agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
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.daff.gov.za*

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 all 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 2,10,15):					
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 - 8º 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