RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR THE REGISTRATION OF CLEANING CHEMICAL PRODUCTS

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) 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 cleaning chemicals (Law N° 003/2018, article 3 & 8) in order to improve the accessibility of cleaning products (agents/chemicals) which play an essential role in our daily lives. By safely and effectively removing soils, germs and other contaminants, those cleaning chemicals/products help us to stay healthy, care for our homes and possessions, and make our surroundings more pleasant.

The users and environmental health safety is the fundamental principle of cleaning chemical products registration. The Rwanda FDA, through the registration process, gather adequate information for quality, safety and efficacy assessment of cleaning chemical products.

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

11/03/2022

Dr Emile BIENVENU
Director General

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ABBREVIATIONS AND ACRONYMS

AI:	Active Ingredient
CAS:	Chemical Abstract Service
CCS:	Cleaning chemical product
CD-ROM	Compact Disc Read-Only Memory
COA:	Certificate of Analysis
EAF	Easy assessment format
EC	European Community
FP:	Finished product
GMP:	Good Manufacturing Practice
I&I	Institutional or industrial
INN	Non-proprietary Name
ISO:	International Organization for Standardization
IUPAC:	International Union of Pure and Applied Chemistry
LTR:	Local Technical Representative
MAH:	Market Authorization Holder
SDS:	Safety Data Sheet
SOPs:	Standard Operating Procedures
PD:	Product Dossier
RM:	Raw materials

GLOSSARY

The definitions provided below apply to the words and phrases used in these guidelines. The following definitions are provided to facilitate interpretation of the guidelines.

Authority

The Rwanda Food and Drugs Authority or "Rwanda FDA" established by Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organisation, and functioning.

Active Ingredient (AI)

Means any compound or substance that provides intended cleaning activity by safely and effectively removing soils/dust and stains, kill germs and other contaminants in the prevention of spread of infectious diseases and then control allergens for the public health protection. Detailed information can be found in the Rwanda FDA glossary of terms.

Agent/ Local Technical Representative (LTR)

Every applicant who is not resident in Rwanda shall appoint a registered wholesale company or an accredited manufacturer's representative in Rwanda to deal with their products as an agent/Local Technical Representative (LTR). The appointment shall be notified to the Authority by submitting a letter of appointment supported by original copy of power of attorney duly notarised in country of origin, and registered with registrar of Companies in Rwanda.

Applicant

An applicant is a person or company who applies for registration of any kind of cleaning chemical products to Rwanda FDA, who must be the owner of the marketing authorisation of the product. S/He may be a manufacturer or a person whose order/permission is provided by the CCP manufacturer.

The applicant shall therefore be responsible for signing the registration application form. In the event that the applicant wants another person or company to register the CCP on her/his behalf, then Power of Attorney copy, duly notarised in the country of origin, and registered with the Registrar of Companies in Rwanda shall be provided. Once the product is registered, the applicant shall be the Marketing Authorisation Holder.

Appropriate fee/fees

The fee prescribed in the regulation n° CBD/TRG/004 related to the regulatory services tariff/ fees and charges in Rwanda FDA.

Approval

It means an official consent by the Authority as an acceptance of a registration of the concerned CCP or practices related to that on the Rwandan market;

Authorised person

A person responsible for the release of batches of finished product for sale or distribution. The batch documentation of a finished product must be signed by an authorised person from the production department and the batch test results by an authorised person from the quality control department for the batch release.

Batch (or lot)

A defined quantity of starting material(s), packaging material(s), or product processed in a single process or series of processes so that it could be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterised by its intended homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch.

Batch number (or lot number)

A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, etc.

Batch records

All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product as well as all circumstances pertinent to the quality of the final product.

Container

Any form of packaging device, material and an appropriate closure which is used to properly store cleaning chemical product.

Chemical substance

A form of matter having constant chemical composition and characteristic properties.

Cleaning

means the process by which an undesirable deposit is removed from a substrate or from within a substrate and brought into a state of solution or dispersion (AISE))

Cleaning chemical

Cleaning products Any product used for the purpose of cleaning any surface or material, such as toilet soaps, laundry soaps, dishwashing products, liquid laundry detergents, glass cleaners, car washing products, powdered detergents, scouring powder, solvent cleaner product……...

Detergent

Means any substance or preparation containing soaps and/or surface tension coefficient for the purpose of cleaning and washing, which may present in any form (liquid, powder, paste, bar, a cake, etc.) and marketed for or used in household or institutional or industrial purposes specially formulated for cleaning through the process of detergency.

Other products to be considered as detergents are:

a. **Auxiliary washing mixture'**, intended for soaking (pre-washing), rinsing or bleaching clothes, household linen, etc.;
b. **Laundry fabric-softener'**, intended to modify the feel of fabrics in processes which are to complement the washing of fabrics;
c. **Cleaning mixture'**, intended for domestic all purposes cleaners and/or other cleaning of surfaces
d. **Consumer detergent'** means a detergent placed on the market for use by non-professionals. It includes laundry and automatic dishwasher detergent
e. **Institutional and industrial detergent**: means a detergent intended to be used in the institutions or industrial sectors and not made available to general public.

