RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF ANTISEPTIC AND DISINFECTANT PRODUCTS

MAY, 2020

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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 antiseptic and disinfectant in order to improve access to antiseptic and disinfectant in Rwanda.

Considering the provisions of the technical regulation N° CBD/TRG/010 governing the control of medicinal products especially in its articles 6, 7, 8, 9, 12 and 32, the authority has to issue these Guidelines N° *DHT/GDL/027 on submission of documentation for registration of antiseptic and disinfectant products.*

The guidelines provide guidance to applicants to make sure that the products they manufacture or produce and apply for registration meet Rwandan requirements.

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

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

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

Dr. Charles KARANGWA
Ag. Director General

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO BY COUNSULTANTS	23 January 2020
ADOPTION BY RWANDA FDA	14 February 2020
STAKEHOLDERS CONSULTATION	20 February 2020
ADOPTION OF STAKEHOLDERS`COMMENTS	04 March 2020
DATE FOR COMING INTO EFFECT	20 May 2020

TABLE OF CONTENT

ABBREVIATIONS AND ACRONYMS

COA Certificate of Analysis

EAC East African Community

GMP Good Manufacturing Practice

IUPAC Internation Union of Pure Applied Chemistry

SDS Safety Data Sheet

SRAs Stringent Regulatory Authority(ies)

TDS Technical Data Sheet

WHO World Health Organization

WLAs WHO Listed Authority(ies)

DEFINITIONS

In these regulations, unless the context otherwise requires:

1. **"Active substance"** 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 owns a formula or trademark of a product, who may be a manufacturer or a person to whose order and specifications the product is manufactured, and who shall be the registration holder and have the primary responsibility of the product on the Rwandan market.
4. **"Authority"** means the Rwanda Food and Drugs Authority, or the acronym "Rwanda FDA' established by Law nº 003/2018 of 09/02/2018 Article (1)(2)(3).
5. **"Bactericide"** means an antimicrobial agent capable of destroying bacteria, but not necessarily bacterial spores or mycobacteria.
6. **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;
7. **"Biocidal product"** means an active substance and preparation containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.
8. ***Claim"*** refers to any message or representation including pictorial, graphic, symbolic or any form of representation, which states, suggests or implies that a antiseptic or disinfectant has particular characteristics relating to its origin, function, nature, composition or any other characteristics
9. "**Container**" means any form of packaging of an antiseptic and disinfectant product for sale as a single item whether by completely or partially enclosing the antiseptic and disinfectant and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer.

10. **"Contract manufacturer"** means any person who manufactures any product on the order of another person to whom a manufacturer's licence has been issued under these Regulations;
11. **"Disinfectant"** means an antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on environmental surfaces and inanimate objects.
12. **"Distributor"** means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a antiseptic and disinfectant product available on the Community market;
13. **Emulsions:** In the world of antiseptic and disinfectant, "emulsion" is a common term. Most lotions and creams are emulsions. Mix two fluids that usually don't mix together well and you have an emulsion. Think oil and water getting along happily.
14. ***"Free Sales Certificate"*** refers to a document that indicates that the product is freely sold in that country;
15. **Gels**: are active ingredients suspended in a base of water and a thickening agent, such as xanthan gum. Gels tend to be lighter and less moisturizing than creams or lotions, making them a suitable option for those with oily or acne-prone skin.
16. **"Hard surface disinfectant"** means a disinfectant that kills potentially pathogenic microorganisms on hard non-porous inanimate surfaces or inanimate objects.
17. **"Importer"** means any person or body corporate permitted and authorized under the laws and regulation in Rwanda pertaining to antiseptic and disinfectant to import antiseptic or disinfectant products
18. **"Immediate packaging"** refers to the container or other form of packaging immediately in contact with the antiseptic and disinfectant product;
19. **Ingredients** means any substance that is one of the components of a antiseptic and disinfectant and includes colouring agents, botanicals, fragrance and flavour, but does not include substances that are used in the preparation of the antiseptic and disinfectant but that are not present in the final product as a result of the chemical process
20. **"Inner label"** means primary packaging material label;
21. "**Law"** means Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning

22. **"Leaflet of a antiseptic and disinfectant"** refers to a printed paper and includes any written information related to a antiseptic and disinfectant;
23. **"Licence"** means permission from Authority to manufacture and sell one or more of its products.
24. **"Licenced manufacturer"** means a person to whom a manufacturer's licence has been issued under these Regulations, and includes a contract manufacturer;
25. **"Licenced wholesaler"** means a person to whom a wholesaler's licence has been issued under these Regulations;
26. **Lotions:** lotion in singular is a low-viscosity topical preparation intended for application to the skin, while a lotion may be used as a medicine delivery system, many lotions, especially hand lotions and body lotions are meant instead to simply smooth, moisturize, soften and perhaps perfume the skin
27. **"Manufacturer"** means a person or firm that is engaged in the manufacture of antiseptic or disinfectant product(s).
28. **"Marketing authorization"** refers to an official approval of the antiseptic and disinfectant product to be marketed or distributed in Rwanda mainland;
29. "**marketing communications**" includes "advertising as well as other techniques, such as promotions, sponsorships and direct marketing, and should be interpreted broadly to mean any communications produced directly by or on behalf of marketers intended primarily to promote products or to influence consumer behavior".
30. **"Media":** means newspaper, magazine, medical/journal, television, radio, the internet; Out of home, vehicle branding, posters, handbills, cinema, point of sale material; online, digital and social media, any form of projected light and sound recordings or any of such means of communication.
31. **"Mycobactericide"** means an antimicrobial agent capable of destroying mycobacteria.
32. **"Outer label"** Outer label" means secondary packaging material label;
33. ***"Outer packaging/* outer container"** refers to the packaging into which is placed the immediate packaging/inner container
34. ***"Package"*** refers to any box, packet or any other article in which one or more containers of antiseptic and disinfectant are to be enclosed in one or more other boxes, packets or article in question, the collective number thereof;

