RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF LABORATORY CHEMICALS

NOVEMBER, 2022

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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 and safety of laboratory chemicals in order to protect public health by increasing the access and availability of quality and safe laboratory chemicals.

Considering the provisions of the technical regulations N° CBD/TRG/013 governing the registration of pesticides, laboratory and cleaning chemicals, the Authority has developed the Guidelines N° DFAR/CHCAR/GDL/005 on submission of documentation for registration of laboratory chemicals. These guidelines were developed in reference to a number of stringent regulatory authorities' regulations such as Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency. We also referred to the EU regulations on chemicals, food additives and labelling and classification of substances, and the National Institute of Health striving for Registration, Evaluation, Authorization and Restrictions of chemical substances.

The purpose of these guidelines is to provide the guidance to stakeholders on the documentation requirements and the Authority to assess the conformity of laboratory chemicals for essential principles of quality and safety before issuing the market authorization.

The compliance to these guidelines by the stakeholders will timely facilitate assessments and approval of laboratory chemical substances dossiers by the Authority for marketing authorization and post-marketing review.

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

Dr. Emile BIENVENU
Director General

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ABBREVIATIONS AND ACRONYMS

cGMP	: Current Good Manufacturing Practice
EC	: Economic Commission
EINES/ELINCS	: European Inventory of Existing Chemical Substances /European List of Notified Chemical Substance
EP	: Essential Principles
GMP	: Good Manufacturing Practice
IUPAC	: International Union of Pure and Applied Chemistry
NLP	: No-Longer-Polymer
PRC	: Peer Review Committee
QMS	: Quality Management Systems
REACH	: Registration, Evaluation, Authorization, and Restriction for Chemicals
Rwanda FDA	: Rwanda Food and Drugs Authority

GLOSSARY

For the purpose of these guidelines, the following definitions shall be applied:

1. "**Labelling**" is all labels and other written, printed, or graphic matter (l) upon any article or any of its containers or wrappers.

2. "**Applicant**": It is a person or a company who applies for registration of any kind of laboratory chemical products to Rwanda FDA, which may be the owner of the marketing authorization of the product. He/she may be a manufacturer or person whose order or permission is provided by the laboratory chemical product manufacturer. The applicant shall therefore be responsible for signing application form/cover letter. In the event that the applicant wants another person or company to register the laboratory chemical product on his/her behalf, the power of attorney copy, duly notarized in the country of origin, a local registered company with registrar of companies in Rwanda shall be provided. Once the product is registered, the applicant shall be the Marketing Authorization Holder.

3. "**Authority**" means "Rwanda FDA",

4. "**Batch number** (or lot number)" a distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, etc.

5. "**Distributor**": means any natural or legal person established within Rwanda, EAC, any other place around the world such as EU etc, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties.

6. "**Fee**" means the fee prescribed in Regulation CBD/TRG/004 related to regulatory services and fines.

7. "**Import**": means the physical introduction into the customs territory of Rwanda.

8. **"Importer"**: means any natural or legal person who is responsible for import and permitted by the authority, including a retailer, who only stores, and places on the market the laboratory chemical products, on its own and for third parties.

9. "**intended use/purpose**" The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

10. "**Label**" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to a laboratory chemical substance.

11. **"Laboratory chemical"**: refers to standard chemical reagents or simple chemicals that serve as basic ingredients to synthesize more complex chemicals such as IVD reagents, pesticides,

cleaning chemical products and any ingredient used in formulation of cosmetic product, etc.

12. "**Law**" means Law No 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning.

13. "**Local Technical Representative (LTR)/Agent**" Any applicant who is not resident in Rwanda shall appoint a registered chemical wholesale or retail company or an accredited manufacturer's technical representative in Rwanda to deal with their laboratory chemical 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 notarized in the country of origin.

14. "**manufacture**": means production or extraction of substances in the natural state. Or, all operations that involve preparation, processing, filling, transforming, packaging, repackaging and labelling of laboratory chemicals;

15. "**manufacturer**": means any natural or legal person who manufactures a substance. In other words, a person or a firm that is engaged in the manufacture of laboratory chemicals.

16. "**Packaging material**" means any material, including printed material, used in the packaging of a laboratory chemical substance, excluding any outer packaging used for transportation or shipment.

17. "**Packaging**" means all operations, including filling and labelling, that a laboratory chemical substance has to undergo.