Distributor

Means any natural or legal person permitted by the Authority, including a retailer, who only stores and places on the CCPs, on its own and or for third parties;

Finished product (FP)

A finished dosage form of a product, which has undergone all stages of manufacture, including packaging in its final container and labelling.

Good Manufacturing Practices

Means a system for ensuring that products are consistently produced and controlled according to quality standards

Hazard pictogram (also referred to as "pictogram" in this document)

Means a graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or color that is intended to convey specific information;

Hazard statement

Means a phrase assigned to a hazard class and category that describes the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard.

Label

Means an appropriate group of written, printed or graphic information elements concerning a CCPs, selected as relevant to the target sector (s), that is affixed to, printed on, or attached to the immediate container of a CCP, or to the outside packaging of CCP.

Operation license/ Operating certificate

Means any approval, a company is required to possess in order to legally and effectively conduct the business of CCP such as manufacturing, manufactured, importation, exportation, distribution, within Rwanda

Importer

Any person or body corporate permitted by the Authority to import cleaning chemical product as regulated by Rwanda FDA.

In-process control

Checks performed during production in order to monitor and if necessary to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.

Industrial and institutional detergent

means a detergent for washing and cleaning outside the domestic sphere, carried out by specialised personnel using specific products.

Manufacturer

A manufacturer is a natural or legal person with responsibility for manufacturing of a cleaning chemical product. It involves operations such as production, packaging, repackaging, labelling and relabelling of product.

Manufacturing

Means production or extraction of substances in the natural state;

Manufacturing process

Means any technical manufacturer works with raw materials to come up with a complete and commercially viable cleaning chemical product through a single operation or a sequence of operations.

Marketing authorisation (registration certificate)

A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeia or other recognised specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.

On-going stability study

The study carried out by the manufacturer on production batches according to a predetermined schedule in order to monitor, confirm and extend the projected retest period (or shelf-life) of the FP.

Packaging

means one or more containers and any other components or materials necessary for the containers to perform their containment and other safety functions;

Packaging material

Any material, including printed material, employed in the packaging of a product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

Preparation

Means a mixture or solution composed of two or more substances

Rwanda FDA

The Rwanda Food and Drugs Rwanda FDA or its acronym "Rwanda FDA", established under Article 2 of the Law N° 003/2018 of 09/02/2018

Soap

Means an anionic surface active agent which exhibits the phenomenon of reversible hydrolysis by action of water. Their reaction is alkaline

Scouring powder

A mixture consisting essentially of a finely divided abrasive, suitable additive and builders together with an active ingredient which may be an anionic or non-ionic or a soap synthetic detergent or their mixture (RS EAS 294: 2001)

Specification

A document describing in detail the requirements with which the products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality control and or evaluation.

Substance

means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (AISE)

Surfactant

Means any organic substance and/or preparation used in detergent which has surface active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such nature and size that is capable of reducing the surface tension of water and forming spreading and adsorption monolayers at the water-air interface, and of forming emulsion and/or micro emulsion and/or micelles and of adsorption at water-solid interfaces.

Surface active agent

A chemical compound which, when dissolved or dispersed in a liquid, is preferentially adsorbed at an interface, thereby giving rise to a number of physico-chemical properties of practical interest. The compound includes at least one group having an affinity for markedly polar surfaces, ensuring in most cases solubilization in water, and another group which has little or no affinity for water

Washing

means the cleaning of laundry, fabrics, dishes and other hard surfaces. (AISE))

Validation

The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.

Validation report

A document in which the records, results and evaluation of a completed validation program are assembled. It may also contain proposals for the improvement of processes and/or equipment.

CHAPTER ONE: INTRODUCTION

1.1 Background

The "*Guidelines on Submission of Documentation for Registration of cleaning chemical products' Rev_0'* is the Authority's publication which sets out procedures and requirements for the implementation of cleaning chemical products registration. These Guidelines contain two Sections in easy assessment format (EAF) (refer to annex III)

Section 1: Administrative information and product information requirements
Section 2: Technical data requirements

Adherence to these guidelines by the manufacturers/applicants will facilitate timely assessment and decision making for submitted cleaning chemical product dossiers by the authority for pre-marketing evaluation, marketing authorisation/registration and post-marketing review.
We wish to express our gratitude to all individuals and partners who actively participated in the development of these guidelines.

1.2 Scope

In pursuance of article 1 and article 3 of the regulation *N° CBD/TRG/013 Rev_0 Governing the registration of pesticide, laboratory and cleaning chemicals,* the purpose of these Guidelines are hereby made to provide guidance to the applicants on the procedures and requirements for the registration of cleaning chemical products and provide guidance to the Authority in managing and assessment applications for registration of cleaning chemical products using easy assessment format (EAF)

These guidelines describe procedures for dossier applications for registration of all types of registration as the state in this document (1.6), as well as labelling of cleaning chemical products

Applicants are encouraged to familiarise themselves with this document and the law before completing the application form.

1.3 Objective of registration

The purpose of the registration of cleaning chemical products is to ensure that the registered products are safe for users and their environment and then make sure that they comply with the recommended quality and efficacy requirements.

Registration enables the Authority to exercise control over the quality, use levels, claims, labelling, packaging, advertising, thus ensuring that public health is properly protected.

