



**GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR
REGISTRATION OF PUBLIC HEALTH ANTISEPTIC AND
DISINFECTANT PRODUCTS**

AUGUST, 2025

FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety and efficacy of antiseptics and disinfectants for public health in order to improve access to quality and safety antiseptics for public health available on Rwandan Market.

Considering the provisions of the technical regulation No DD/HMDR/TRG/001 Rev_3 governing registration of medicinal products especially in its article 32; the authority has to issue this Guidelines No DD/CHCR/GDL/003 on submission of documentation for registration of antiseptic and disinfectant for public health products.

These guidelines have been developed to provide guidance to the applicants and the authority in managing applications for registration of antiseptics for public health.

Applicants are encouraged to familiarize with the guidelines and follow it when preparing and submitting applications for registration of antiseptic and disinfectant for public health Products.

Adherence to these guidelines will ensure that all relevant information is provided for registration of antiseptics and disinfectants for public health. This will facilitate efficient and effective evaluation as well as approval process. It will also help to avoid queries which result in unnecessary delays in approving documents.

The Authority acknowledges all the efforts of key stakeholders who participated in development and validation of these guidelines.

Prof. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

First issue date	20/05/2020
Effective date of this version	Refer to the approval date

DOCUMENT REVISION HISTORY

Date of revision	Revision number	Changes made and/or reasons for revision
20/05/2020	0	First version
Refer to the approval date	1	<ol style="list-style-type: none"> 1. Time line for new application dossier processing has been reduced from 6 months to 3 months. 2. Application for renew has been fixed to 2 months 3. The registration requirements for local manufactured products has been separated from the registration requirements for foreign manufactured products taking into consideration to the process of manufacturing license issued to local premises. 4. The requirements on raw materials has been amended. 5. Changes to IRIMS has been included to ensure that the system meet the current requirements 6. The manufacturing process data for foreign manufacturers has been waived as a result of relying on international standards compliance or being subject to Rwanda FDA GMP when it is deemed necessary due to quality and safety concern. 7. Further changes were made to align the format with the requirement of the SOP on document control as per current approved revisions. 8. Information required for packaging material have been revised and improved. 9. Statement for reliance have been added in guidelines 10. Annual Retention on the Register has been removed

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ACCRONYMES AND ABBREVIATIONS

cGMP	: Current Good Manufacturing Practice
CHC	: Cosmetics and Household Chemicals
CHCR	: Cosmetics and Household Chemicals Registration
GMP	: Good Manufacturing Practice
IRIMS	: Integrated Regulatory Information Management System
LTR	: Local Technical Representative
PRC	: Peer Review Committee
QMS	: Quality Management Systems
Rwanda FDA	: Rwanda Food and Drugs Authority

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GLOSSARY

In these regulations, unless the context otherwise requires:

