is sold to each such person;

(d) complaints which were received in connection with the composition or efficacy of the stock 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-regulation (1) as well as the formula for formulating a batch of a stock remedy there shall be preserved at such establishment and for at least five years after the date on which the batch concerned was manufactured. In the case of raw materials after the date of first receipt provided that if a complaint referred to in sub-regulation (1) (d) was received, the records in respect of the batch in question shall not be destroyed within two years from the date of such complaint. Records must always be available at an establishment for inspection by the authority.

PART V

SAMPLING AND PERMISSIBLE DEVIATIONS

Sampling of stock remedies

18. (1) A stock remedy which is sold in containers shall be sampled by selecting at different places from the stock of a particular stock remedy the number of containers required to obtain a statistically significant quantity for a sample of such a stock remedy:

(a) Such containers shall be similarly labelled and the stock remedy therein shall originate from the same batch.

(b) If a sample is composed of the contents of more than one container, such a sample shall be thoroughly mixed before being divided in terms of section 15(3) (c) of the Act.

(c) Despite the provisions of sub regulation (1)(a), at least three sealed containers in which a stock remedy is sold, may also be taken as the sample of such stock remedy and the containers comprising such sample shall, without being opened, be divided in terms of section 15(3)(c) of the Act.

(2) A stock remedy which is not sold in a container shall be sampled by taking small quantities at different places from the stock of such stock remedy to obtain a sufficient quantity for a sample. Such a 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 a stock remedy referred to in sub regulation (1) prior to the packing thereof in containers, and the sampling of an active ingredient used in the manufacture of a stock remedy.

(4) Where a stock 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 stock remedy, shall be procured. The containers thus procured shall be split up into three groups, each of which shall contain one or more unopened containers and which shall further be dealt with as prescribed by section 15(2) of the Act.

(5) A certificate which in terms of section 15(4) (b) of the Act is forwarded to an analyst together with a sample of the stock remedy, shall be in the prescribed form. Annexure F.

(6) A certificate on which the result of a test, examination or analysis of a sample of a stock remedy is to be recorded in terms of section 15(4) (b) of the Act, shall be in a prescribed form. Annexure G.

(7) That part of a sample of a stock 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 stock remedy concerned, or does not comply with any requirements referred to in these regulations, be retained until the action arising from such certificate is concluded;

(b) may otherwise be destroyed.

Permissible deviations in active ingredient contents

19. Despite anything to the contrary contained in these regulations, a stock 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 a stock remedy indicates that the active ingredient concentration is within 10 % of the registered label claim, when the product is within its shelf life, and stored as instructed.

PART VI

HANDLING, STORAGE AND DISPOSAL OF STOCK REMEDIES

Handling of Group I Stock Remedies

20. Any person in control of an establishment selling, supplying or making available danger group I stock 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

21. All requirements with regard to South African National Standards must be complied with.

PART VII

IMPORTS

Importation of Stock Remedies

22. No person shall import a stock remedy into the Republic unless such remedy is registered: Provided that the Registrar may permit, in writing, the importations into the Republic of a specified quantity of a stock remedy which is not registered for purposes of experimentation or for some purpose other than the sale of such remedy.

Harbours and places through which imports may be made

23. Stock remedies may only be imported through the ports of entry as outlined in Annexure E.

PART VIII

APPEALS

Submission of appeals

24. (1) An appeal in terms of section 6 of the Act shall be submitted to the Minister by delivering the documentation to the Director-General: Agriculture 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 statement which is sworn to or attested;

(b) state the reference number and date of the document 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 Outlined in Annexure B.

(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 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: 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 24(1) shall:

(1) when forwarded by post, be addressed to the Director-General, Department of Agriculture, Private Bag X 250, Pretoria, 0001; and

(2) when delivered by hand, be delivered to the Director-General, Department of Agriculture, Agriculture Building, 20 Beatrix Street, Pretoria.

PART IX

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. The fine will be determined by the Adjustment of Fines Act, 1991 (Act No.101 of 1991).

Payment of fees

27. (1) The postage on and 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 consigner.

(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 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, 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:

(1) when forwarded by post, be addressed to:
The Registrar: Act No. 36 of 1947, Private Bag X 343, Pretoria, 0001; and

(2) when forwarded by rail or delivered by hand, be addressed or delivered to:
The Registrar: Act No. 36 of 1947, Agriculture Building, 20 Beatrix Street, Pretoria.

Amendment and repeal of certain regulations

29. The following regulations are hereby repealed:

(1) The Regulations relating to Stock Remedies published under Government Gazette Notice No. R857 of 28 May 1971 and;

(2) The Regulations relating to Stock Remedies published under Government Notice No. R. 1449 of 1 July 1983.

ANNEXURE A

agriculture

Department:
Agriculture
REPUBLIC OF SOUTH AFRICA

INFORMATION FOR APPLICANTS

1. The application form must be duly completed **in all respects.**
2. Handwritten applications will not be accepted
3. Each page except for the final page must be initialled
4. The application must be submitted to the **Registrar: Act 36 of 1947**
5. All applications must be accompanied by the prescribed registration fee.
6. Please refer to "Submission Document Requirements" for a full explanation of the application process
7. For further information visit our website at *http://www.nda.agric.za/act36/main.htm*

FERTILIZERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947 (Act 36 of 1947), as amended

APPLICATION FOR: THE REGISTRATION OF A STOCK REMEDY OR AMENDMENT OF THE REGISTRATION OF A STOCK REMEDY (SRA01)