These guidelines describe the requirements for registration and explain how applications are made to the Rwanda FDA to register cleaning chemical products used in household or institutional or industrial settings.

1.4 Types of cleaning chemical products

Based on the principle method by which the cleaning chemical products remove soils/dust/germs as well as their respective composition, they may be categorised into the following types:

1.4.1 Detergents

Hand washing detergents

The liquid detergent shall consist of anionic, cationic, non-ionic or surface-active agents or their mixture. It may contain added materials such as buffers, preservatives, emollients, opacifiers, stain removers, perfumes, viscosity controlling agents, foam control agents or approved colouring agents. Under normal usage conditions, these shall not have any irritant or undesirable effect on the skin and hands.

Dishwasher detergents (consumer and I&I),

It is a detergent made for washing dishes in a dishwasher.

Laundry detergents (consumer and I&I),

It is a detergent made for washing clothes in a laundry machine.

All-purpose cleaners

They are used for cleaning floors, furniture, toilets, bathrooms and kitchen settings.

Glass cleaners

They are used for cleaning glasses.

Drain & Heavy Duty Cleaners

They are used for cleaning heavy-duty stains in sinks and drainage.

1.4.2 Degreasers (Solvent cleaners)

Degreasers are cleaning chemicals that dissolve grease, oil, and oily dirt. The ingredients in solvents include (but are not limited to) acetones, denatured alcohols, and mineral spirits.

1.4.3 Abrasive products

Abrasives are rough or gritty. They clean surfaces by creating friction that lifts off hardened food particles, grease, tarnish, and stains. Anything rough to the touch can be considered an abrasive when used to remove spots or stains from a surface. Types of abrasives include:

a. Powdered (Scouring powder) Cleansers,
b. Liquid Cleansers,

1.4.4 Other cleaning chemical products/agents

Other cleaning chemicals that do not fall into the class of detergent, degreasers and abrasive products are categorised into other cleaning chemical products or agents. They can include acid cleaners, alkalis cleaners, and organic solvents, etc.

1.5 Responsibility

1.5.1 Responsibility of the Authority

The Rwanda FDA has the sole authority, and responsibility to register all cleaning chemical products (CCP) manufactured, imported, exported, distributed, advertised, or used on the Rwandan territory. Registration of the CCP is the process whereby Rwanda FDA approves the sale and use of a CCP following the assessment of comprehensive scientific data demonstrating that the concerned product is effective for the intended purposes and does not pose any unacceptable risk to users and their environment.

1.5.2 Responsibility of the applicant

The applicant shall be responsible for the CCP and all information supplied in support of their application to register the concerned product by facilitating communication with the Authority. The applicant should be accountable for all responsibilities regarding the safety, quality and efficacy of CCP on the Rwandan market.

1.6 Submission of application

An application for CCP registration for locally manufactured or imported shall be made in writing via a cover letter and application form duly filled in, dated and signed by the applicant. If the applicant is a foreign company or a person, S/he shall appoint an LTR through whom an application shall be submitted. The LTR shall be a registered wholesale company or an accredited manufacturer's representative.

The applicant shall prepare and present the CCP dossier information in EAF according to the requirements as stipulated in these guidelines (Annex III):

a) The application should be typed in English. Any document in a language other than English must be accompanied by a certified or notarised English translation.
b) A separate and complete application for the registration of CCP shall be submitted for each product or product variant.
c) A separate and complete application for registration of products shall be submitted for each CCP with different ingredients and formulation, intended use, forms and manufacturing site.
d) The PDF documents should be in Optical Character Recognition (OCR), selectable and searchable
e) Payment of fees shall be made according to the *Regulation N° CBD/TRG/004 related to regulatory services tariffs/ fees and charges*. The fees are for each respective product registration, excluding transfer and other charges.
f) The application addressed to Rwanda FDA should be submitted in free virus CD-ROM or any other electronic device. The applicant can also submit the product for registration via official online platforms.

The application should be submitted to Rwanda FDA through the authorised LTR to the following address:

Director-General Rwanda FDA
Rwanda Food and Drugs Authority
P. O. Box 1948
Kigali- Rwanda

1.7 Categories of certificate for CCP registration

1.7.1 Full registration

It is registration that has fulfilled all Rwanda FDA registration requirements

1.7.2 Conditional registration

It is a registration conditioned upon the completion of certain specified data requirements. Once conditions of registration have been met, the conditions are removed and a full registration can be granted.

1.8 Types of Applications

For the purposes of submission of CCP Dossier for registration to Rwanda FDA, applications are classified into four categories as follows:

1.8.1 New applications for CCP registration

An application for CCP registration that is intended to be placed on the Rwandan market for the first time or products which were on the market without registration certificate.

An application for CCP registration in Rwanda shall include the following:

1. Duly signed and dated original hard-copy of cover letter
2. Duly signed and dated well filled application form for new registration
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.
5. Two commercial samples of the FP with COAs and its coloured artwork/Label. For more details and clarification, the reference shall be made to the guidance on the sample handling.

1.8.2 Renewal of CCP registration

Referring to the *Regulations No: CBD/TRG/013 governing the registration of pesticides, laboratory and cleaning chemicals*, the application for renewal of a registered CCP shall be made at least 3 months before the expiry date of the last registration.