1. **“Active ingredient”** means a biologically or chemically active substance or compound that is intended to be used in the manufacture of a product as an active compound (ingredient).
2. **“Antiseptic”** means a product that inactivates, reduces, prevents or arrests growth of microorganisms with the inherent intent to mitigate or prevent disease on the skin or mucous membrane (mouth washes only).
3. **“Applicant”** means a person who applies for registration of antiseptic or disinfectant products to Rwanda FDA, who must be the owner of the product. He may be a manufacturer or a person to whose order and specifications, the product is manufactured. After the product is registered, the applicant shall be the “Marketing Authorisation Holder”
4. **“Authority”** means the Rwanda Food and Drugs Authority, or its acronym “Rwanda FDA” established by Law n° 003/2018 of 09/02/2018 Article (1)(2)(3).
5. **“Batch number or Lot”** means the number or a combination of numbers and letters specifically given to an antiseptic or disinfectant product which is linked to the manufacturing history of the product;
6. **“Container”** means any form of packaging of an antiseptic for public health product for sale as a single item whether by completely or partially enclosing the antiseptic for public health and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer.
7. **“Disinfectant”** means an antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on environmental surfaces and inanimate objects.
8. **“Distributor”** means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an antiseptic and disinfectant for public health product available on the Community market;
9. **“Importer”** means any person or body corporate permitted and authorized under the laws and regulation in Rwanda pertaining to import antiseptic or disinfectant products.
10. **“Ingredients”** means any substance that is one of the components of an antiseptic or disinfectant for public health and includes colouring agents, botanicals, fragrance and flavour, but does not include substances that are used in the preparation of the antiseptic and disinfectant for public health but that are not present in the final product as a result of the chemical process
11. **“Law”** means Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning.
12. **“Manufacturer”** means a person or firm that is engaged in the manufacture of antiseptic or disinfectant product(s).
13. **“Marketing authorization”** refers to an official approval of the antiseptic and disinfectant for public health product to be marketed or distributed in Rwanda mainland;
14. **“Package”** refers to any box, packet or any other article in which one or more containers of antiseptic or disinfectant for public health are to be enclosed in one or more other boxes, packets or article in question, the collective number thereof;
15. **“Package labelling”** includes the label on the immediate container plus all other printed matter such as outer wrapper, carton or leaflet associated with the package;
16. **“Registrant (Market Authorization Holder)”** means any person who may either be the trademark owner or person authorized by him, who has rights to sale the product and is responsible for placing the product on the Rwandan market.

17. **“Sanitizer”** means a product that reduces the level of microorganisms present by significant numbers, e.g. 99.9% or more, or to acceptable levels.
18. **“Specifications”** means the combination of physical, chemical, biological and microbiological test requirements that determine whether an antiseptic or disinfectant product is suitable for the intended use.
19. **“Sporicide”** means an antimicrobial agent capable of destroying bacterial spores.
20. **“Fee”** means the fee prescribed in Regulations No. ODDG/RES/TRG/001 Version 5 governing tariff/fees and charges on services rendered by Rwanda food and Drugs Authority

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CHAPTER I: INTRODUCTION

I.1. Background

The Authority was given the power to regulate different products including antiseptics and disinfectants for public health and similar disinfectants available on the Rwandan market to ensure their safety, efficacy and quality. In that regard, the Authority developed the guidelines which are involved while submitting an application for registration of the mentioned products. The Marketing Authorization Certificate will be granted to the products that meet Quality, Safety and Efficacy requirements.

Antiseptics are antimicrobial substances that are applied to living tissue/skin to reduce the possibility of infection, sepsis, or putrefaction, while disinfectants are substances that are applied to non-living objects to destroy microorganisms.

The most commonly used antiseptic and/or disinfectant groups includes; alcohols, quaternary ammonium compounds, chlorhexidine and other diguanide, antibacterial dyes, chlorine and hypochlorite, inorganic iodine compounds, metals, peroxides and permanganates, Air disinfectants, Aldehydes, Oxidizing Agents, Phenolic Acids, Silver, Copper, Alloy Surfaces, halogenated phenol derivatives and quinolone derivatives preparations with the appropriate strength & formulations containing active ingredients listed in annex I are products eligible for approval under the antiseptics and disinfectants for public health category. Other active ingredient internationally recognized and not harming life can be accepted in antiseptic or disinfectant products

I.2 Scope

These guidelines shall provide guidance for dossier applications for registration of antiseptics and disinfectants for public health, renewal of registered antiseptic and disinfectant for public health products.

I.3. Submission of application

I.3.1 Submission of technical dossier

An application for product registration for either locally manufactured or imported, shall be submitted along with a dated and signed letter of application addressed to Rwanda FDA. If the applicant is a foreign company, the applicant shall appoint a local technical representative through whom an application shall be submitted. The LTR shall be a registered wholesale company or an accredited manufacturer's representative company registered in Rwanda.