18. "**Radioactive substances**" are substances that contain one or more radionuclides of which the activity or concentration cannot be disregarded as far as radiation protection is concerned. Radioactive substances are covered by specific legislation and therefore exempted from Registration, Evaluation, Authorization and Restriction for Chemicals.

19. "**Reactant**": A substance that is consumed in the course of a chemical reaction.

20. "**Substance**": means a chemical element and its compounds in the natural state or obtained by any manufacturing process.

1.0: INTRODUCTION

1.1 Background

Rwanda Food and Drugs Authority (Rwanda FDA) is 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 the laboratory chemicals in order to improve access to quality and safe laboratory chemicals in Rwanda.

Considering the provisions of the technical regulations ref. Doc.N°: CBD/TRG/013 governing the registration of pesticides, laboratory and cleaning chemicals, the authority has developed these "Guidelines on Submission of Documentation for Registration of Laboratory Chemicals". These guidelines illustrate the procedures and requirements for the implementation of laboratory chemical products registration.

Any laboratory chemical classes on their own, in mixtures or in articles shall not be manufactured or imported or placed on the Rwandan market unless they have been registered in accordance with these guidelines. Unless otherwise, any manufacturer or importer of a laboratory chemical, shall submit an application for registration of the laboratory chemical product to the national regulatory authority.

Adherence to these guidelines by the manufacturers/importers/applicants will timely facilitate assessments and approvals of the concerned laboratory chemical products/substances dossiers by the authority for pre-marketing evaluation, marketing authorization/registration and post-marketing review.

These guidelines contain two main Sections in easy assessment format (E.A.F.):

Section 1: Administrative information and product information requirements;

Section 2: Technical data requirements,

1.2 Scope

These guidelines will assist manufacturers and applicants to acquire the appropriate requirements and guidance to place their respective laboratory chemicals on Rwandan market.

1.3 Objective

The purpose of these guidelines is to ensure a high level of protection of human health including promotion of alternative methods for safety and quality assessment of laboratory chemicals as well as their free circulation on the Rwandan market.

These guidelines will help to ensure that the manufactures, importers and users manufacture, place on market or use such laboratory chemicals that do not adversely affect human health. They

provide guidance on the summary technical documentation to be submitted to the Authority for assessment and registration.

According to the application and exemption, the following chemical substances categories are not part and concerned of these guidelines:

a) Radioactive substances: in relation to basic safety standards for the protection of health of workers and the general public against the dangers arising from ionizing radiation

b) Substances which are subject to customs supervision, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation or in-transit

c) The carriage of dangerous substances and dangerous substances in dangerous mixtures

d) Waste: it is not a substance or mixture

1.4 Responsibility

1.4.1 National Regulatory authority

Rwanda FDA has the sole authority, and responsibility to register all laboratory chemical products manufactured, imported, exported, distributed, advertised, and used on the Rwandan territory. The registration of the laboratory chemical products is the process whereby Rwanda FDA approves the sale and use of laboratory chemical product following the assessment of comprehensive scientific data illustrating that the concerned product is effective for the intended purposes and does not pose any dangerous risk to the health and their environment.

1.4.2 Responsibility of the applicant

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

1.5 Submission of application

An application for laboratory chemical substance registration for either locally manufactured or imported shall be made in writing and supported by an official cover letter (Annex...) and application form (Annex…) duly 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 technical representative shall be a registered chemical wholesale or retail company or an accredited manufacturer's technical representative.

The applicant shall prepare and present the laboratory chemical product dossier information in Easy Assessment Format (EAF) according to the requirements as stipulated in these guidelines:

a) The application should be written in English. Any document in a language other than English must be accompanied by a certified or notarized English or Kinyarwanda translation.

b) A separate and complete application for the laboratory chemical product shall be submitted for each product or product variant.

c) A separate and complete application for registration of the laboratory chemical product shall be submitted for each product with different formulation and ingredients (if applicable), 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 Related to regulatory services tariff/fees and fines. 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 laboratory chemical product dossier for registration via official online electronic address of Rwanda FDA.

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

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

1.6 Categories of certificate for the laboratory chemical products

1.6.1 Full registration

It is registration that has fulfilled all Rwanda FDA registration requirements.

1.6.2 Conditional registration

It is a registration conditioned by Rwanda FDA upon the completion of certain specified data requirements. Once conditions of registration have been met, the conditions are withdrawn and a full registration may be granted.