The application dossier shall be accompanied by:

a. A duly and signed covering letter
b. Supporting documentation for any variations since the product was last registered
c. Two commercial samples of the FP with COAs and its coloured artwork/Label. For more details and clarification, the reference shall be made to the guidance on the sample handling.
d. Non-refundable application fee as specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service tariff/fees and fines.

1.8.3 Variation of a registered product

If for any reason the applicant changes any matter related to the registered CCP including but not limited to change in packaging, labeling or any other change affecting the quality of the CCP, before introducing the CCP with the new variation to the market notify and obtain the Authority's approval of the change. The application shall be accompanied by:

1. A duly signed covering letter
2. Documentation supporting the variation made
3. Two commercial samples of the FP with COAs and its coloured artwork/Label reflecting the variation. For more details and clarification, the reference shall be made to the guidance on the sample handling
4. A non-refundable variation fee as specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service tariff/fees and fines

1.8.4 Retention of CCP on the register

The registered CCP is annually retained on the register. The application is made by:

a. A duly signed covering letter
b. Non-refundable fees as specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service tariff and fees

1.9 Receiving new applications for CCP registration and Dossier Assessment Procedures

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 to the CCP application file and it will be used in all subsequent correspondences relating to that application.

Thereafter, the CCP dossier is assessed by two assessors to provide scientific and regulatory oversight regarding the quality, safety and efficacy of the CCP dossier under assessment.

Indeed, Rwanda FDA reserves the right to request any additional scientific information related to the quality, safety and efficacy of the concerned CCP. In the course of the assessment, additional data and/or samples may be requested through an official communication letter. If so, once the query(ies) has/have been issued to the applicant, the assessment process stops until Rwanda FDA receives the written response(s) to the raised query(ies).

Further processes of the application may only be resumed if the response(s) to the issued query(ies)in the official communication letter has/have been received by the Rwanda FDA. Failure to comply with

the above-mentioned condition or if the query(ies) has/have been reissued for the fourth time while the applicant provides unsatisfactory response(s), the CCP application file shall be rejected.

In the event that the responses to the queries are not submitted within sixty calendar days from the date they were issued, it will be considered that the applicant has withdrawn the application unless the applicant has requested for the deadline extension to Rwanda FDA. Hence, registration of the product may only be considered upon submission of a new application.

1.10 Restricted and banned products in CCPs

Some active substances are banned from use in Rwanda and products containing these active substances shall not be registered. These include product listed as banned in international conventions that Rwanda has signed and ratified. Refer to the list of banned products as determined in the **Ministerial Order N° 26/03** and **27/03 of 23/10/2008** published in official Gazette.

CHAPTER TWO: GENERAL REQUIREMENTS FOR REGISTRATION

This chapter contains two sections including administrative information and technical data requirements which compose application dossier for registration. Applicants are encouraged to get familiarised with this chapter and consider it when preparing and submitting applications for registration of CCP.

SECTION 1: ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION REQUIREMENT

It contains all administrative documents such as application forms and certifications, labelling, general correspondence and annexes. Generally, all of the documents in Section 1, other than the annexes, can be provided in a single volume. The annexes to this section should be in the end of this section (1.1.11). Documents should be organised in the order listed below.

2.1.1 Table of contents

The table of contents should include a complete list of all documents provided under section 1.

2.1.1.1 Cover letter

Applicants should include a cover letter for each CCP application dossier. A copy of the letter should be placed at the beginning of Administrative data. The cover letter template (***Refer to the Annex-I***) as available in the annexes to the guidelines for registration of cleaning chemicals. For product registration shall be dated and signed by the applicant as stipulated in these guidelines

2.1.1.2 Application form.

An application to register a CCP must be accompanied by a completed product application form (***refer to the Annex II, document N° DAR/FOM/163***) downloadable from Rwanda FDA website. The application form should be duly filled with relevant information and attachments, dated signed and stamped by the applicant/license holder.

2.1.1.3 Proof of payment of non-refundable registration application fee

A scanned copy of the proof of Appropriate fees payment must appear on the CD-ROM or External Driver containing product dossier

2.1.1.4 Manufacturing license or Operation license

The applicant should submit valid Certificate of cleaning chemical manufacturing granted by competent authorities in the country of manufacturing.

2.1.1.5 Contract Manufacturing Agreement (if applicable)

If a product is manufactured on contract, evidence of the contract shall be produced in the documentation submitted. And this shall be clearly stated on the label of the product.

2.1.1.6 Valid GMP Certificate or other applicable internationally recognized Management System certification

For all foreign product, all key manufacturing and/or processing steps in the production of finished products must be performed in plants that comply with Rwanda FDA GMP guidelines. Therefore, to the submission, a valid GMP Certificate or other applicable internationally recognised quality management system certification must be enclosed in the application. Otherwise, the applicant has to apply for GMP inspection to Rwanda FDA.

2.1.1.7 Local technical representative (LTR)

a. If the applicant is a foreign company, the later shall appointed an LTR. through whom the application shall be submitted.
b. The LTR shall be a registered company or an accredited manufacturer's representative registered in Rwanda.
c. Appointment letter of the LTR with original copy of Power of attorney must be enclosed in this section from the product manufacturer.
d. For local manufacturer, they must specify the information of the qualified person in charge of the CCP safety monitoring and post marketing surveillance.