All application documents shall be in one of the official languages used in Rwanda. Any document which is in any language other than official language must be accompanied by a certified or notarized document translated in an official language. The application dossier shall be submitted to Rwanda FDA through Integrated Regulatory Information Management System (IRIMS) available at <https://irims.rwandafda.gov.rw/portal/#/public/app-home>.

I.3.2 Submission of commercial samples for registration

The submission of samples for registration shall be in the final package proposed for marketing of the product in Rwanda and shall have 60% of its remaining shelf-life. This notwithstanding, products with a shelf life of less than 24 months shall at least have 80% of its shelf life remaining at the time of submission. Two commercial samples must be directly submitted to Rwanda FDA headquarter on the addresses below:

Rwanda Food and Drugs Authority
P. O. Box 1948 Kigali
Nyarutarama Plaza, KG 9 Avenue

The additional samples may be requested once deemed required during the registration process. Where it's not possible due to big pack size (above 5L or 5kg), the applicant shall contact the Authority for further guidance. A hard copy of the latter should be brought with samples for reception acknowledgement by the Authority.

I.4 Types of applications

For the purpose of submitting the antiseptic and disinfectant for public health and similar disinfectant products dossier application for registration with Rwanda FDA, applications are categorized into three distinct groups as outlined below:

I.4.1 New applications for registration

An application for registration of a product that is intended to be placed on the Rwanda market for the first time or product which was on the market without a registration certificate.

I.4.2 Renewal application for registration

For applications for renewal of the marketing Authorization of product that has been previously registered, application dossier shall be submitted to the Authority at least 3 months before the expiry date of existing marketing Authorization Certificate.

I.4.3 Variation application

Variation application refer to the application for any change in the registered products. An application for variation shall be submitted as per the requirements set out in the guidelines for variation of registered antiseptics and disinfectant for public health and similar disinfectants, vector control products and laboratory reagents for public health.

I.5 Receiving of applications for product registration

An application is electronically submitted as documents through IRIMS accessible via the following link: <https://www.irims.rwandafda.gov.rw/portal/>. Application of product registration is screened through the system and the applicant is queried for any document that is not fulfilling the application requirements. The reference number assigned to a product during the application is used in all subsequent correspondences relating to the application. An acknowledged receipt of application will be issued by the system.

A separate and complete application for registration of products shall be submitted for each antiseptic and disinfectant for public health or similar disinfectant products with different commercial name, ingredients, formulation, intended use, forms and/or site of manufacture.

I.6 Timelines for product dossier assessment

Product dossiers shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance of the requirements. For New applications, assessment process shall be processed within three (3) months from the date of submission, with feedback provided to the applicant. Regarding the renewal and variation application of the registered products, the assessment shall be processed within two (2) months from the date of submission, with feedback provided to the applicant. The applicant will be required to provide any requested additional data within sixty (60) calendar days. Assessment of submitted additional data or query responses shall be processed within thirty (30) calendar days from the day of submission with feedback provided to the applicant.

I.7 Compliance to Good Manufacturing Practices (GMP)

The applicant shall submit a valid GMP Certificate or ISO certificate or other applicable internationally recognized Management System certification for foreign manufacturers. Regarding to the quality and safety concern of the product, the applicant may be requested to apply for GMP inspection to Rwanda FDA. More information on GMP requirements and application for GMP inspection is detailed in the Rwanda FDA Guidelines on Good Manufacturing Practice and its annexes accessible *via* Rwanda FDA Website.

I.8 Reliance

The Authority may rely on other regulatory agencies from regional, international and other Stringent Regulatory Authorities' decisions in regard to product market authorization when it deems necessary. The Authority may apply reliance procedures for granting Marketing Authorization in the following situations:

1. The product should have been evaluated and listed on register of EAC countries, WHO and other Stringent Regulatory Authorities or Regulatory Authorities with ML3/4 with signed MoU with Rwanda FDA.
2. The product should have been evaluated through work sharing (Joint) or regional reliance mechanisms.

