Application form for new Registration of Public Health Antiseptic and Disinfectant Products

1. ADMINISTRATIVE INFORMATION		
1.1 Name(s) and complete physical address(es) of the manufacturer(s): Company name: Physical address: Postal address: Country: Telephone: Fax: Email:		
1.2. Particulars of Applicant/ Registrant Name: Physical Address: Postal Address: Country: Phone: Fax: Email: Status of applicant (tick where appropriate): Manufacture: ……. Importer: ……. Exporter: ……. Other: ……		
1.3 Particulars of Local Technical Representative/Distributor (if applicable) Physical Address: Postal Address: Country: Phone: Fax: Email:		
2. PRODUCT DETAILS		
2.1	Type of the product application (choose as appropriate	
	Antiseptic	◯
	Disinfectant	◯
2.2	Brand name of the product	
2.3	Proprietary name of the product/Generic name	

2.4	Name and strength of active substance(s)	
2.5	Form of the product: (Powder, Tablet, Capsule, Liquid, Gel, Cream, Lotion, Spray, Aerosol, Gaseous, Emulsion, Cream….)	
2.6	Intended use	
2.7	Means of application: (Spray, hand rub, Fumigation etc)	
2.8	Physical description	
2.9	Packaging Material/pack size:	
2.10	Do you hold Marketing Authorization (s) of this product from other regulatory authorities? **Yes ☐ No ☐** If yes state; Market Authorization Number: Market Authorization issuance date: Name of Regulatory Authority issued the Market Authorization: Country:	
2.11	Description of container closure	
2.12	Proposed shelf life (in months):	
2.13	Proposed shelf life after reconstitution or dilution (if applicable)	
2.14	Proposed shelf life (after first opening container):	
2.15	Proposed storage conditions	
2.16	**LABELLING** 4.1. 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. …… …… …… 4.2. Mode of use …… ……	
2.17	Proposed storage conditions after first opening (If applicable):	

List the qualitative and quantitative composition per unit pack (Please, add or delete as many rows and columns as needed.

Name of ingredients	Chemical Abstract service number	Purpose	Amount (%)

Details on administrative & Technical documents submitted with the application

Technical documents	Annex, Page number, etc.
Quantitative and qualitative composition of the formulation (Introduction of active ingredients and their functions)	
Manufacturing Process	
Certificate of analysis	
Product specifications and test methods	
Toxicity data	
Antimicrobial efficacy data	

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 Food and Drugs Authority.

It is hereby confirmed that fees have been paid according to the Rwanda Food and Drugs Authority fees and regulations.

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 Food and Drugs Authority regulations.

Name: ……..……

Position in the company: ……

Signature: ……

Official stamp: …….

Date: …….