35. "**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;
36. **"Persistence"** means a claim that the product will deliver a longer action than only the immediate reduction of microorganisms.
37. **"Premises"** means any place that includes a vehicle, vessel, railway carriage, aircraft and building
38. **"Product variants"** means a range of products produced by the same manufacturer in the same site, similar in composition and intended for the same use but available in different colours, fragrances and flavours**.**
39. **„recall"** means any measure aimed at achieving the return of an antiseptic or disinfectant product that has already been made available to the end user;
40. "**Registration holder**" means the holder of the marketing authorization for the biocidal products.
41. "**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.
42. **"Registered product"** means a product currently registered in accordance with the provisions of these Regulations
43. **"Resident organisms"** means those organisms normally permanently reside on the skin.
44. **"Sanitizer"** means a product that reduces the level of microorganisms present by significant numbers, e.g. 99.9% or more, or to acceptable levels.
45. **"Specifications"** means the combination of physical, chemical, biological and microbiological test requirements that determine whether antiseptic or disinfectant product is suitable for the intended use.
46. **"Sporicide"** means an antimicrobial agent capable of destroying bacterial spores.
47. **"Sterilant"** means a chemical agent which is used to sterilize medical devices.
48. **"Transient organisms"** means organisms picked up by contact with the environment but may remain in situ long enough to be transferred (e.g. from patient to patient, from surgeon to patient or animal, etc).
49. "**Virucide**" means an antimicrobial agent capable of destroying viruses.

CHAPTER 1: INTRODUCTION

1.1 Scope

These guidelines shall be used on submission of documentation for registration of antiseptics and disinfectants. It describes procedures for dossier applications for registration of antiseptics and disinfectants products, variation and renewal of registration as well as labelling.

1.2 Classification of antiseptics and disinfectants

1.2.1 Antiseptics

Antiseptics are antimicrobial substances that are applied to living tissue/skin to reduce the possibility of infection, sepsis, or putrefaction.

Some antiseptics are germicidal in nature, implying that they have the ability to completely destroy microbes. these types of antiseptics are referred to as **bacteriocidal antiseptics**. Other antiseptics only inhibit the growth of microbes (or prevent the growth of microbes altogether). Such substances are commonly referred to as **bacteriostatic antiseptics**.

Antiseptics can also be classified according to their chemical structure. Commonly used antiseptic groups include:

a) Alcohols
b) Quaternary ammonium compounds
c) Chlorhexidine and other diguanides
d) Antibacterial dyes
e) Chlorine and hypochlorites
f) Inorganic iodine compounds
g) Metals
h) Peroxides and permanganates
i) Halogenated phenol derivatives
j) Quinolone derivatives.

1.2.2 Disinfectants

Disinfectants: Disinfectants are substances that are applied to non-living objects to destroy microorganisms that are living on the objects.

Types of disinfectants include:

a) Air disinfectants,

b) Alcohols,

c) Aldehydes,

d) Oxidizing agents,

e) Phenolics,

f) Quaternary ammonium compounds,

g) Silver,

h) Copper alloy surfaces.

1.3 Submission of application

An application for product registration for either locally manufactured or imported, shall be made in writing via a cover letter and application form dated and signed by the applicant. If the applicant is a foreign company, the applicant shall appoint a local technical representative through whom an application shall be submitted. The local agent shall be a registered wholesale company or an accredited manufacturer's representative. All application document shall be in English

The application should be submitted to Rwanda FDA through the authorized local technical Representative to the following address:

Director General
Rwanda Food and Drugs Authority
P. O. Box 84
Kigali- Rwanda

1.4 Types of Applications

For the purposes of submission of Product Dossier to Rwanda FDA, applications are classified into three categories as follows:

1. **New applications for registration:** an application for registration of product that is intended to be placed on the Rwanda market for the first time or product which was on the market without registration certificate.
2. **Renewal of product registration:** Applications for renewal of a registered product. The application shall be made at least 3 months before the expiry of existing registration.
3. **Variation of a registered product:** an application for any change in the registered products. All applications for variation to a registered product shall be made according to requirements as stipulated in the Rwanda FDA Guidelines for Variation of Registered medicinal products.

1.5 Application requirements

An application for antiseptics and disinfectants registration in Rwanda shall include the following:

1. Signed and dated original hard-copy of cover letter *(refer to the annex I, document N^{o} DHT/FMT/31)*
2. Signed and dated application form for new registration of antiseptic and disinfectant products *(refer to the annex II, document N^{o} DHT/FOM/047)*
3. Proof of payment of non-refundable registration fee at the time of submission
4. Two CD-Rom or external driver virus free containing all information on safety, quality and efficacy of the product distributed in the following sections (*Detailed information for each section are presented in the chapter 2*):
   - Section 1: Administrative requirement informations
   - Section 2: Technical requirements
5. Two commercial samples of the products with certificate of analysis.