I.9. Rwanda FDA Peer Review Committee for CHC Product Registration

A final dossier assessment report shall be presented to CHCR Peer Review Scientific Committee before making final decisions for granting or refusing Market Authorization.

When there are deficiencies related to safety, quality and/or efficacy to be resolved as per the decision of the CHCR Peer Review Scientific Committee, application shall remain pending until the raised queries are resolved.

I.10 Validity of issued registration certificate

The Market Authorization issued by Rwanda FDA, unless otherwise revoked, shall be valid for five (5) years from the date of its approval and it is renewed.

CHAPTER II: GENERAL REQUIREMENTS FOR REGISTRATION

This chapter provides guidance of components expected in the application for registration of antiseptic and disinfectant products for public health and similar disinfectant products.

II.1 Data requirements for new application

Data requirements for a new application contains two parts with each part having administrative requirements and technical data requirements. Part 1 relates to the requirements for local manufacturers while part 2 relates to the requirements for foreign manufacturers.

II.1.1 Requirements for local manufactured products

II.1.1.1 Section A: Administrative requirements

All administrative documents should be provided in part of administrative requirements as follow:

II.1.1.1.1 Cover letter

Applicants should include a cover letter within the dossier applications. A dated and signed copy of the cover letter should be uploaded using the cover letter format (Refer to the Annex-I)

II.1.1.1.2 Application form

A dossier application must include a completed application form (refer to the annex II, document No DD/CHCR/FOM/003) available on Rwanda FDA website. The application form should be duly filled with relevant information and dated, signed and stamped appropriately.

II.1.1.1.3 Manufacturing License

The applicant should submit a valid manufacturing license issued by Rwanda Food and Drugs Authority.

II.1.1.1.4 Contract Manufacturing Agreement (where applicable)

An agreement between two parties (the party who manufactures any product on the order of another party) is required. If a product is manufactured on contract, evidence of the contract shall be included in the documentation submitted, and this shall be clearly stated on the label of the product.

II.1.1.1. 5. Samples of the product

Two (2) samples of the product(s) shall be submitted. Where necessary additional samples may be requested depending on tests or parameters to be carried out.

II.1.1.1.6. One coloured artwork/Label of the product

The applicant should submit one coloured artwork/Label of the product.

II.1.1.2. Section B: Technical requirements

A technical data requirement is a document that includes various pieces of information about final product.

II.1.1.2.1. Data on raw materials

The applicant should submit the Safety Data Sheet (SDS) for each raw material (ingredients) that describing all sections.

II.1.1.2.2 Data on Final Product

II.1.1.2.2.1 Certificate of analysis (CoA)

The dated and signed CoA should include the batch number tested, parameters tested, test results, manufacture date and expiry date along with the standards testing used for quality control.

II.1.1.2.2.2 Packaging and labelling information.

The applicant shall provide information on packaging material such as primary and or Secondary (e.g. PVC, HDPE, PE...). This shall be made of substances/materials which are safe and suitable for the product. Products labels should be clearly legible, indelible letters and written in one of the official languages used in Rwanda bearing the following information:

- a) Brand name,
- b) Manufacturer's name and physical address,
- c) Lot or batch number,
- d) Manufacturing and Expiry dates,
- e) Net content (weight/volume),
- f) List of ingredients used,
- g) intended use of Antiseptic or disinfectant product,
- h) Instructions for use,
- i) Country of origin,
- j) Storage conditions,
- k) Warnings and cautions if any.

II.1.1.2.2.3 Commitment letters

For ongoing stability studies, applicant must submit the commitment letter indicating when the final data on stability will be availed. The authority reserves its total rights to request the applicant to submit the commitment letter wherever it is applicable

II.1.2 Requirements for foreign manufactured products

II.1.2.1 Section A: Administrative requirements

II.1.2.1.1 Cover letter

Applicants should include a cover letter within the dossier applications. A dated and signed copy of the cover letter should be uploaded using the cover letter format (Refer to the Annex-I).