Trade name of product: _____ **G number:** _____ **(if applicable)**

1. Type of application:					**Indicate by X**
New Drug Application (complete ALL sections)					
Generic Product application (complete ALL sections):					
Biological Product application (complete ALL sections):					
Parallel/Daughter Registration Product Application (complete Aadministratll sections)					
Parallel Registration					
Based on product:	Name:		G/ Reg No:		
Daughter Registration:					
Based on product:	Name:		G/ Reg No:		
Change of Formulation/ Composition (complete sections 2,6,12,13,14,15)					
Change of Formulation/ Composition					
Change of/ Additional source of Active Pharmaceutical Ingredient(complete sections 2,4,12,13,14,15)					
Change in source of Active Pharmaceutical Ingredient					
Additional source of Active Pharmaceutical Ingredient					
Change of / additional manufacturing site/ Change of/ additional manufacturer (complete sections 2,5,15):					
Change of manufacturing site:					
Additional manufacturing site:					
Change of manufacturer:					
Additional manufacturer					
Change of Shelf-life of final product (complete sections 2,10,16):					
Change of Shelf-life of final product					
Change of / additional packaging material or pack size of the final product (complete sections 2,9,10,15):					
Change of packaging material or pack size of the final product					
Additional packaging material or pack size of the final product					
Change of / additional withdrawal period (complete sections 2,8,15):					
Change of withdrawal period					
Additional withdrawal period (e.g. new species, or food product)					

2. APPLICANT DETAILS						
Corporate name of company or applicant:						
Company registration number: (attach certificate as annex)						
Name of designated contact person:						
Status (of final product)	Importer		Manufacturer		Other	
Physical Address:						
Postal Address:						
Tel No.: (and area code)						
Fax No.: (and area code)						
e-mail:						

3. PRODUCT DETAILS				
Designation: (Description of product)	Trade name:			
	Trade mark:			
Customs Tariff Code: (Brussels Tariff Nomenclature)				
Type of formulation (e.g. injectable solution):				
Function of product (e.g. vaccine etc.):			If anthelmintic, indicate coding:	
Target species (e.g., pigs, horses, cats): List individually separated by commas				

4. ACTIVE INGREDIENT(S) DETAILS			
Please note that if a manufacturer is GMP compliant proof of this must be attached:			Dossier Page Ref:
Active ingredient(s): (Common name/s)	Manufacturer: (Name and address)	Min a.i. % purity or min titre per dose:	Dossier Page Ref:

5. MANUFACTURER DETAILS

Please note that if a manufacturer is GMP compliant proof of this must be attached:		Dossier Page Ref:
Manufacturer (Name):	Address:	Dossier Page Ref:

6. COMPOSITION

Ingredients	Function (e.g., emulsifier)	Unit formula concentration include SI units	Range %	Dossier Page Ref:

7. TOXICOLOGY (Rodent)

Active ingredient(s)	Acute Oral (LD_{50} mg/kg)	Dossier Page Ref:	Acute Dermal (LD_{50} mg/kg)	Dossier Page Ref:

Formulated Product (if applicable)

	Acute Oral (LD_{50} mg/kg)	Dossier Page Ref:	Acute Dermal (LD_{50} mg/kg)	Dossier Page Ref:
Experimental:				

8. WITHDRAWAL PERIOD

Species	Food (e.g. milk, meat)	Proposed withdrawal period	Dossier Page Ref:

Residue Studies (Formulation as applied for)				
Active ingredient:	Species	Food (e.g. milk, meat)	Lowest MRL used for WP	Dossier Page Ref:

9. PACKAGING DETAILS		
Pack size(s)*	Packaging material / container (e.g. glass bottle, etc.):	Dossier Page Ref:
*(also indicate number of vials/bottles per carton etc.):		

10. SHELF LIFE		
		Dossier Page Ref:
indicate conditions (e.g. between 2 - 8° C):		
Pack size(s)*	Stability of product (years/months):	Dossier Page Ref:

11. CONTROLLED DISEASES		
Are claims of treatment or prevention a controlled disease (Act 35 of 1984) being made:	Yes	No
If yes, name the controlled disease(s):		

12. GENETICALLY MODIFIED ORGANISMS (GMO)		
Does the product contain GMO(s) or the product(s) of GMO(s) :	Yes	No
If yes, describe:		

13. IMPORTED INGEDIENT(S) / PRODUCT OF ANIMAL ORIGIN		
Are *imported* ingredient(s) or is the *imported* product of animal origin:	Yes	No
If yes, describe:		

14. IMPORTED INGEDIENT(S) / PRODUCT OF PLANT ORIGIN		
Are *imported* ingredient(s) or is the *imported* product of plant origin:	Yes	No
If yes, describe:		

15 . DECLARATION BY APPLICANT OR THE DULY APPOINTED REPRESENTATIVE	
Trade name of product:	
For and on behalf of ..... I hereby certify that the above mentioned 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 ONLY Registration is: Recommended Not Recommended Technical Adviser:
	Date
	FOR OFFICIAL USE ONLY Registration is: Recommended Not Recommended External Technical Adviser:
	Date

ANNEXURE B

TABLE 1

PAYABLE FEES

	PURPOSE	AMOUNT PAYABLE PER APPLICATION
A..	Application for the registration of:	
	(a) a fertilizer, farm feed or sterilizing plant	R1 100
	(b) an agricultural remedy or a stock remedy	R2 250
	(b) a pest control operator	R 480
B.	Application for the renewal of the registration of:	
	(a) a fertilizer, farm feed 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, farm feed 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

ANNEXURE C

agriculture

Department:
Agriculture
REPUBLIC OF SOUTH AFRICA

DATA REQUIREMENTS FOR THE REGISTRATION OF STOCK REMEDIES UNDER FERTILIZERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947 (ACT 36 OF 1947)

Registrar: Act 36/1947
Private Bag x343
0001 Pretoria

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1. Introduction

This document has been prepared by the Sub-Directorate Agricultural Production Inputs (API) of the Food Safety and Quality Assurance Directorate of the Department of Agriculture (DoA). It provides guidance to applicants on the required data that must be submitted to support an application for the registration of a Stock Remedy or for amendment to an existing stock remedy registration.