Note: A separate and complete application for registration of antiseptic and disinfectant products shall be submitted for each product or product variant.

A separate and complete application for registration of products shall be submitted for each antiseptics and disinfectants products with different ingredients and formulation, intended use, forms and site of manufacture.

A separate and complete application for registration of products shall be submitted for product with the same ingredients and formulation but with different colours and/or fragrance

1.6 Receiving of applications for antiseptic and disinfectant products registration

An application consists of electronic copies, online submission or specified hard copies where applicable. The application of product registration is only received by the Authority when the payment of prescribed registration fees is made. After receiving a product registration application, a reference number is assigned and it will be used in all subsequent correspondences relating to the application. An acknowledged receipt will be issued.

1.7 Validity of issued registration certificate

a) A successful application will be issued a Certificate of Registration with a validity period of five (5) years.

b) A license issued under Rwanda FDA regulations and guidelines, unless otherwise revoked, shall be valid for five years from the date of its issue and may be renewed annually.

1.8 Retention of antiseptics and disinfectants on the register

The registered antiseptics and disinfectants are retained on the register annually. The antiseptics and disinfectants shall be removed from the register if application and payment of fees is not effected

Application for retention on the register shall be submitted thirty (30) calendar days before the due date.

The application shall be accompanied by:

a. A covering letter

b. Non-refundable fees as specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service tariff and fees

CHAPTER 2: GENERAL REQUIREMENTS FOR REGISTRATION

2.1 Data requirements for new application

Data requirements for a new application contains administrative requirements and technical data requirements. This chapter provide a guidance of component expected in each section (*Refer to the annex-VII for arrangement of data requirements for registration of antiseptic and disinfectant*).

2.1.1 Section A: Administrative requirements

All administrative documents (for example, application forms, certifications,…), general correspondence and annexes should be provided in part of administrative requirements as follow:

2.1.1.1 A.1 Cover letter

Applicants should include a cover letter with all applications. A copy of the letter should be placed at the beginning of Administrative data. The cover letter for product registration shall be dated and signed by the applicant (*Refer to the annex-I document N^{o} DHT/FMT/31*) downloadable from Rwanda FDA website in list of annexes to the guidelines for registration of human medicinal products.

2.1.1.2 A.2 Application form

An application to register an antiseptic or a disinfectant must be accompanied by a completed product application form (*refer to the annex II, document N^{o} DHT/FOM/047*) downloadable from Rwanda FDA website. The application form should be duly filled with relevant information and attachments, dated signed and stamped appropriately.

2.1.1.3 A.3 Contract Manufacturing Agreement

(where applicable)

2.1.1.4 A.4 Manufacturing license

The applicant should submit proof of marketing authorization granted by other competent regulatory authorities if applicable.

2.1.1.5 A.5 Valid GMP Certificate or other applicable internationally recognized Management System certification

For all product, irrespective of the country of origin, all key manufacturing and/or processing steps in the production of active ingredient, ingredients and finished products must be performed in plants that comply with Rwanda FDA GMP guidelines. Therefore, to the submittion, a valid GMP Certificate or other applicable internationally recognized management system certification must be enclosed in the applicatilon.

2.5.1.6 A.6 Product samples

Two pictures of commercial samples of the product and two coloured artwork/Label of the product as well as leaflet insert of the product where applicable must be submitted in the product dossier.

2.5.1.7 A.7 Local technical representative

Appointment letter of the local technical representative with original copy of Power of must be enclosed in this section attorney from the product manufacturer if it is imported. For local manufacturer, they must specify the information of the person in charge of post marketing surveillance.

2.1.1.9 A.8 Commitment letters

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

2.1.1.10 A.9 Product license or approval in other countries

1. Registration status within EAC and SRAs/WLAs

The applicant should provide a list of countries in EAC and countries with SRAs/WLAs in which a similar application has been submitted, dates of submission (if available) and the status of these applications. And valid certificates.

2. Statement on rejection or withdrawn application

Applicant must declare whether a marketing application for the product has been rejected prior to submission of the application in Rwanda. If the medicine has been rejected,

repeatedly deferred, withdrawn or suspended then reasons must be stated. If rejection occurs during the Rwanda FDA evaluation process, Rwanda FDA should be informed.

2.1.1.11 A.10 Proof of payment of non-refundable registration application fee

A scaned copy of the proof of payment must appear on the CD drive.