2.1.1.8 CCP samples

a. Two commercial samples in the final packing size shall be submitted with their respective certificate(s) of analysis. For more details and clarification, the reference shall be made to the guidance on the sample handling.
b. Two coloured artwork/Label of the product must be submitted in/with the CCP dossier.
c. For the submitted samples for CCP registration in Rwanda, its remaining shelf-life remaining should not be less 60%. This notwithstanding, products with a shelf life of less than 24 months, the CCP shall have at least 80% of its remaining shelf life at the time of submission.
d. All samples of products submitted shall comply with current labelling requirements of these guidelines.

2.1.1.9 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 Product license or approval in other countries

2.1.1.10.1 Registration status

The applicant should provide a list of countries in EAC and other countries where a similar application has been submitted as well as a valid copy of registrcertificates (if applicable).

2.1.1.10.2 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 CCP 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 Annex

All other administrative supporting documents should be provided under this heading (Annex).

SECTION 2: TECHNICAL DATA REQUIREMENTS

2.2.1 RAW MATERIALS

With CCP becoming more and more popular throughout our country, quality has become even more critical for companies involved in the manufacture of CCP.

We all know the importance of raw materials (RMs) to a high-quality product. RMs are in fact the foundation of a qualified final product. Without a qualified material, all efforts at producing a good product would be like building a palace on a sandy base.

With hundreds, if not thousands, of items produced in a manufacturing facility, it is very difficult for a company to handle materials from the very beginning to the end of the final product fulfilment. We are relying more and more on our stakeholders/manufacturer to provide high-quality materials for manufacturing of finished products. Therefore, the information related to raw material should be submitted as below.

2.2.1.1 Table of content

The table of contents should include a complete list of all documents provided under section 2.

2.2.1.2 Name and address of manufacturer for each active ingredients

2.2.1.2.1 General information

2.2.1.2.1.1 Nomenclature

The listed chemical composition names should be consistent with those appearing in scientific literature and those appearing on the product labelling information which provided. For example: International Non-proprietary Name (INN); International Nomenclature of cosmetic ingredients. INCI or International Union of Pure and Applied Chemistry (IUPAC).

This may be listed in tabular form

No	Other Chemical or commercial name	CAS	INN/INCI	IUPAC name
1				
2				
3				

2.2.1.2.1.2 Address of manufacturer

The name and address of each manufacturer/company supplier, including contractors, and each proposed production site or facility involved in manufacturing and marketing should be provided.

The list of manufacturers/company supplier should specify the actual addresses of production or manufacturing site(s). Telephone number(s), fax number(s) and e-mail address (es) should be provided.

No	CAS	INN/INCI	Manufacturer	Address
1				
2				
3				

2.2.1.3 Supporting document of sources of ingredients

The applicant has to submit a supporting document demonstrating the source of active ingredient used by the manufacturer during the manufacturing process of the CCP. The mentioned evidence might be

the certificate of analysis, the invoice for purchasing the raw materials or any other evidence. In case a COA is provided, it must meet international or national standards and enclose:

- Name of the Raw Materials
- Batch number
- Manufacturing date and expiry date or "retest" date
- Manufacturing and control location
- Used specifications of the control method and standards used
- Parameters tested
- Results of the controls
- Approval of the results with date, signature and stamp of qualified personnel

2.2.1.4 Material Safety Data Sheets (MSDS) for each ingredient

Safety Data Sheet for each ingredient used to manufacture the final CCP. The SDS should contain the necessary information with reference to the following required data:

1. Product Identification: Brand name and chemical name
2. Hazards identification and analysis
3. Composition and information on ingredients
4. Safety data for each ingredients
5. Handling and storage
6. Exposure controls and personal protection
7. Physical and chemical properties
8. Stability and reactivity
9. Toxicological information
10. Transport information
11. Critical control points
12. Quantitative and qualitative composition of the an antiseptic and disinfectant product
13. Microbiological quality
14. Undesirable effects and serious undesirable effects
15. Labelled warnings and instructions for use
16. Any data on animal testing if applicable
17. Summary of safety data
18. Environmental safety data

2.2.1.5 Annex

All other document to support safety and quality of RMs other than document provided in this section from 2.1.2 up to 2.1.7 should be provided under this heading.

2.2.2. FINISHED PRODUCT TECHNICAL DATA REQUIREMENTS

2.2.2.1 Table of content

The table of contents should include a complete list of all documents provided under section 2.2.

2.2.2.2 Description of the FP and intended use

2.2.2.2.1 Description of the FP

The description of the finished CCP should include but not limited,

a. The physical description (visual description)
b. FP form
c. Packing type (s) and packaging size
d. Shelf-life and storage conditions
e. As well as any other distinguishable characteristics.

2.2.2.2.2 Intended use

Full description on intended use of CCP must be availed and submitted. Where It is applicable, any literature and other research outputs that were carried in relation with the intended use on the CCP, it has to be summarised in this section.

2.2.2.3 Composition of the FP

This is a list of all ingredients of the production batch, and their amount on a per unit basis and the function or role of the ingredients. Composition of FP should be summarised in tabular format (ingredients, quantity, role) and express the quantity of each component on a per unit basis and quantity per batch as in the following table.