The purpose of registration is to ensure that all stock remedies meet acceptable standards of safety, quality and efficacy before they are manufactured for distribution or sold in South Africa.

Registration of stock remedies involves consideration of requirements as stipulated in Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947) and its regulations. Applicants must ensure that they are aware of their obligations under Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947) and other Acts.

Other Related Acts include but are not limited to:

- Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act No 54 of 1972).
- Animal Diseases Act, 1984 (Act No 35 of 1984).
- Medicines and Related substances Control Act, 1965 (Act No 101 of 1965, as amended by Act 90 of 1997).
- Hazardous Substance Act, 1973 (Act No. 15 of 1973).
- Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).
- Environmental Conservation Act, 1989 (Act No. 73 of 1989).
- National Environmental Management Act, 1998 (Act No. 107 of 1998).
- The Standards Act, 1993 (Act No. 29 of 1993).

Applications for registration must include technical data and/or relevant **scientific evidence** to support

- the safety , quality and efficacy of a stock remedy
- and any possible impact on trade resulting from use of stock remedy in food producing animals (e.g. Maximum Residue Limits (MRL) differences between countries and hence different Withdrawal Period (WP)).

The following are types of applications that can be forwarded to Sub-Directorate Agricultural Production Inputs (API) (Act No. 36 of 1947):

A. New Drug application.
B. Generic Product Registration.
C. Amendments to an existing registration Application.
D. Request for Import Permit.
E. Others.

2. Data Requirements for the different types of applications:

A. <u>New Drug Application</u>

This is an application for

- a product containing an active pharmaceutical ingredient(s) that has not previously been assessed/registered in South Africa for use in animals;
- or a product with an active pharmaceutical ingredient(s) that has not been registered through Act No. 36 of 1947 but is listed in the Schedules of Act 101.
  In both cases the application must be accompanied by a letter from Medicines Control Council of the Medicines and Related substances Control Act, 1965 (Act No 101 of 1965, as amended by Act 90 of 1997), granting the said product an exemption from scheduling under Act 101, so that the product can be registered under Act 36 of 1947.
- or a new dosage form (of which the active pharmaceutical ingredient(s) has previously been registered).

Data/Information required

- Pharmaceutical data
  - Chemistry
  - Formulation and Manufacturing
  - Stability data
- Pre-clinical data
  - Pharmacological (PD/PK)/ Metabolic
  - Mammalian toxicity
  - Eco-Toxicity
- Safety data
  - Occupational Health
  - Target Species

- Efficacy data
- Residue data (For Food Producing Animals).

Note that the applicant must also comply with "Requirements for Toxicological Assessments of Agricultural and Stock Remedies" issued by Directorate Food Control within the Department of Health for registrations of Stock Remedies to be used on food producing animals.

B. Generic Product Registration Application

These are applications that are similar to the currently/previously registered product in Act No. 36 of 1947. "To be similar" means:

- same active ingredient(s)
- same concentration of active ingredient
- same dosage form
- same dosage on an active ingredient basis
- same use pattern

Data/Information required

- Pharmaceutical
  - Chemistry data
  - Formulation and Manufacturing data
  - Stability data (shelf-life determination)
- Pre-clinical data (summary)
- Safety
  - Safety data:
    - Injection site safety studies/administration site safety studies/Mammary gland safety studies
    - Target species data depending on the dosage form

    (Target species data depending on the dosage form IF registration is NOT based on bioequivalence)
- Bioequivalence data OR Efficacy data (abridged in certain instances) for formulation
- Residue data (In Food Producing Animals) for formulation

C. Amendments to an Existing Registration Application

(i) Change in formulation

These are applications for any change in the composition of the final formulation of a registered trade name product.

Data/Information required

- Formulation and Manufacturing data
- Where necessary
  - batch comparison and
  - stability data
- Efficacy data (depending on the change)
- Residue data (For Food Producing Animals) – depending on the change
- Target Species Safety data (depending on the change)

(ii) Change in source of Active Pharmaceutical Ingredient

These are applications for the change in source of Active.

Data/Information required

- Method of synthesis
- Certificate of analysis
- Pharmaceutical and chemical equivalence

(iii) Change in the Manufacturing Process/ Site/ Manufacturer

These are applications for the:
Change in method of manufacture of the product
Change in site of manufacturer
Change in manufacturing process
New or additional manufacturer
Change in manufacturing equipment

Data/Information required

- Good Manufacturing Practice (GMP) Certificate, where possible in the case of Site/Manufacturer change plus sworn statement that process has not changed.
- Certificate(s) of analysis.
  - For change in site/manufacturer or additional site/manufacturer, the certificates of analysis must be from the current site/manufacturer as well as from the new site/manufacturer or the additional site/manufacturer. Both certificates must be recent.
- Any other relevant information.

(iv) Change in specifications of final product

Data/Information required

- Substantiation for change in specifications.

(v) Additional Target Species

These are applications for extension of use to include an additional target species.

Data/Information required

- Safety data for that particular species.
- Efficacy data for that particular species.
- Residue data for that particular species (For Food Producing Animals only).