2.1.2 Section B: Technical requirements

Application technical requirements clarify all product information and should contains 2 main parts defining the detailed antiseptic and disinfectant product dossier which are Safety data sheet and Technical data shee**t.**

2.1.2.1 B.1 Safety Data Sheet (SDS)

The Safety data of each ingredients for an antiseptic or a disinfectant must be included in the dossier as follow:

1. B.1.1 Product Identification: Brand name and chemical name
2. B.1.2 Hazards identification and analysis
3. B.1.3 Composition and information on ingredients
4. B.1.4 Safety data for each ingredients
5. B.1.5 Handling and storage
6. B.1.6 Exposure controls and personal protection
7. B.1.7 Physical and chemical properties
8. B.1.8 Stability and reactivity
9. B.1.9 Toxicological information
10. B.1.10 Transport information
11. B.1.11 Critical control points
12. B.1.12 Quantitative and qualitative composition of the an antiseptic and disinfectant product
13. B.1.13 Microbiological quality
14. B.1.14 Undesirable effects and serious undesirable effects

15. B.1.15 Labelled warnings and instructions for use
16. B.1.16 Any data on animal testing if applicable
17. B.1.17 Summary of safety data
18. B.1.18 Environmental safety data

2.1.2.2 B.2 Technical Data Sheet (TDS)

A technical data sheet (TDS) is a document provided with a product that lists various pieces of information about the product. It includes information about product composition, methods of use, operating requirements, common applications, warnings and pictures of the product.

2.1.2.2.1 B.2.1 Data on raw materials

1. B.2.1.1 Chemical name (IUPAC) of each ingredient
2. B.2.1.2 Active ingredients and their mode of action
3. B.2.1.3 Name and address of manufacturer for each ingredient
4. B.2.1.4 Certificate of Analysis (COA) for each ingredient and Method of analysis
5. B.2.1.5 Safety Data Sheets (SDS) for each ingredient as specified in the guidelines

2.1.2.2.2 B.2.2 Data on final product

2.1.2.2.2.1 B.2.2.1 Specification of the product

1. B.2.2.1.1 Brand name/Biological family/Chemical family
2. B.2.2.1.2 Common name
3. B.2.2.1.3 Physical Characteristics
    a. Form (*Refer to the Annex V of this document*)
    b. Color
    c. Odor/Fragrance
    d. Viscosity
4. B.2.2.1.4 pH of Concentrate and pH of Working Solution (if applicable)
5. B.2.2.1.5 Foaming Tendency
6. B.2.2.1.6 Entire label read by applicators and supervisors
7. B.2.2.1.7 Safety precautions on label statements
8. B.2.2.1.8 Residue precautions on label statements

2.1.2.2.2.2 B.2.2.2 Manufacturing process

1. B.2.2.2.1 Flow chart and narrative of manufacturing process
2. B.2.2.2.2 Concentration percentage of each ingredients
3. B.2.2.2.3 Reference methods used
4. B.2.2.2.4 Description on the precautions and in-process controls that are made in connection with different stages of manufacturing shall be indicated

2.1.2.2.2.3 Product efficacy

1. B.2.2.3.1 Nature of the targeted object (for disinfectant)/ application area (for antiseptic)
2. B.2.2.3.2 Spaulding's Classification, Level of Disinfection and/or Speed of action of Antiseptic
3. B.2.2.3.3 Microbicidal Activity and Anti-bacterial sensitivity
4. B.2.2.3.4 Possible mechanisms of microbial resistance to antiseptics and disinfectants
5. B.2.2.3.5 Concentration and Potency of Disinfectants/Antiseptic
6. B.2.2.3.6 Application and mixing instructions, including method of application, type of equipment used, application techniques and rates for each use site, and type and volume of diluent per unit of area or volume (Where applicable)
7. B.2.2.3.7 Methods of Sterilization and other data supporting total sterilization (Where applicable)

2.1.2.2.2.4 ta for the quality of a product

1. B.2.2.4.1 Microbiological testing and specification of reference standards
2. B.2.2.4.2 Susceptibility of Antibiotic-Resistant Bacteria to Disinfectants
3. B.2.2.4.3 Comprehensive Certificate of Analysis of the Final product.
4. B.2.2.4.4 Method of analysis

5. B.2.2.4.5 Quality Control Methods for evaluating efficacy before use (Where applicable)

2.1.2.2.2.5 uman health safety data

1. B.2.2.5.1 Study data for adverse and chronic toxicity due to exposure (Oral, eye and skin toxicity).
2. B.2.2.5.2 A statement about any risk arising from the recommended methods and precautions and handling procedures, in order to minimize those risks (e.g. precautionary statements of the Globally harmonized system of classification and labelling of chemicals)
3. B.2.2.5.3 Information on antidotes, if any, and medical treatment in the case of accidental exposure; names of co-formulas that may influence the toxicity of the product
4. B.2.2.5.4 Product carcinogenic (Where applicable)

2.1.2.2.2.6 ronmental safety information

1. B.2.2.6.1 Surface compatibility and Residual effect on treated surfaces (Corrosive to aluminum, paint, concrete, rubber, plastic, …)
2. B.2.2.6.2 Zoonotic potential of environment
3. B.2.2.6.3 Procedures for cleaning application equipment, if relevant to the proposed use
4. B.2.2.6.4 Proposed hazard classification (according to WHO classification), labelling and safety phrases and symbols

2.1.2.2.2.7 lity studies data

1. The stability studies data (accelerated and long term stability data) for batches: The applicant shall provide stability data supporting the proposed shelf life for at least two batches. The stability studies shall be conducted in the container closure system in which it will be marketed in Rwanda.