II.1.2.1.2 Application form

A dossier application must include a completed application form (refer to the annex II, document No DD/CHCR/FOM/003) available on Rwanda FDA website. The application form should be duly filled with relevant information and dated, signed and stamped appropriately.

II.1.2.1.3 Contract Manufacturing Agreement (where applicable)

An agreement between two parties (the party who manufactures any product on the order of another party) is submitted. If a product is manufactured on contract, evidence of the contract shall be included in the documentation submitted. And this shall be clearly stated on the label of the product.

II.1.2.1.4 Valid Manufacturing license.

Applicant should submit valid Manufacturing License from the manufacturer granted by competent authorities.

II.1.2.1.5 Valid GMP Certificate or other applicable internationally recognized Management System certification

For all foreign products, all key manufacturing and/or processing steps in the production of finished products must be performed in plants that comply with GMP or other applicable internationally recognized Management System certification. Regarding to the quality and safety concern of the product, the applicant may be requested to apply for GMP inspection to Rwanda FDA.

II.1.2.1.6 Appointment letter of the Local technical representative

Appointment letter of the LTR with original copy of Power of attorney must be enclosed in the product dossier. The LTR shall be a wholesale company registered in Rwanda FDA or manufacturer's representative company registered in Rwanda.

II.1.2.1.7 Samples of the product

Two (2) samples of the product(s) shall be submitted. Where necessary additional samples may be requested depending on tests or parameters to be carried out.

II.1.2.1.8 One coloured artwork/Label of the product

The applicant should submit one coloured artwork/Label of the product.

II.1.2.1.9 Commitment letter (where applicable)

For ongoing stability studies, the applicant must submit the commitment letter indicating when the final data on stability will be available.

II.1.2.2 Section B: Technical requirements

A technical data requirement is a document that includes various pieces of information about the raw materials and the final product.

II.1.2.2.1 Data on raw material

The applicant should submit the Safety Data Sheet (SDS) for each raw material (ingredients) that include all sections.

II.1.2.2.2 Data on final product

II.1.2.2.2.1 Certificate of analysis (CoA)

The dated and signed CoA should include the batch number tested, parameters tested, test results, manufacture date and expiry date along with the standards testing used for quality control.

II.1.2.2.2.2 Method of analysis

Method of analysis for the finished product shall include the equipment, reagent and analytical method.

II.1.2.2.2.3 Product efficacy data

The applicant shall submit information on:

- a) Effectiveness studies data in regards with the claimed intended use of the product.
- b) Nature of the application area and method of use;
- c) Standards Methods used for evaluating the efficacy

II.1.2.2.2.4 Packaging and labelling information

The applicant shall provide information on packaging material such as primary and or Secondary (e.g. PVC, HDPE, PE...). This shall be made of substances/materials which are safe and suitable for its intended use. Products labels should be clearly legible, indelible letters and written in one of the official languages used in Rwanda bearing the following information:

- a) Brand name,
- b) Manufacturer's name and physical address,
- c) Lot or batch number,
- d) Manufacturing date and Expiry date/best before,
- e) Net content (weight/volume),
- f) List of ingredients used,
- g) Intended use of Antiseptic or disinfectant products product,
- h) Instructions for use,
- i) Country of origin,
- j) Storage conditions,
- k) Warnings and cautions if any.

II.1.2.2.2.5 Stability data

The proposed shelf life should be justified by submission of stability data.

The applicant shall provide stability data supporting the proposed shelf life. The stability studies shall be conducted in the container in which it will be marketed in Rwanda. Stability study report critically examine the method used to determine the established product shelf life including:

- a) Study design (protocol);
- b) Test conditions (humidity and temperature), testing interval;
- c) Duration:

Storage conditions	Duration	Testing interval (Months)
Long term stability studies at 25±5°C/60% RH	Shelf life	0, 3,6,9,12,18,24,36,48
Accelerated stability studies at 40°C/75% RH	6 months	0,3,6

- d) Type of container used (Testing should be conducted using containers and closures intended for marketing of products);
- e) Parameters to be tested should be those susceptible to change and are likely to influence the quality and safety of the finished product.