(vi) Additional Therapeutic Claim with no change in dosage

These are applications for the extension of use to include additional therapeutic claim(s).

Data/Information required

- Efficacy data

(vii) Change in Dosage

These are applications where there is a change in the dosage administered to the target species. This can either be a change in the dose or a change in the frequency or number of treatments.

Data/Information required

- Target Species Safety data (where dosage, number of treatments is increased, and/or interval between treatments is decreased).
- Efficacy data.
- Residue data (For Food Producing Animals, where dosage is increased and/or interval between treatments is decreased and/or treatment period is increased).

NOTE: In the case of Extra strength **formulations**, a full dossier is required, including Efficacy, Target Species Safety Data, and Residue Data (for FPA). The product will be registered separately as an individual product.

(viii) Change in the Withdrawal Period

These are applications for the change in the withdrawal period for meat/milk/egg (edible animal products).
Plus application where the MRL used in the determination of withdrawal period has changed.

Data/Information required

- Residue data.

(ix) Change in Shelf-Life of the trade name product

These are applications for any change to the shelf-life of a final (batch-size) product.

Data/Information required

- Stability Data.

(xi) Change in Packaging material or pack size of the trade name product

These are applications for any change to the packaging specifications or Pack sizes of a final product.

Data/Information required

- Packaging Specifications.
- Stability Data
  - depending on the size change
  - if change is from more stable to less stable packaging

D. Request for Import Permit

A *detailed* Trial Protocol (according to the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) **Good Clinical Practices (GCP)** guidelines) including expected starting dates with special attention to the fate of Food from food producing animals (e.g. will be discarded) and drug accountability is required.

The applicant is also referred to "submission requirements" for details of the content (information) required in the accompanying covering letter.

In the case of Requests for import permits for products containing ingredients of animal origin or intended for the use in prevention or treatment of controlled diseases permission will also have to be obtained from Animal Health Directorate.

In the case of Requests for import permits for products containing ingredients of plant origin permission will also have to be obtained from Plant Health Directorate.

In the case of Requests for import permits for products containing genetically modified organism(s) permission will also have to be obtained from Genetic Resources Directorate.

E. Other Applications

These are applications that are essentially administrative in nature (requiring no supporting technical data) and the applicant is therefore referred to "submission requirements" or "Annual Renewals".

- Parallel registration
- Change in Registration Holder/ Transfer of Registration.
- Annual Renewals.

3. Dossier/ Data Package Overview

A well structured dossier greatly facilitates the evaluation process. Evaluators are better able to review the presented scientific data resulting in the optimal use of available evaluation time.

The data package/ dossier should be divided into sections and structured as follows:

A. General Information

1. Table of Contents/ Index for *whole* dossier.
2. Purpose of Application.
3. Justification of the new product/ new use.
4. Product Summary.
5. FULL Registration status / Overseas registration including whether registrations have been refused, or withdrawn and reasons must be included.
6. Certificates (e.g. Australian, US, EU, Canadian, UK, New Zealand) must be included, and translated (by certified translator) if in any language other than English.
7. Approved International label text in English (Australian, US, EU, Canadian, UK, New Zealand), if there is no English international label a translated (by certified translator) label is required.
8. Proposed South African Label (must be cross referenced to dossier by section (e.g. B 2 ii a) and page number). This should preferably be done in tabular format.
9. Exemption letters from the MCC's Scheduling Committee (if relevant) should be included in this section.
10. In the case of products containing genetically modified organism(s), an approval for the use of those ingredients should be obtained from the Genetic Resources Directorate within Department of Agriculture. (An approval letter from the Genetic Resources Directorate should accompany the application for registration of a stock remedy)

B. Pharmaceutical Data

A table of contents for Section B must be inserted, *if* it is submitted as a separate volume.

A Summary/ Expert report on the Pharmaceutical Data may be inserted in the beginning of the section.

1. Active Pharmaceutical Ingredient:

(i) INN name/ Chemical Names/CAS No/ Approved/Internationally recognized name/ Common names/ synonyms.
(ii) Empirical formula.
(iii) Molecular weight.
(iv) Occurrence of isomers and polymorphism where applicable.
(v) Structure elucidation if New Chemical Entity.
(vi) Possible impurities and degradation products (describe).
(vii) Basic Physical and Chemical Properties.
(viii) Specification/ Standards of active (referenced pharmacopoeial or if expharamacopoeial must be substantiated), plus validation reports of analysis methods and detailed description of analysis methods.
(ix) Certificates of analysis - 2 batches (on valid letterhead of manufacturer).
(x) Source of active (name/address/site) plus appearance, identification and assays. If multiple sources: Comparative critical tests e.g. Identification, assay, solubility, particle size, optical rotation, residual solvents and impurity profiles, performed on samples from each source to demonstrate physical and chemical equivalence, must be performed by the same laboratory (either the laboratory of the manufacturer or an independent laboratory). The same analytical methods and equipment must be used for these tests. These results must be presented in tabulated format.
(xi) Stability data of the active pharmaceutical ingredient(s)

All specifications should be at the level of the latest editions of recognised pharmacopoeial reference books and departure from such sources must be fully substantiated (e.g. in-house specifications). CoA's or MSDSs are NOT acceptable specifications)

2. Formulation

(i) Product Details:

(a) Trade name/ Registered name.

(b) Dosage form.

(ii) Formulation composition (showing **all** approved names – INN) in tabular format

(a) expressed for unit formula (must correspond to name and amount given in PI).