No	Ingredients name	Quantity per batch	Quantity %	Function
1				
2				

The function of each component (e.g. diluent/filler, binder, antimicrobial preservative.) should be stated. If an ingredient performs multiple functions, all function should be indicated. From predominant function.

2.2.2.4 Manufacturing process

1. Flow chart and narrative of manufacturing process.
   A flow diagram should be presented giving the steps of the process and showing where materials enter the process
2. Description on the precautions and in-process controls that are made in connection with different stages of manufacturing process should be indicated

2.2.2.5 Certificate of Analysis for the FP

a) Duly dated and signed 2 batches CoA include CoA referring to the same batch/lot number of the sample submitted; written/translated in English on the letterhead of manufacturer shall include the following:
   1. Batch /Lot number
   2. Manufacturing date and expiry date or "retest" date.
   3. Manufacturing site
   4. Used specifications of the control method and standards used
   5. Limits stated parameters on technical specifications of the finished product.
   6. All test or analysis/controls results based on technical specifications of FP.

b) The result on CoA submitted must meet international or national standards.

c) In addition to stating the specific enzymes used in the formulation of powder detergents, adequate documentation should be submitted to justify the mode of culturing and/or synthesis of enzymes used in the formulation of washing powder detergents.

d) For locally manufactured products, the original recognised certificate of analysis should be submitted.

e) For imported products, an appropriate certificate of analysis of the finished product shall be submitted.

2.2.2.6 Packaging and labelling information

All written information, printed or graphic material on or accompanying a product, this includes labels, inserts, promotional literature or any other written or printed information distributed with a product.

2.2.2.6.1 Packaging

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 to human and environment.

An appropriate container should be selected according to the characteristics of the scheduled wastes. The characteristic of scheduled wastes shall be compatible with the type of material used for the container to prevent any reaction which will deteriorate the container

2.2.2.6.2 Labelling

The Cleaning chemical product label conveys to the end user the information needed to make decisions on how, when and how much of the product to use. It is therefore essential that end users understand the necessary information on the label sufficiently to motivate them to use the product properly and to take the necessary precautions if required.

Cleaning chemical product labelling must meet the minimum requirements specified in these Guidelines.

2.2.2.6.2.1 Product information content

Cleaning chemical products manufacturers, importers, or distributors must ensure that each container of CCP is labelled, tagged or marked with the following information:

a. Name, address and telephone number of the manufacturer, or responsible party.
b. Product name
c. Manufacturer's name and physical address
d. Manufacturing date and Expiry date
e. Net content (weight/volume)
f. Lot or batch number
g. List of ingredients used
h. Instructions for use
i. Mode of dilution
j. Storage conditions
k. Country of origin

2.2.2.6.2.2 Hazard and safety information

a. Product identifier
b. signal word;
   A signal word means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label and if a hazard is generally more severe or less severe.

   The label should include the relevant signal word in accordance with the classification of the hazardous cleaning chemical product or mixture. In case your CCP displays a more

severe hazard, the label should bear the signal word '**danger**', and in case of less severe hazards, it should bear the signal word '**warning**'

c. hazard statement(s);
d. precautionary statement(s)
e. pictogram(s)

2.2.2.7 Stability data

The applicant shall provide stability data supporting the proposed shelf life for at least 2 batches. The stability studies shall be conducted in the container closure system in which it will be marketed.

2.2.2.7.1 Study design (protocol)

Stability study protocol critically examine the method used to determine the established product shelf life and A summary of the studies undertaken such as batches, analytical procedures.

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

Storage conditions	**Duration**	**Testing interval (Months)**
Long term stability studies at 25°C / ambient Relative Humidity	Shelf life	0, 3,6,9,12,18,24,36,48, 60
Accelerated stability studies at 37°C/ ambient Relative Humidity	6months	0,3,6
Accelerated stability studies at 37°C / 80 % Relative Humidity	6 months	1

Other testing conditions other than the presented in the above table has to be justified by sufficient scientific literature to be acknowledged. The long-term stability studies must be conducted initially on the testing intervals of 0, 3, 6, 9, 12, 18, 24 and 12 months after covering 24 months until the shelf-life of the product is justified. The commitment for ongoing long-term stability studies has to be issued.

2.2.2.7.3 Type of container used

Testing should be conducted using containers and closures system intended for marketing of products

2.2.2.7.4 Parameters to be tested

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 be based on national or other recognised international standard.

2.2.2.7.5 Test results

Results of the stability studies should be presented in an appropriate format, brief discussion of the results and conclusions of the stability studies and analysis of data should be included. Conclusions with respect to storage conditions and shelf-life and, if applicable, in use storage conditions and shelf-life should be given.

2.2.2.8 Material Safety Data Sheets of finished product

Safety Data Sheet for final product. The SDS should contain the necessary information. It is up to the applicant to ensure that the information contained in the material safety data sheet is relevant to the product manufactured and or sold by him as the case may be.

2.2.2.9 Annex

All annexes under this section and other document to support safety and quality of FP should be provided under this heading.

