RWANDA FDA
Rwanda Food and Drugs Authority

DHT/FOM/031

Application form for registration of Antiseptic and Disinfectant products

1.0 ADMINISTRATIVE INFORMATION	
1.1	Type of the product application (choose as appropriate) Antiseptic ◯ Disinfectant ◯
1.2	Brand name of the product
1.3	Proprietary name of the product
1.4	Name and strength of active substance(s)
1.5	Form of the product: Solution: (choose as appropriate) ☐ Suspension ☐ Gel ☐ Aerosol ☐ Emulsion ☐ Gaseous ☐ Powder ☐ Cream ☐ Capsule ☐ Tablet ☐ Lotion Others: (specify)
1.5.1	Intended use
1.6	Packing/pack size:
1.7	Physical description
1.8	Proposed shelf life (in months):
1.8.1	Proposed shelf life (after reconstitution or dilution):
1.8.2	Proposed shelf life (after first opening container):

1.8.3	Proposed storage conditions:
1.8.4	Proposed storage conditions after first opening:
1.9.1	Do you hold Marketing Authorization (s) of other product (s) containing the same active substance (s) in the other regulatory authorities? ◯ **Yes** ◯ **No** If yes state; Product name (s): strength (s): product form (s): Indication(s):
1.9.2	Have you applied for Marketing Authorization medicinal product (s) containing the same active substance (s) in the Rwanda FDA? ◯ **Yes** ◯ **No** If yes state; Product name (s): strength (s): product form (s): Indication(s):
1.10	Distribution category: **Pharmacy Only** ☐ **General sale** ☐ **Others** ☐
1.11	Country of manufacture:
1.12	Product Marketing Authorization in the country of manufacture. If not registered/licensed state reasons

Authorised Country: Date of authorisation: Proprietary name: Authorisation number:	Withdrawn (by applicant after authorisation) Country: Date of withdrawal: Proprietary name: Reason for withdrawal:

Refused Country:		Suspended/revoked (by competent authority) Country:	
Date of refusal:		Date of suspension/revocation:	
Reason for Refusal:		Reason:	
		Proprietary name:	

1.13	Name(s) and complete physical address(es) of the manufacturer(s)
1.13.1	Name(s) and physical address (es) of the manufacturing site of the finished product.

Company name:	
Physical address:	
Postal address:	
Country:	
Telephone:	
Telefax:	
E-mail:	

1.13.2 Particulars of Applicant/ Registrant

Name:			
Physical Address:			
Postal Address:			
Country:			
Phone:		Fax:	
Email:			

Status of applicant (tick where appropriate):

Manufacture ☐ Importer ☐ Exporter ☐ Other:

1.13.3 Particulars of Local technical representative/Distributor

Name:	
Physical Address:	
Postal Address:	

Country:			
Phone:		Fax:	
Email:			

2.0 LABELLING (Specify important information on label)

3.If the formula is considered to be confidential seal in an envelope and mark confidential and then attach.

4. Brief description of the type and properties of packaging material and the seal and its liner if any and provide justification for the suitability of the packaging material and the seal and its liner used.

5. Brief description of the method used to determine the shelf life.

Product Formulation Information

See page 6 for instructions

1. Brand Name:

2. Proprietary Name (Common name):

3. pH (if water soluble liquid):

4. Active Ingredient Give common chemical name for each active ingredient listed on the label. Microbials should show genus, species, and strain.	5. Chemical Abstracts Service (CAS) (or ATCC) No.	6. Brand name of **source product** for active ingredient	7. Percent by weight of **source product** in formulated product.	8. Percent by weight of **active ingredient** in formulated product.

9. Inert Ingredient (common chemical name)	10. Chemical Abstracts Service (CAS) No.	11. Brand name of **source product** for inert ingredient.	12. Purpose in formulation.	13. Percent by weight of **source product** in formulated product.	14. Percent by weight of **inert ingredient** in formulated product.

If space is not sufficient, attach additional pages. Inert ingredients information given on this form is considered to be confidential business information and is protected from disclosure under the Rwanda FDA Law).

Total _____
Columns 7 + 13
=100.00%

Total _____
Columns 8+14
=100.00%

Instructions for Product Formulation Information

Applications with **incomplete product formulation** information cannot be processed, and the first page **will be returned.**

4. **Active Ingredient:** List each active ingredient in this formulation as it appears on the label. Please list all active ingredients from one source product together for ease of calculation of percentages.
5. **CAS No.:** The CAS Number may be obtained from the Chemical Abstract Service of the American Chemical Society, P.O. Box 3012, Columbus, Ohio, 43210. Microorganisms should be identified by ATCC (American Type Culture Collection) or other recognized type culture collection number.
6. **Name of Source Product:** The name of the product which provides that active ingredient in the formulation.
7. **Percent by Weight of Source Product in Formulated Product:** Each source product listed in Column #6 must have a value in Column #8. For example, if active ingredient A and active ingredient B are both from the same source product which makes up 50% of the formulated product, the single entry in Column 8 is 50%.
8. **Percent by Weight of Active Ingredient in Formulated Product:** This percentage should be **identical** to that given on the labeling.
9. **Inert Ingredient:** List each inert ingredient component in this formulation. **NOTE:** If you do not know the identity of an inert ingredient in your product, have your supplier submit the chemical name of each inert ingredient, source product name, purpose in formulated product and percent by weight of the source product in the formulated product directly to the Authority, with reference to your firm name, your product brand name and Rwanda FDA Reg. No.
11. **Brand Name of Source Product:** The name of the product which is the source of the inert ingredient listed in Column #09.
13. **Percent by Weight of Source Product in Formulated Product:** Give the percentage by weight of each **SOURCE PRODUCT** in the formulated product. If the percent of a source product is already listed in column #7, do not list the same figure again in column #13.
14. **Percent by Weight of Inert Ingredient in the Formulated Product:** The percentage by weight of the inert ingredient in column #09 in the formulated product.

8. Declaration by the Applicant/ Registrant

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I also agree that I shall carry out vigilance to monitor the safety of the product in the market and provide safety update reports to Rwanda FDA.

It is hereby confirmed that fees have been paid according to the Rwanda FDA fees and regulation.

I understand that if any information given here above is found false or incorrect, I will be reliable for appropriate action under the provisions of the Rwanda FDA regulation

Name:	
Position in the company:	
Signature: Official stamp: Date:	

* Note: If fees have been paid, attach proof of payment