2. Stability study report critically examine the method used to determine the established product shelf life including:

    i. Study design (protocol);

    ii. Test conditions (humidity and temperature), testing interval and Duration:

Storage conditions	**Duration**	**Testing interval (Months)**
Long term stability studies at $4^{o}C$	Shelf life	0, 3,6,9,12,18,24,36,48
Long term stability studies at $25^{o}C$ / ambient Relative Humidity	Shelf life	0, 3,6,9,12,18,24,36,48
Accelerated stability studies at $37^{o}C$/ ambient Relative Humidity	6 months	0,3,6
Accelerated stability studies at $37^{o}C$ / 80 % Relative Humidity	6 Months	1

    iii. Type of container used (Testing should be conducted using containers and closures intended for marketing of products);

    iv. Parameters to be tested should be those susceptible to change and are likely to influence the quality and safety of the finished product. They shall at least cover appearance (clarity, color, homogeneity and odor) for product form, levels of characteristic ingredients, physicochemical properties (such as pH, purity, and consistency), average weight or volume, assay of active ingredient and microbial limits depending on the nature of the product.

    v. Test results from item (iv) above.

2.1.2.2.2.8 rs supporting documents

Other available supporting documents for safety, efficacy and quality of the product

2.1.2.2.2.9 Packaging and labelling information

The applicant shall provide information on packaging material. This shall be made of substances/materials which are safe and suitable for its intended use and which shall preserve its hygienic, safety and quality.

Antiseptics and disinfectants product labels should be clearly legible, indelible letters and written in one of the official languages used in Rwanda bearing the following information:

1. The brand name
2. Common name of the product
3. Manufacturer's name and physical address
4. lot or batch number
5. Manufacturing date and Expiry date
6. Net content (weight/volume)
7. List of ingredients used
8. intended use of antiseptic and disinfectant product,
9. Instructions for use
10. Country of origin
11. Registration number assigned to it in a manner as prescribed by the authority
12. Storage conditions
13. Warnings and cautions if any

2.2 Data requirement for Variation

If for any reason the applicant changes any matter related to registered antiseptic and desinfectant including but not limited to change of packaging, labeling or any other change, shall before selling the changed antiseptic and disinfectant product, notify and obtain the Authority'approval of the change. The application shall be accompanied by:

2.2.1 A cover letter

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

2.2.2 Application form

Signed and dated application form for variation of registered antiseptic and disinfectant products (*refer to the annex IV, document No DHT/FOM/049*)

2.2.3 Documentation in support of variation

The applicant must specify all information supporting the variation and indicating the safety, efficacy and quality of affected part of manufacturing. For example, If there has been a change affecting the calibration of instruments, a certificate of analysis must be provided for the batch released after calibration. However, Changes involving product (s) composition and manufacturing sites shall be treated as new application.

The Authority will evaluate reasons provided in the notice and if satisfied with such reasons it will approve the changes by issuing approval notice and if it is not satisfied the applicant will be notified by stating the reasons thereof.

2.2.4 Product samples reflecting the variation

The applicant must submit two samples of the commercial product supporting the variation.

2.2.5 Proof of payment of variation fee

As specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service tariff and fees, the applicant must show a proof of payment for a non – refundable variation fees according to the product.

2.3 Renewal of product registration

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

2.3.1 Cover letter

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

2.3.2 Application form

Signed and dated application form for renewal of registered antiseptic and disinfectant products (*refer to the annex III, document No DHT/FOM/048*)

2.3.3 Supporting documentation for any variations since the product was last registered

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

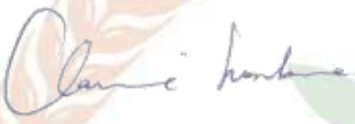
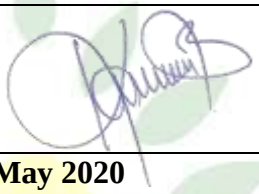
2.3.4 Samples of the product in the final package

The applicant must submit two samples of the commercial product supporting the variation.

2.3.5 Proof of payment for reneawal application fees

As specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service tariff and fees, the applicant must show a proof of payment for a non – refundable reneawal application fees according to the product.

ENDORSEMENT OF THE GUIDELINES

	Author	**Authorized by**	**Approved by**
Title	Division Manager of Drugs and Health Technologies	Head of Food and Drugs Assessment and Registration	Director General
Names	**Mrs IRASABWA Clarisse**	**Mr KABATENDE Joseph**	**Dr Charles KARANGWA**
Signature			
Date	**19th May 2020**	**19th May 2020**	**19th May 2020**

ANNEXES

ANNEX I – COVER LETTER

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

<Rwanda FDA>
<P.O.BOX 84> <Kigali>
< Rwanda >

Dear Sir/Madam,

Subject: Submission of Application for registration of antiseptic or 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 antiseptic or disinfectant details are as follows:

Name of the product(s): ……

Product form : ……

Intended use(s): ……

You will find enclosed the submission dossier as specified hereafter:

☐ The relevant fees for this applicantion have been paid.