ENDORSEMENT OF THE GUIDELINES

	Author	**Authorized by**	**Approved by**
Title	Division Manager of Cosmetics and Household Chemicals Assessment and Registration	Head of Food & Drugs Assessment and Registration Department	Director General
Names	**Dr MUKIZA Janvier**	**KABATENDE Joseph**	**Dr Emile BIENVENU**
Signature			
Date	**11/03/2022**	**11/03/2022**	**11/03/2022**

ANNEXES

ANNEX I: Cover Letter

Letter header of the applicant

< 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 Cleaning chemical product <Brand Name(s), Common Name (s) and product form(s)

We are pleased to submit our Application Dossier(s) for a registration of cleaning chemical product that details are as follows:

Name of the cleaning chemical product as follow:

Brand name (s): ……

Proprietary (Common Name (s): ……

Name and strength 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 CD room/external driver that contains product information in word format and in PDF

□ 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>

ANNEX II: APPLICATION FORM FOR NEW REGISTRATION OF CLEANING CHEMICAL PRODUCTS

Rwanda Food and Drugs Authority
Nyarutarama Plaza, KG 9 Avenue,
P.O. Box 1948, Kigali, RwandaE-
Email: info@rwandafda.gov.rw
Website: www.rwandafda.gov.rw

Format: DAR /FOM/163
Revision No: 0
Effective Date: 14 Mar. 2022

APPLICATION FORM FOR NEW REGISTRATION OF CLEANING CHEMICAL PRODUCTS

1. ADMINISTRATIVE INFORMATION	
1.1	**Name(s) and complete physical address(es) of the manufacturer(s)** Company name: …… Physical address: …… Postal address: …… Country: …….. Telephone: …….. Telefax: …….. E-mail: ……..
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 agent/ Distributor (if applicable)** Name: ..... Physical Address: .... Postal Address: ..... Country: ..... Phone: ..... Fax: ..... Email: .....
1.4	Marketing Authorisation
	1.4.1 Have you applied for Marketing Authorization of CCPs 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): .....

	1.4.2 Have you applied for Marketing Authorization of CCPs containing the same formulation with different fragrance or perfume (s) in the Rwanda FDA? Yes/No If yes state: ..... Product name (s): ..... strength (s): ..... product form (s): ..... Indication(s): ..... Short description of difference..... ....
	1.4.3 Product Marketing Authorisation in the country of manufacture of the same product. Product name: ..... Authorised Country: ..... Date of authorisation (dd-mm-yyyy): ..... Authorisation number: ..... If not registered/licensed state reasons: ..... Date of refusal (dd-mm-yyyy): ..... Reason for Refusal: .....
	1.4.4 Product Marketing Authorisation in the country of manufacture of the same product. (Withdrawn by applicant after authorisation) Withdrawn Country: ..... Date of withdrawal: (dd-mm-yyyy): .....

	Product name: …… Reason for withdrawal: ……
	1.4.5 Product Marketing Authorisation in the country of manufacture of the same product. (Suspended/revoked by competent authority) Suspended/revoked Country: …… Date of suspension/revocation (dd-mm-yyyy): …… Product name: …… Reason for suspension/revocation: ……..
	2. Product information
2.1	**Proprietary name of the product and Brand name (exactly as shown on label):**
2.2	**Name and strength of active substance(s)**……
2.3	**a. Type of cleaning chemical product** **1. Detergent** ☐ Hand washing detergent products ☐ Dishwasher detergent products ☐ Laundry detergents ☐ All-purpose ☐ Glass cleaners ☐ liquid laundry detergents ☐ car washing ☐ Other(specify)…… **2 Soap** ☐ toilet soaps ☐ laundry soaps ☐ Other(specify)…….. **3. Acid cleaners ☐**

	4. Solvent cleaners/Degreaser ☐ **5. Alkaline cleaners** ☐ **6. Abrasive products** ☐ Powdered (**Scouring powder**) Cleansers ☐Liquid Cleansers, ☐ Other(specify)……..
2.4	**Hazard class (If any):** ☐ **Class Ia** ("DANGER-POISON") ☐ **Class Ib** ("DANGER - POISON") ☐ **Class II** ("WARNING") ☐ **Class III** ("CAUTION")
2.5	Packing type:
2.6	Intended use:
2.7	Pack size:
2.8	Visual description:
2.9	Proposed shelf life:
2.10	Proposed shelf life (dilution if any):
2.11	Proposed shelf life (after first opening container):
1.10	Proposed storage conditions:
1.11	Proposed storage conditions after first opening:
1.12	Other sister products registered or applied for registration
1.13	Distribution category: ☐ Institutional ☐ Industrial ☐ General public. ☐ Other……
1.14	Country of (origin) manufacture:

1.15 Qualitative and Quantitative composition (active substance (s) and excipient(s)

No	Name of ingredient	Quantity/unit (ml, g)/ batch	Reasons of inclusion	Manufacturer and/or Supplier's full address
1				
2				
3				
4				
	etc			

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

3. Type of Formulation

3.1 Solids

☐Powder ☐Wettable Powder ☐Soluble Powder ☐tablet

☐ Pellet ☐Cake ☐ Other (specify)

3.2 Liquids

☐ Emulsifiable Concentrate ☐ Flowable Concentrate

3.3 Other

☐Suspension ☐Gel ☐Aerosol ☐Emulsion ☐ ☐Gaseous

☐Powder: ☐ Paste ☐Others (Specify).....

