REQUIREMENTS FOR REGISTRATION OF ANTISEPTIC AND 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.8 Appointment 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.2.2.5.1 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