(b) manufacturing formula (Indicate whether raw ingredients are used in the formulation or to manufacture the formulation), if potency adjustment is required, state so, and describe how this is to be done and how this impacts on excipients).

(iii) The Animal Health Directorate of the Department of Agriculture should be consulted in the case of Stock remedies containing imported ingredients of animal origin – Certificates of origin and disease status (e.g. Bovine Spongiform Encephalopathy free) will be required in these cases. (An approval letter from the Animal Health Directorate should accompany the application for registration of a stock remedy)

(iv) The Plant Health Directorate of the Department of Agriculture should be consulted in the case of Stock remedies containing imported ingredients of plant origin. (An approval letter from the Plant Health Directorate should accompany the application for registration of a stock remedy)

3. Raw material specifications and control procedures

(i) Specification/ Standards and limits of inactive and other raw material (referenced pharmacopoeial or if expharamacopoeial must be substantiated), plus validation reports of analysis methods and description of analysis methods and control procedures of inactives must be fully described.

(ii) Purpose of each inactive (e.g. emulsifier).

(iii) Identification of inactive and other raw material irrespective of whether CoA is supplied by supplier must be performed.

(iv) Water testing procedures and results where applicable.

All specifications should be at the level of the latest editions of recognised pharmacopoeial reference books and departure from such sources must be fully substantiated (e.g. in-house specifications). CoA's or MSDSs are NOT acceptable specifications

4. Containers and packaging materials

(i) Full details of immediate container and applicator and administration set specifications, and limits (incl. nature of the material, dimensions, closure systems). Sketches may also be appropriate.

(ii) Where applicable the control procedures.

(iii) Describe outer container.

(iv) Include all pack sizes.

5. Manufacturing procedures

(i) Manufacturing Process (*including* flow chart including all material used plus quality control (In process and terminal control) procedure.

(ii) Batch Formula and batch size.

6. Finished Product

(i) Final product specifications.

(ii) QC of final formulation (Batch release documentation).

(iii) Certificate of analysis (at least 1 batch).

(iv) Manufacturing Facility/ies physical address/es.

(v) Copy of Good Manufacturing Practices Certificate or approval(s) if applicable.

7. Stability data (3 batches)

A stability study summary in tabular format must be inserted in the beginning of the section, include batch no., Date of manufacture, Source of API, indicate whether production or pilot batch, storage conditions, tests and limits, results, container.

(i) Proposed and discussion of shelf life.

(ii) Summary of packaging details. These must coincide with packaging specifications.

(iii) Stability studies (real time stability studies or real time stability studies plus accelerated stability studies), may been extended during submission and after.

(a) Refer to applicable method(s) in Annex 1 of 8 Analysis.

(b) Refer to applicable validation(s) of method(s) in Annex 2 of 8 Analysis.

(c) Storage conditions.

(d) Time points.

(e) If necessary (where pilot batch has been used) substantiate that the pilot batch reflects the full scale batch.

8. Analysis

(i) Annex 1.

(a) Description of method of analysis (or reference if applicable).

(ii) Annex 2.

(a) Validation report of method of analysis or reference if previously stated in data package.

9. Pharmaceutical development

(i) Where applicable (e.g. the dossier contains a lot of information regarding developmental formulations), Pharmaceutical development must be described.

C. Pre-clinical Data

A table of contents for Section C must be inserted, *if* it is submitted as a separate volume.

- Pharmacological/ Metabolic Data

A summary/ Expert report on the Pharmacological/ Metabolic may be inserted in the beginning of the section behind the summary table.

- Pharmacodynamics of chemical group
- Pharmacodynamics of active
- In vitro efficacy, MIC
- Pharmacokinetics of active in animals (incl. target), various routes of administration claimed
- Dose determination trials/ Preclinical trials/ Minimum effective concentration/ Justification of combinations

A summary/ Expert report on the mammalian toxicity may be inserted in the beginning of the section behind the summary table.

- Mammalian toxicity studies.
  - The applicant is referred to the MCC guideline entitled "guideline on preclinical safety studies for veterinary medicines" available on the MCC website: www.mccza.com
  - In the case of a new product or generic product this data should be presented in summary (preferably tabular format) and be referenced appropriately
  - Environmental studies/ Eco-toxicity (phase 1 and 2 where applicable) (The applicant is referred to the MCC guideline entitled "guideline on preclinical safety studies for veterinary medicines" available on the MCC website: www.mccza.com and VICH for the appropriate guidelines.

D. Efficacy Data

A table of contents for Section D must be inserted, *if* it is submitted as a separate volume.

An efficacy trial summary in tabular format must be inserted in the beginning of the section (see Safety/ Efficacy/ Residue summary table).

A summary/ Expert report on the Efficacy Data may be inserted in the beginning of the section behind the summary table.

- Clinical Efficacy Trials with FAAF.
- Field trials.
- The Animal Health directorate of the Department of Agriculture should be consulted in the case of Stock remedies for the treatment or prevention of controlled diseases. The contact person is: Director: Animal Health.

E. Safety Data

A table of contents for Section E must be inserted, (see Safety/ Efficacy/ Residue summary table), *if* it is submitted as a separate volume.

A safety trial summary in tabular format must be inserted in the beginning of the section.

A summary/ Expert report on the Safety Data may be inserted in the beginning of the section behind the summary table.

- Occupational Health/ Safety.
- Target Species Safety.
  - Toxicological studies
  - Field studies
  - Injection site data/safety studies, administration site safety studies, Mammary gland safety studies depending on the dosage form
  - Margin of Safety study, Reproductive safety studies, Target species data from field studies depending on the dosage form and type of registration (e.g. generic registrations based on bioequivalence are exempt from this)
- Other Safety Information, (e.g. disposal).
- MSDS, First Aid.