☐ Two CD rom/external driver that contains product information in word format and in PDF

☐ Two commercial samples of the product

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

☐ The electronic submission contains the following sections:

Section 1: Administrative requirement informations

Section 2: Technical requirements

Section 3: Packaging and labelling information

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>

ANNEX II: APPLICATION FORM FOR NEW REGISTRATION OF ANTISEPTIC AND DISINFECTANT PRODUCTS

1. Signed and dated original hard-copy of cover letter ***(refer to the annex I, document N° DHT/FMT/31)***
2. Signed and dated application form for new registration of antiseptic or disinfectant products
3. Proof of payment of non-refundable registration fee at the time of submission
4. Two CD-ROM or external driver virus free containing all information on safety, quality and efficacy of the product. (where applicable)
5. Two commercial samples of the products with certificate of analysis.
6. A separate application shall be submitted for each product or product variant.

1.0 ADMINISTRATIVE INFORMATION	
1.1	Type of the product application (*choose and tick as appropriate*) Antiseptic: Disinfectant:
1.2	Name of the product:
1.3	Chemical 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: Bar: Tablet: Cream: Others: specify…….
1.5.1	Intended use:
1.6	Packing/pack size:

1.7	Visual 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	Other sister products registered or applied for registration:
1.9.1	Do you hold Marketing Authorization (s) of other product (s) containing the same active substance (s) in the other FDA? 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 (dd•mm•yyyy): Proprietary name: Authorisation number: Refused Country: Date of refusal (dd•mm•yyyy): Reason for Refusal:	Withdrawn (by applicant after authorisation) Country: Date of withdrawal: (dd•mm•yyyy): Proprietary name: Reason for withdrawal: Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd•mm•yyyy): Reason for suspension/revocation: 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:

1.13.3 Particulars of Applicant/ Registrant

Name: ……

Physical Address: ……

Postal Address: ……

Country: ……

Phone: ……..…… Fax: …….

Email: …….

Status of applicant (tick where appropriate):

Manufacture: Importer: Exporter: Other:

1.13.4 Particulars of Local agent/ Distributor

Name:

Physical Address: ……

Postal Address: ……

Country: ……

Phone: ……..…… Fax: ……

Email:

1.14	Qualitative and Quantitative composition (active substance (s) and excipient(s) A note should be given as to which quantity the composition refers (e.g. ml or g).

Name of active substance(s)*	Reference/monograph standard	Quantity /unit (ml, g)	Quantity per batch	Reason of inclusion
1.				
2.				
3.				
e.t.c				
Name Excipient(s)				
1.				
2.				

3				
e.t.c				

2.0 LABELLING

3.0 SUMMARIES

Provide condensed summaries of the key quality, efficacy and safety information from the product dossier. The summaries should include sufficient information from each section of the product dossier to provide an overview of the information submitted in the product dossier. The summaries should also emphasize critical key parameters of the product and provide discussion of key issues that integrates information from sections in the product dossier.

3.1 Chemistry, Manufacturing and Controls	
3.1.1	Chemistry
3.1.2	Manufacturing process
3.1.3	Quality control
3.1.4	Specifications and analytical methods
3.1.5	Stability studies
3.2 Efficacy and Safety	
3.2.1	Efficacy
3.2.2	Safety
3.3 Data to support specific claims (for antiseptics and disinfectants)	
3.3.1	Products used in professional food premises
3.3.2	Log reduction claims

3.3.3	Persistence claims
3.3.4	Time kill claims
3.3.5	Sterility

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

5. 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.

……
…….

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

……..

7. Recommended storage conditions (where applicable) including any relevant information after the product is opened for use or reconstituted:

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 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 FDA regulations

Name: ……..……

Position in the company: ……

Signature: ……

Official stamp: …….

Date: …….

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

9. Fees/ Charges payment (For Official Use only)

Fees to be Paid …….

Name and Signature of Authorized Officer…….

Name and Signature of Cashier ……...

Receipt Number ……...

Date …….

Stamp…….

NB: Cashier should attach copy of receipt

ANNEX III: APPLICATION FORM FOR RENEWAL OF REGISTRATION OF ANTISEPTICS/ DISINFECTANTS.

1.0 ADMINISTRATIVE INFORMATION	
1.1	Type of the product application (tick as appropriate) Antiseptic ☐ Disinfectant ☐
1.2	Proprietary Name of the product
1.3	Generic name of the product
1.4	Name and strength of active substance(s)
1.5	Name and address (physical and postal) of Applicant
(Cmpany) Name: Address: Country: Telephone: Telefax: E•Mail:	
1.5.1	Form of the product: (choose as appropriate) Solution: Suspension: Gel: Aerosol: Emulsion: Gaseous: Powder: Bar: Tablet: Cream: Others: specify....
1.5.2	Intended use:
1.6	Packing/pack size:
1.7	Visual description
1.9	Proposed shelf life (in months):

1.9.1	Proposed shelf life (after reconstitution or dilution):
1.9.2	Proposed shelf life (after first opening container):
1.9.3	Proposed storage conditions:
1.9.4	Proposed storage conditions after first opening:
1.10	Distribution category: Pharmacy Only General sale Others
1.11	Country of manufacture:
1.12	Product Marketing Authorisation in the country of manufacture. If not registered/licensed state reasons

Authorised Country: Date of authorisation (dd•mm•yyyy): Proprietary name: Authorisation number: Refused Country: Date of refusal (dd•mm•yyyy): Reason for Refusal:	Withdrawn (by applicant after authorisation) Country: Date of withdrawal(dd•mm•yyyy): Proprietary name: Reason for withdrawal: Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd•mm•yyyy): Reason for suspension/revocation: Proprietary name:

1.13	Name(s) and complete physical address(es) of the manufacturer(s) (Cmpany) Name: Address: Country: Telephone: Telefax: E•Mail:

3.0 VARIATION

Submit summaries of all variations made to the product from last date of registration.