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

.....

.....

5. Declaration by the Applicant/ Registrant

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

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

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

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

Name: .....

Position in the company: .....

Signature: .....

Official stamp: .....

Date: .....

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

ANNEX III: ARRANGEMENT OF DOCUMENT REQUIRED FOR REGISTRATION OF CCP IN EASY ASSESSMENT FORMAT

The document is subdivided in two main sections and must contains all information necessary for registration of CCP and must be arranged as the following to make the document to be assessed in easy way.

Section 1: Administrative information and product information requirement

Section 2: Technical data requirements

Section 2.1 Raw materials

Section 2.2: Finished product technical data requirements

Note: All sections and subsections of this document must be presented on the CD as directed in the guideline (1.5 g) and if, due to the form of the product, there are information which cannot be completed, NA 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. Also online submission is acceptable.

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 notarised English translation.

c) Application Form and section 2.2 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 1: ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION REQUIREMENT

1.1 Table of contents

1.1.1 Cover letter

1.1.2 Application form

1.1.10 Proof of payment of non-refundable registration application fee

1.1.3 Manufacturing license or Operation license

1.1.4 Contract Manufacturing Agreement

1.1.6 Valid GMP Certificate or other applicable internationally recognised Management System certification. Otherwise, the applicant has to apply for GMP inspection to Rwanda FDA.

1.1.7 Appointment letter supported by the power of attorney of the Local technical representative (LTR) for the foreign product. For local manufacturer, they must specify a qualified person in charge of the CCP safety monitoring and post marketing surveillance.

1.1.8 Product samples

1.1.9 Commitment letters

1.1.10 Product license or approval in other countries

1.1.8.1 Registration status

1.1.8.2 Statement on rejection or withdrawn application

1.1.11 Annex

SECTION 2: TECHNICAL DATA REQUIREMENTS

2.1 RAW MATERIALS

2.1.1 Table of content

2.1.2 Name and address of manufacturer for each Chemical ingredients

2.1.2.1 General information

2.1.2.1.1 Nomenclature

2.1.2.1.2 Address of manufacturer

2.1.3 Supporting document of source of each ingredient

2.1.4 Material Safety Data Sheets (MSDS) for each ingredient

2.1.5 Annex

2.2: FINISHED PRODUCT TECHNICAL DATA REQUIREMENTS

2.2.1 Table of content

2.2.2 Description of the FP and intended use

2.2.2.1 Description of the FP

2.2.2.2 Intended use

2.2.3 Composition of the FP

2.2.4 Manufacturing process

2.2.5 Certificate of Analysis for the FP

2.2.6 Packaging and labelling information

2.2.6.1 Packaging

2.2.6.2 Labelling

2.2.6.2.1 Product information content

2.2.6.2.2 Hazard and safety information

2.2.7 Stability data

2.2.7.1 Study design (protocol)

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

2.2.7.3 Type of container used

2.2.7.4 Parameters to be tested

2.2.7.5 Test results

2.2.8 Material Safety Data Sheets of finished product

2.2.9 Annex

ANNEX IV: REGISTRATION CERTIFICATE TEMPLATE FOR REGISTERED CCP

DAR/FMT/146

RWANDA FDA
Rwanda Food and Drugs Authority

REGISTRATION CERTIFICATE OF CLEANING CHEMICAL PRODUCT

Made under Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning in his article 3 and article 8 and regulation No. CBD/TRG/013. The Authority here issues

Registration number: Rwanda FDA-CCP-MA-.....

This is to certify that the product described below has been registered in Rwanda subject to conditions indicated at the back of this certificate.

Brand Name:

Type of cleaning chemical:

Intended use of the product:

Pack size and Packaging type:

Shelf life in months and Storage statement:

Name of Marketing Authorization Holder:

Name and address of manufacturer:

Name and address of Local Technical Representative:

Issued on: Day Month Year **Expires on:** Day Month Year

Dr. Emile BIENVENU
Director General

Conditions for cleaning chemical product registration

1. This certificate must be returned to the Authority if canceled, invalidated or if the registered cleaning chemical product is withdrawn.

2. Any change in the information submitted for the purpose of registration must be notified to the Rwanda FDA within 30 days of the change.

3. This certificate shall be invalid immediately after the expiry date and the Marketing Authorization Holder shall ensure that application for renewal of registration is made 90 days before expiry of registration.

4. Registered product cannot be advertised without prior approval of the Authority.

5. The cleaning chemical product shall comply with all relevant provisions of Rwanda FDA regulations at all times.

6. The Marketing Authorization Holder shall ensure that the product complies with Rwandan labelling and packaging requirements at all times.

7. The Marketing Authorization Holder shall ensure that the manufacturing facilities where cleaning chemical product is produced comply at all times with Rwanda FDA Good Manufacturing Practice requirements.

8. The Marketing Authorization Holder shall notify Rwanda FDA of the change of a Local Technical Representative at all times.

9. The registration of the cleaning chemical product shall continue to be valid for five (5) years provided that annual retention fee is paid.

10. The Authority reserves the right to withdrawal this certificate when conditions 1 to 7 are contravened and when the risks of using this product outweighs the benefits or it is in public interest to do so