F. Residue Data (in the case of FPA)

A table of contents for Section F must be inserted (see Safety/ Efficacy/ Residue summary table), *if* it is submitted as a separate volume. If is separate a copy of section should be included in this section as well.

This particular section (F) may be separate from the rest of the dossier.
A residue trial summary in tabular format (see Safety/ Efficacy/ Residue summary table) must be inserted in the beginning of the section.

(i) Acceptable Daily Intake (ADI) and No Effect Level (NOEL)/ No Adverse Effect Level (NOAEL).

(ii) Proposed and referenced MRLs.
For the evaluation of residue data and the determination of withdrawal period, the applicant must submit an approved Maximum Residue Limit (MRL) from Department of Health, unless the specific MRL is published in the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).*

(iii) Proposed withdrawal periods for each species.

(iv) Formulation residue studies for each major species. (Residues studies guidelines can be obtained from the Medicine Control Council (MCC) website).

(a) Analytical methods.
(b) Validation of methods.

*The Department of Health determines MRL's for New Chemical Entities to be used in FPA.
For this, the Toxicological assessment requirements must be obtained from DoH: Food Control Directorate.

4. Notes:

A. Laboratory studies:

- All Laboratory studies must conform to Good Laboratory Practices and this must be reflected in the data produced.
- All reports must be signed.
- Summaries of the validation of methods of analysis must be included.
- Summaries of the methods of analysis or references for the methods must be included.

B. Animal studies:

- All Animal Studies must conform to Good Clinical Practices according to VICH GL9 and this must be reflected in the data produced.
- All reports and protocols must be approved as per GCP.
- All trials must stipulate batch numbers used and CoAs of the particular batches must be included.
- If a reference product is used it needs to be appropriately described, including:
  - The quality of the product needs to be substantiated by means of active assays (done at the same time and by the same lab as the reference product), batch numbers, manufacture date/ expiry date. If the reference product was not sourced in SA, but is registered in SA, proof of source (if possible) and comparative active assays with the reference product sourced in South Africa.

- **Please Note that the Raw Data of at least one pivotal trial is required**

C. Presentation of Data

- For new stock remedies (without registration number).
  - Please note that data presented in the data package should always be properly **bound** (arch lever files and plastic tube binders are not acceptable).

- The title of the Data and volume (e.g. volume 2 of 4) should be clearly visible on the front of the volume and the spine.
- **Sequential pagination** is required (539, 540, 541....).

- In the case of amendments or Parallel registration:
  - the data needs to be bound (arch lever files and plastic tube binders are not acceptable) and
  - should have a detailed table of contents/ index and
  - be sequentially paginated
  - The **title page** must indicate
    - the contents and the reason (e.g. Change in Manufacturing Site for ABC (G5678)
    - and be dated.
    - Be designated as an Annexure to the original data package.
  - The applicable application form must refer to pages in this data package so it cannot be confused with the original data package (e.g. Annexure 1, page 34).

- In the case of required supplementary information after submission of an application:
  - the data needs to be bound (arch lever files and plastic tube binders are not acceptable) or adequately stapled if stapling will effectively bind the data.
  - should have a detailed table of contents/ index and
  - be sequentially paginated
  - The **title page** must indicate
    - the contents and the reason (e.g. Supplementary data for ABC (G5678)
    - and be dated.
    - Be designated as an Annexure to the original data package.

- **Note that JECFA, EMEA and/or reports of other regulatory bodies MAY NOT be presented as data, as these are copyrighted for commercial purposes.**

D. Guidelines

The use of International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and the World association for the Advancement of Veterinary Parasitology (WAAVP) are encouraged.

E. Data requirements for Biologicals

Data requirements for biologicals see MCC guidelines on efficacy of veterinary biologicals

F. Information Waivers:

All data required for application must be provided. However an applicant may wish to apply to the Registrar in advance, for waiver of certain data requirements. The Information Waiver MUST be obtained before an application is forwarded to API (Act 36 of 1947) and such a waiver approval MUST be provided with an application when submitted.

Summary Table of Safety/ Efficacy/ Residue Studies (delete that which is not applicable)
NB: The test product is the formulation as applied for and this should be stated

Trial Description	Used batches	Category of test animals	Number of Test animals	Trial Design	Results	Page in dossier
Trial number, name/ number/ code of trial, date, name of facility, location of facility NB: Indicate Pivotal study(s) (e.g. CRD 1234	Batch numbers, expiry dates, indicate if production batch	Species, breed, sex, age, disease/ serological status, reproductive status (where relevant)	Indicate numbers in treated AND control groups	Briefly discuss dose (e.g. mg/ kg) and frequency, route and any other relevant information e.g. when 1st dose was given (if age is relevant), test	Briefly (this is a SUMMARY) discuss the results	

Trial Description	Used batches	Category of test animals	Number of Test animals	Trial Design	Results	Page in dossier
(pivotal study...)				samples taken at day X, etc.		

ANNEXURE D

agriculture

Department:
Agriculture
REPUBLIC OF SOUTH AFRICA

LABELING REQUIREMENTS FOR THE REGISTRATION OF STOCK REMEDIES UNDER FERTILIZERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947 (ACT 36 OF 1947)

Registrar: Act 36/1947
Private Bag x343
0001 Pretoria

1. Labelling of immediate container of every Stock Remedy (of more than 500 ml or 500 g) intended for administration shall have a label attached on which only the following particulars pertaining to the contents of such package shall appear in clearly legible letters in at least two of the official languages in the following sequence, of which English is the main language:

1.1. Main Panel: Preferably not be larger than 40% of the printed surface of the label. Where there are two main panels each may not be larger than 20% of such surface.