4.0 DECLARATION BY AN APPLICANT

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 will be paid/have been paid according to the Rwanda FDA fees and regulation

Name: ……

Position in the company: ……

Signature: ……

Date: ……

Official stamp: ……...

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

ANNEX IV: APPLICATION FORM FOR VARIATION OF A REGISTERED ANTISEPTIC OR DISINFECTANT PRODUCT

1.0 ADMINISTRATIVE INFORMATION	
1.1	Type of the product application (tick as appropriate) Antiseptic ☐ Disinfectant ☐
1.2	Proprietary Name of the product
1.3	Generic name of the product
1.4	Name and strength of active substance(s)
1.5	Name and address (physical and postal) of Applicant
Company name: Address: Country: Telefax: Telephone: E-mail:	
1.5.1 Particulars of Local agent/ Distributor Name: ……. Physical Address: …… Postal Address: …… Country: ……. Phone: …….……. Fax: …… Email:……..	
1.5.2	Form of the product: (choose as appropriate)

	Solution: Suspension: Gel: Aerosol: Emulsion: Gaseous Powder: Bar: Tablet: Cream: Others: specify....
1.5.3	Intended use:
1.6	Packing/pack size:
1.7	Visual 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	Country of manufacture:
1.10	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:
2.0 VARIATIONS	
2.1	Changes made to the product
2.2	Description of the changes

2.3	Justification for changes

3.1 DECLARATION BY AN APPLICANT

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.

It is hereby confirmed that fees will be paid/have been paid according to the Rwanda FDA fees and regulations

Name: ……

Position in the company: ……

Signature:

Date: ……

Official stamp: ……

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

ANNEX V: EXPLANATORY NOTES ON FORMS OF ANTISEPTICS AND DISINFECTANTS

Aerosol products: are a mixture of liquefied gas, propellant, solvent(s) and active ingredients that are packaged under pressure in a container with a valve. When the valve is opened, typically by pressing a button on the top of the can, the internal pressure forces the aerosol up the dip tube and out of the valve. Many aerosol products require shaking before use to completely mix the ingredients prior to spraying. Failure to do this can mean the propellant (part that helps push the ingredients out of the can) would be used first, which would then trap the remaining ingredients in the can.

Capsule: A solid dosage form consisting of a shell and a powder or liquid filling example bath oil capsules.

Cream: Cream is a preparation usually for application to the skin. Creams are semisolid dosage forms containing more than 20% water or volatile components and typically less than 50% hydrocarbons, waxes, or polyols as vehicles.

Emulsion: Usually a white, opaque system that consists of at least two immiscible liquids, one of which is dispersed as droplets (internal phase) in the other (external phase). The system is generally stabilized with emulsifiers.

Gel: A clear semisolid dosage form that contains a gelling agent, which provides stiffness to the product.

Granules: bath pellets, crystals, pearls, etc.

Loose powder: A solid dosage form containing a freely flowing mixture of different dry solid ingredients, e.g. dusting powder, talcum.

Lotion: A low-viscosity liquid emulsion.

Ointment: A highly viscous, usually greasy, semisolid dosage form. It is more viscous than a cream.

Pressed powder: A solid dosage form that contains a freely flowing mixture of different dry solid ingredients in a compressed form, e.g. blush, eye makeup.

Pressed Cake: A solid dosage form that consists of primarily dry solid particles mixed and/or pressed together, or waxy ingredients molded into a specific shape, e.g. soap, bath bar.

Solution: A clear, homogeneous liquid dosage form that contains one or more chemical substances dissolved in a solvent or mixture of mutually miscible solvents.

Stick: A solid dosage form that is made of waxes and a smaller amount of oils and is prepared in a relatively long cylindrical form, e.g. lipsticks, eyebrow pencil.

Other (Please specify) - Product which does not fall into one of the general categories above.

ANNEX VI: EXPLANATORY NOTES ON INTENDED USES

A. INTENDED USES OF ANTISEPTICS

Washes: Antiseptic 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 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: 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: 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 microbiocidal 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 peroxo acids: Peroxycarboxylic acids and inorganic peroxo 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 disinfectants.

ANNEX VII: ARRANGEMENT OF DATA REQUIREMENTS FOR REGISTRATION OF ANTISEPTIC OR DISINFECTANT

This arrangement is subdivided in two sections: administrative requirement, and technical data requirements.

Note: All sections and subsections of this document must be presented on the CD as directed and if, due to the form of the product, there are information which cannot be completed, N.A must be indicated on that part.

a) The application and supporting document should be submitted in CD-ROM or External driver addressed to Rwanda FDA

b) The application form should be typed in English. Any document which is in any language other than English must be accompanied by a certified or notarized English translation.

c) Application Form and part three should be in both PDF and word format

d) The PDF documents should be selectable and searchable

e) All pages of the application should be numbered in the style: ***page x of y***.

Therefore, the applicant shall prepare and present the product dossier information in the following format.