II.1.2.2.2.6 Materials safety data sheet (SDS)

The applicant should submit the SDS that include **all sections** (Human health data sheet, Environmental safety information and Toxicity...).

CHAPTER III: GENERAL REQUIREMENTS FOR RENEWAL OF PRODUCT REGISTRATION

An application for Market Authorization renewal shall be made ninety (90) calendar days before expiration of the last registration.

III.1 Cover letter

Signed and dated cover letter addressed to the DG of Rwanda FDA must be submitted.

III.2 Application form

Signed and dated application form for renewal of registered antiseptic or disinfectant for public health products (*refer to the annex IV, document No. DD/CHCR/FORM/005*)

III.3 Copy of previous registration certificate

The applicant shall submit the copy of previous registration certificate issued by Rwanda FDA.

III.4 Supporting documentation for any variations since the product was last registered

During the renewal of the product, the applicant must submit the data for the variations that have been reported and also the variations which were not reported yet (variation that happened in the last year of certificate validity).

III.5 Samples of the product in the final package

The applicant must submit two samples of the product supporting along with the artwork/label.

ENDORSEMENT OF THE GUIDELINES

	Prepared by	Checked by		Approved by
Title	Division Manager/CHCR	Head of Drugs Department	Division Quality Assurance Management	Director General
Names	Dr. Janvier MUKIZA	Dr. Védaste HABYALIMANA	Mrs. Marie Ange UWASE	Prof. Emile BIENVENU
Signature				
Date				

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ANNEXES

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ANNEX I: COVER LETTER

Letter header of the applicant/manufacturer/LTR

< Applicant>
< Address>
<Postal Code>
< Town>
<Country>
<Date>

<Rwanda FDA>
<P.O.BOX 1948> <Kigali>
< Rwanda >

Dear Sir/Madam,

Subject: Submission of application for registration of public health antiseptic/disinfectant product <Brand Name(s), Common Name (s) and product form(s)>

We are pleased to submit our Application Dossier(s) for a registration of public health antiseptic/disinfectant product that details are as follows:

Name of the public health antiseptic/disinfectant product as follow:

Brand name (s):
Proprietary (Common Name (s):
Name and strength/purity of active ingredient(s):
.....
Product form:
Intended use(s):
Manufacturer:

You will find enclosed the submission dossier as specified hereafter:

- The relevant fees for this application have been paid.
- Two commercial samples of the product
- The electronic submission contains the following sections:

Section 1: Administrative information and product information requirement

Section 2: Technical data requirements

We confirm that the electronic submission has been checked with up-to-date and state-of-the-antivirus software.

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

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>

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ANNEX II: EXPLANATORY NOTES ON INTENDED USES

A. INTENDED USES OF ANTISEPTICS OR DISINFECTANT

Washes: Antiseptic or disinfectant wash products, also known as antibacterial soaps, are intended for use with water and are rinsed off after use, and include hand washes /soaps and body washes.

Rubs: Rubs are leave-on products, or hand “sanitizers,” as well as antiseptic or disinfectant wipes. These products are intended to be used when soap and water are not available, and are left on and not rinsed off with water.

Handwashing: chlorhexidine gluconate and povidone iodine solutions are often used in hand scrubs and hand rubs in hospital settings.

Pre-operative skin antiseptics or disinfectants: applied to the operation site to reduce the resident skin flora. Caution should be used in facial use of solutions containing chlorhexidine, as these can injure the eye causing keratitis.

Mucous membrane antiseptic or disinfectant: irrigations may be instilled into the bladder, urethra or vagina to treat infections or cleanse the cavity prior to catheterisation.

Preventing and treating infected wounds and burns antiseptic: preparations are available over-the-counter from your pharmacist to treat minor cuts, abrasions and burns.