(a) "For (external) animal use only"

This wording must appear on all Stock Remedy labels except those of pigeon remedies and disinfectants. It is to appear right at the top of the panel and must be clearly legible. No equivalent wording need appear on disinfectants but on pigeon remedies the words: "For (external) pigeon use only" are to appear right at the top of the panel.

(b) Name of Remedy

This must correspond exactly with the registered name of the product as it is given in the registration certificate. The print size of the name of the remedy must be the largest of the label with the concession that, where the name is exceptionally long, the trade name may be printed in larger print than the rest of the registered name.

(c) Registration Number

Reg. No. ... Act 36 of 1947
This must always appear directly below the registered name.

(d) Claims for Remedy

Must correspond exactly with the claims given in the approved registration application dossier. Reference from the dossier/ data submitted must be linked to each claim made on the label

(e) Toxicity Indications

In red – in letters of print size not less than half the size of the largest letter in the name of the remedy.

Group I – Skull and crossbones on contrasting colour background with the words: "POISON – EXTREMELY TOXIC"

Group II – Words: "POISONOUS" on contrasting colour background.

Group III – Words: "CAUTION" on contrasting colour background.

Group IV – No poison group indication on label.

Refer to Annexure 1 for definitions of toxicity.

(f) Storage Instructions

E.g. Store from 0° - 2° in refrigerator in clearly legible print.

(g) Composition

The active ingredient(s) must be in bold print. Only the active ingredient(s) need be stated. The amount of pure active ingredient(s) must be stated. It may be given in g/kg, ml/l.

(h) Contents, i.e. size (volume / quantity) of product pack

Must appear on the main panel. The applicant may decide where exactly he wants it placed in the layout but it must appear below the composition. It must be clearly legible.

(i) Name and Address of Applicant

The name and address of the registration holder, without any preceding wording, must appear on the label. The registration holder retains the right to give other information (e.g. the name of the manufacturer or distributor where this is other than that of the registration holder) on the main panel space permitting. The manufacturer's or distributor's name must then be stated as such in print size smaller than that in the name and address of the registration holder and must appear hereunder.

1.2 Side Panel(s)

(a) (Warning(s) – appear(s) right at the top and must include the "following clauses"

"Keep out of reach of children, uninformed persons and animals
"Although this remedy has been extensively tested under a large variety of conditions, failure thereof may ensure as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder."

(b) Precaution(s)

As regards (a) and (b), it is optional whether each statement appears on a new line or not.

(c) Directions for Use with the words: "Use only as directed" thereafter.

(d) Tables, if any, as e.g. in the case of efficacy tables of anthelmintics.

(e) Expiry Date or Expiry Date and Date of Manufacturers as applicable.

These must, if possible, appear right at the bottom of the panel. The expiry date or expiry date and date of manufacture must be preceded by the words: "Expires ...". It need only appear once and may be abbreviated as follows:

"Lot No.: ..."	"Lot No.: ..."
"Exp. ..."	"Manuf. ..."

1.3 Print

The minimum permissible print size is 8pt and it must be clearly legible.

1.4 Depictions / illustrations / picture on labels may not be larger than 20% of the size of the panel on which they appear, with the concession that, where an applicant wants a larger picture on the label, a layout of the proposed label and the reasons must be submitted.

1.5 **Pictures on labels etc.** must be in context with the remedy.

Picture(s), together with the subject matter thereof, must be indicated in the application. Otherwise it (they) will not be permitted on the printed item(s).

2. Labelling of the immediate container of every Stock Remedy of 500 ml or 500 g and smaller

2.1 Smaller containers (500 ml or 500 g and less) may have an abbreviated label but then a package insert must be included in the packing.

2.2 **Abbreviated labels / cartons require the following sequence of information:**

(a) Registered name of remedy – identical to that in registration certificate.
(b) Reg. No. ... Act 36 of 1947.
(c) Claim(s) for remedy – exactly the same as given in registration certificate.
(d) Warning statement according to poison classification – in red letters at least one half the size of the largest letter in name.
(e) Composition – pure content of active ingredient(s) only.
(f) "For full particulars see enclosed package insert".
(g) Batch No. (at bottom of label)
(h) Expires (at bottom of label)
or: Manufactured (date) (at bottom of label)
(i) Registration holder – Name and address.

3. Labelling of Intramammary Infusions

Syringe or Tube

Must have an abbreviated label, as indicated below, printed on each syringe or tube but the wording may differ according to the size of the syringe or tube. Deviations must be approved by the Registrar of Act 36 of 1947.

Large Syringe or Tube (10 ml / 10 g or more)

(i) Registered name of product.
(ii) Registration number Act 36 of 1947.
(iii) Contents (e.g. 10 g).
(iv) Composition.
(v) Name and address of registration holder.
(vi) The wording: "See enclosed package insert".

Small Syringe or Tube (under 10 ml / 10 g)

(i). Registered name of product.
(ii) Registration number Act 36 of 1947.
(iii). Contents (e.g. 5 g).
(iv) The wording: "See enclosed package insert".

These may be packed as follows:

(i) In printed carton.
(ii) In a printed opaque plastic envelope.
(iii) In a transparent plastic envelope in which case there need be no printing thereon if the printed syringe or tube is clearly visible through it.
(iv) The syringe or tube need not be packed in one of the above if the package insert is firmly attached thereto

These must then be packed in an outer carton with a full label thereon.