Section A. Administrative requirement

A.1 Dated and signed cover letter

A.2 Application form

A.3 Contract Manufacturing Agreement (where applicable)

A.4 Manufacturing license

A.5 A valid GMP or other applicable internationally recognized Management System certification

A.6 Two (2) samples of commercial product(s)

A.7 Two (2) coloured artwork of the product and leaflet insert of the product (where applicable).

A.8Appointment letter of the local technical representative with original copy of Power of attorney from the product manufacturer (if imported)

A.9 Commitment letters (Ongoing stability studies) where applicable

A.10 Product license or approval in other countries

A.11 Proof of payment of non-refundable registration application fee

Section B. Technical requirements

B.1 Safety Data Sheets (SDS) for each ingredient as specified in the guidelines

B.1.1 Product Identification: Brand name and chemical name

B.1.2 Hazards identification and analysis

B.1.3 Composition and information on ingredients

B.1.4 Safety data for each ingredients

B.1.5 Handling and storage

B.1.6 Exposure controls and personal protection

B.1.7 Physical and chemical properties

B.1.8 Stability and reactivity

B.1.9 Toxicological information

B.1.10 Transport information

B.1.11 Critical control points

B.1.12 Quantitative and qualitative composition of the an antiseptic and disinfectant product

B.1.13 Microbiological quality

B.1.14 Undesirable effects and serious undesirable effects

B.1.15 Labelled warnings and instructions for use

B.1.16 Any data on animal testing if applicable

B.1.17 Summary of safety data

B.1.18 Environmental safety data

B.2 Technical data sheet

B.2.1 Data of raw materials

B.2.1.1 Chemical name (IUPAC) of each ingredient

B.2.1.2 Active ingredients and their mode of action

B.2.1.3 Name and address of manufacturer for each ingredient

B.2.1.4 Certificate of Analysis (COA) for each ingredient and Method of analysis

B.2.1.5 Safety Data Sheets (SDS) for each ingredient

B.2.2 Data on final product

B.2.2.1 Specification of the product

B.2.2.1.1 Brand name/ Biological family/ Chemical family

B.2.2.1.2 Common name

B.2.2.1.3 Physical Characteristics

a. Form
b. Color
c. Odor/Fragrance
d. Viscosity

B.2.2.1.4 pH of Concentrate and pH of Working Solution (if applicable)

B.2.2.1.5 Foaming Tendency (if applicable)

B.2.2.1.6 Entire label read by applicators and supervisors

B.2.2.1.7 Safety precautions on label statements

B.2.2.1.8 Residue precautions on label statements

B.2.2.2 Manufacturing process

B.2.2.2.1 Flow chart and narrative of manufacturing process

B.2.2.2.2 Concentration percentage of each ingredients

B.2.2.2.3 Reference methods used

B.2.2.2.4 Description on the precautions and in-process controls that are made in connection with different stages of manufacturing shall be indicated

B.2.2.3 Product efficacy

B.2.2.3.1 Nature of the targeted object (for disinfectant)/ application area (for antiseptic)

B.2.2.3.2 Spaulding's Classification, Level of Disinfection and/or Speed of action of Antiseptic

B.2.2.3.3 Microbicidal Activity and Anti-bacterial sensitivity

B.2.2.3.4 Possible mechanisms of microbial resistance to antiseptics and disinfectants

B.2.2.3.5 Concentration and Potency of Disinfectants/Antiseptic

B.2.2.3.6 Application and mixing instructions, including method of application, type of equipment used, application techniques and rates for each use site, and type and volume of diluent per unit of area or volume (Where applicable)

B.2.2.3.7 Methods of Sterilization and other data supporting total sterilization (Where applicable)

B.2.2.4 Quality data for the product

B.2.2.4.1 Microbiological testing and specification of reference standards

B.2.2.4.2 Susceptibility of Antibiotic-Resistant Bacteria to Disinfectants

B.2.2.4.3 Comprehensive Certificate of Analysis of the Final product.

B.2.2.4.4 Method of analysis of Final product

B.2.2.4.5 Quality Control Methods for evaluating efficacy before use (Where applicable)

B.2.2.5 Human health safety data

B.2.2.1.1 Study data for adverse and chronic toxicity due to exposure (Oral, eye and skin toxicity)

B.2.2.5.2 A statement about any risk arising from the recommended methods and precautions and handling procedures, in order to minimize those risks (e.g. precautionary statements of the Globally harmonized system of classification and labelling of chemicals)

B.2.2.5.3 Information on antidotes, if any, and medical treatment in the case of accidental exposure; names of co-formulants that may influence the toxicity of the product

B.2.2.5.4 Product carcinogenic (Where applicable)

B.2.2.6 Environmental safety information

B.2.2.6.1 Surface compatibility and Residual effect on treated surfaces (Corrosive to aluminum, paint, concrete, rubber, plastic, …)

B.2.2.6.2 Zoonotic potential of environment

B.2.2.6.3 Procedures for cleaning application equipment, if relevant to the proposed use

B.2.2.6.4 Proposed hazard classification (according to WHO classification), labelling and safety phrases and symbols

B.2.2.7 Stability studies data

B.2.2.7.1 Accelerated stability data

B.2.2.7.2 Long-term stability data

B.2.2.8 Other available supporting documents for safety, efficacy and quality of the product