Alcohol: Used as a skin disinfectant

Quaternary ammonium compound: Used as skin disinfectant, irrigation, and to preserve eye drops

Chlorhexidine and other diguanide: Used as pre-operative skin disinfectant, to treat wounds, and for bladder irrigation

Antibacterial dye: Used as a skin disinfectant and to treat a wound or burn

Peroxide and permanganate: Used as wound cleanser, gargle and mouthwash, for irrigation and as a skin disinfectant

Halogenated phenol derivative: Used as a skin disinfectant and in medicated soap and solution

Quinolone derivative: Used to treat wounds, in throat lozenges and as a skin disinfectant

Miscellaneous: Bleach baths

B. INTENDED USES OF DISINFECTANTS

Air disinfectants: Air disinfectants are typically chemical substances capable of disinfecting microorganisms suspended in the air.

Alcohols: Alcohol and alcohol plus Quaternary ammonium cation based compounds comprise a class of proven surface sanitizers and disinfectants approved by the EPA and the Centers for Disease Control for use as a hospital grade disinfectant.

Aldehydes: Aldehydes, such as formaldehyde and glutaraldehyde, have a wide microbicidal activity and are sporicidal and fungicidal.

Oxidizing agents: Oxidizing agents act by oxidizing the cell membrane of microorganisms, which results in a loss of structure and leads to cell lysis and death. A large number of disinfectants operate in this way. Chlorine and oxygen are strong oxidizers,

Peroxy and peroxy acids: Peroxycarboxylic acids and inorganic peroxy acids are strong oxidants and extremely effective disinfectants.

Phenolics: Phenolics are active ingredients in some household disinfectants. They are also found in some mouthwashes and in disinfectant soap and handwashes

Quaternary ammonium compounds: Quaternary ammonium compounds ("quats"), such as benzalkonium chloride, are a large group of related compounds. Some concentrated formulations have been shown to be effective low-level disinfectant.

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ANNEX III: APPLICATION FORM FOR NEW REGISTRATION OF ANTISEPTIC AND DISINFECTANT PRODUCTS FOR PUBLIC HEALTH

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 <input type="checkbox"/> No <input type="checkbox"/> 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:

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ANNEX IV: APPLICATION FORM FOR RENEW OF REGISTRATION OF COSMETIC, VECTOR CONTROL PRODUCT PUBLIC HEALTH ANTISEPTIC AND DISINFECTANT AND PUBLIC HEALTH LABORATORY CHEMICAL PRODUCTS

1. Product information

- 1.1 Registration number.....
- 1.2 Date of issue of current Market Authorization.....
- 1.3 Date of expiry of current registration.....
- 1.4 Brand Name of Product:
- 1.5 Product category:.....
- 1.6 Physical description.....
- 1.7 Product Form:
- 1.8 Name and Strength of the Active ingredient(s):.....
- 1.9 Intended use of the product.....
- 1.10 Are there any changes since product was registered? No Yes

If yes, give descriptions of the changes and if such variation was approved by Rwanda FDA

.....
.....

2. Are there any reported adverse reactions?

No Yes

If yes, give descriptions of the adverse reactions and if were reported to Rwanda FDA

.....
.....

3. Particulars of Applicant/ Registrant

Name of company:

Physical Address:

Postal Address:

Country:

Phone:

Fax:

Email:

Status of applicant (tick where appropriate)

Manufacturer Importer Other

If other, please specify:.....

4. Particulars of manufacturer

Name:

Physical Address:

Post Address:.....

Country.....

Phone: Fax: Email:

5. Particulars of Local Technical Representative (if applicable)

Name:

Physical Address:

Postal Address:

Phone Number..... Fax: Email:

Declaration by the Applicant

I.....undersigned certify that all the information filled on this form and accompanying documentation are 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 on 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 liable for appropriate action under the provisions of the Rwanda FDA regulations.

Name:.....

Position:.....

Signature:.....

Officials Stamp:.....

Date:.....