A package insert must be enclosed in each packing

4. Package Insert

A package insert is only mandatory where an abbreviated label is used or where the full label is not on the immediate container.

A package insert must contain all the information as for a full label referred to in 1 (Main and side panels), except:

(a) Batch No.
(b) Expiry Date.
(c) Date of Manufacture.

In addition: Warning statement relative to poison classification need not be in red in the package insert.

The above represents the minimum information required. Applicants may include additional information on approval of the Registrar of Act 36 of 1947.

5. Carton

Need only have information as for an "Abbreviated Label" (2.2), thereon.

6. Unit Sales Packing and / or Display Carton

These must have:

(a) An abbreviated label affixed to the outside as required in (2.2)
(b) Be properly sealed.
(c) Have at least one package insert enclosed in the carton.
(d) Have the following wording printed in large bold print on the main panel(s) and flap where it is to be opened:

"Carton must be sold as a unit. Do not break seal or open before sale"

7. Labelling of vaccines

All small animal (dog and cat) vaccines and other vaccines where appropriate must have the statement

"Only for use by or under the supervision of persons registered in terms of or authorized in terms of section 23 (1) (c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982)"

The statement will also be used on other stock remedies if it can be substantiated that the product should be used by or under the supervision of persons registered in terms of or authorized in terms of section 23 (1) (c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982)

8. Labelling on Stock Remedies used for controlled diseases

The following clause must always appear
Notifiable/ Controlled diseases-contact the state veterinarian and where appropriate specific wording for specific controlled disease (Refer to Animal Health Directorate within Department of Agriculture)

Note Any other amendments, additions or waiver to the labelling requirements MUST firstly be approved by the Registrar.

POISON CLASSIFICATION: *Annexure 1*

Group I:

Oral LD50 less than 50 mg / kg
Dermal LD50 less than 200 mg / kg
Inhalation LD50 less than 2000 mg / l / h.

Label:
"Poison – Extremely toxic
Skull and crossbones, all in red. No smaller than half the size of the largest letter in the name of remedy against a contrasting colour background.

Group II:

Oral LD50 from 51 – 500 mg / kg
Dermal LD50 from – 2000 mg / kg
Inhalation LD50 from 2001 – 20000 mg / l / h
Label:
"Poisonous", in red against a contrasting colour background. Not smaller than half the size of the largest letter in name of remedy.

Group III:

Oral LD50 from 501 – 5000 mg / kg
Dermal LD50 from 2001 – 20000 mg / kg
Inhalation LD50 from 2001 – 200000 mg / l /h

Label:
"Caution", in red, not smaller than half the size of the largest letter in the name of remedy, against a contrasting colour background.

Group IV:

Oral LD50 – 5001 and more mg / kg
Dermal LD50 – 20001 and more mg / kg
Inhalation LD50 – 200001 and more mg / l / h

Label: No warning required.

EXAMPLE: FULL LABEL *Annexure 2*

(more than 500 ml or 500 g)

MAIN PANEL

For (external) animal use only/

NAME OF PRODUCT

(Identical to that given in registration cert.)

Reg. No. G.....Act 36/1947

Claims for product

(This must concur exactly with that given in the registration certificate)

WARNING STATEMENT

(In accordance with poison classification, Groups I – IV – see Annexure 1, in red)

STORAGE

Store in a cool place between 2-7 °C

COMPOSITION

Contains (pure content of active ingredients (-s), given in g/kg or ml/l)

(In bold print)

Nett Mass/Volume 5 g (e.g.)

Name and address of registration holder

(no preceding words)

II SIDE PANELS

1. Warning (-s)
2. Precaution (-s)
3. Directions for Use

   "Use only as directed"
4. Table (-s)

   (In the case of application for anthelmintics a separate efficacy table should be attached to the application).
5. Batch No.: (Preferably at bottom of label)
6. Expiry date: (Preferably at bottom of label)
7. Date of manufacture/ (Preferably at bottom of label)

   or

   Abbreviated to:

   Lot No.: Lot No.:

   Exp. Manuf.

EXAMPLE: ABBREVIATED LABEL, *Annexure 3*

(500 ml or 500 g and smaller)
(and cartons)

For (external) animal use only/

NAME OF PRODUCT
(Identical to that given in registration cert.)
Reg. No. G.....Act 36/1947

Claims for product
(This must concur exactly with that given in the registration certificate)

WARNING STATEMENT
(In accordance with poison classification, Groups I – IV – see Annexure 1, in red)

STORAGE
Store in a cool place

COMPOSITION
Contains (pure content of active principle (-s), given in g/kg or ml/l)
(In bold print)

Nett Mass/Volume 5 g (e.g.)

Name and address of registration holder

"For full particulars see enclosed package insert.

Batch No.
Expires
Manufactured date

Registration holder – Name and address

ANNEXURE E

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			
Vioolsdrif			

ANNEXURE F

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 here by certify that the accompanying sample of Stock 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 STOCK REMEDY FROM WHICH SAMPLE WAS TAKEN

1. Name of registration holder _____
2. Trade/Product name† _____
3. Registration number† _____.Act 36/1947
4. Manufacturer details _____
5. Batch number_____
6. Composition of Stock 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 Stock Remedy from which sample was taken:
   - 8.1 Number of containers _____
   - 8.2 Capacity of containers _____
9. Remarks _____
   _____

_____ _____
Signature of witness Registrar

Notes

* Cross 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 Stock 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 G

Analyst address

.....

.....

CERTIFICATE OF RESULTS OF ANALYSES OR TEST OF A SAMPLE OF STOCK 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

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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.....