1.7. Types of Product Registration Applications

For the purposes of submission of laboratory chemical substances dossier to Rwanda FDA, applications are classified into three categories as follows:

1.7.1 New applications for registration

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

a) Duly signed and dated original hard-copy or electronic copy of cover letter.

b) Duly signed and dated and well filled application form

c) Proof of payment of non-refundable registration fee at the time of submission

d) Two CD-ROM or external driver virus free containing all information on quality and safety of the product.

e) Two commercial samples of laboratory chemical product accompanied with its coloured label artwork. However additional samples might be required during the course of the assessment.

1.7.2 Renewal of laboratory chemical product registration

Applications for renewal of a registered laboratory chemical product shall be made at least 3 months before the expiry date of the existing registration.

a) Duly signed and dated original hard-copy or electronic copy of cover letter.

b) Supporting documentation for any variation since the product has been previously registered.

c) Two commercial samples of laboratory chemical product accompanied with its coloured label artwork. However additional samples might be required during the course of the assessment.

d) Proof of payment of non-refundable application fee at the time of submission

1.7.3 Variation of a registered product

An application for any change in the registered laboratory chemical product. All applications for variation to a registered laboratory chemical product shall be made according to requirements as stipulated in the Rwanda FDA Guidelines for Variation of Registered laboratory chemical product.

a) Duly signed and dated original hard-copy or electronic copy of cover letter.

b) Supporting documentations for all made variations.

c) Two commercial samples of laboratory chemical product accompanied with its coloured label artwork. However additional samples might be required during the course of the assessment.

d) Proof of payment of non-refundable application fee at the time of submission

1.7.4 Retention of the laboratory chemical product on the register

The registered laboratory chemical product is annually retained on the register. The application is made by:

a) Duly signed and dated original hard-copy or electronic copy of cover letter.

b) Proof of payment of non-refundable application fee at the time of submission

1.8 Receiving of new applications for product registration

An application consists of online or hard copies submission. The application for registration of laboratory chemical product is only received by the Authority when the proof of payment of prescribed registration fees is attached to the submitted file. After receiving a product registration application, a reference number is assigned to the application and it will be used in all subsequent correspondences relating to the application. An acknowledged receipt will be issued particularly online application submission.

1.9 Rwanda FDA Dossier Assessment Procedures

After receiving the laboratory chemical product application dossier, the Authority shall proceed with a quick checking of any possible discrepancies and be notified within five working days via the email by the division manager or any other assigned staff.

In case of a positive outcome during quick checking, the application dossier will be scheduled for assessment according to the First in First out (FIFO) rules. Priority assessment may be granted where the laboratory chemical product is intended for use of diagnosis of rare disease conditions or emergency diagnostic experiment supported by a concept note.

A product dossier is reviewed by two assessors to provide scientific and regulatory oversight regarding the quality and safety of the laboratory chemical product under assessment.

The Authority reserves the right to request any additional information to establish the quality and safety of laboratory chemical product. During the assessment, additional data and/or samples may be requested through an official communication letter. Once a query has been issued to the

applicant, the assessment process stops until the Authority receives a written response to the raised queries. Further processing of the application may only be undertaken if responses to queries issued in the official communication letter contains all outstanding information requested in one submission. Failure to comply with this condition or if the queries have been reissued for a third time and the applicant provides unsatisfactory responses, the application will be rejected and start the new application.

In the event that the responses to the queries are not submitted within sixty (60) 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 extension of deadline to the Authority.

Thereafter, registration of laboratory chemical product may only be considered upon submission of a new application.

1.10 Authority's Peer Review Committee for laboratory chemical substance Registration

After laboratory chemical product dossier assessment, a final dossier assessment report shall be presented to the Authority's Peer Review Committee (PRC) before making final decisions for granting or rejecting market authorization of the laboratory chemical product.

In the event, that there are safety and quality issues to be resolved as per the decision of the PRC, the application shall remain pending until the resolution of the raised issues. If the applicant fails to provide the required data within sixty calendar days (60), the application shall be considered as withdrawn.

The Authority will register the laboratory chemical product in the event that data on safety and quality are considered satisfactory and a registration certificate of laboratory chemical product will be granted. The registration shall be valid for a period of five (5) years. In the event that the Authority suspends or cancels the registration validity, a written official communication shall be made to the applicant.

1.11 Timelines for laboratory chemical product registration

Laboratory chemical product dossiers shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance of the requirements. A new application shall be processed within six (6) months of receipt of the application. The applicant will be required to provide any requested additional data within sixty (60) calendar days. Additional data or query responses shall be processed within thirty (30) calendar days.

2.0: PROCESS AND REQUIREMENTS FOR PRODUCT REGISTRATION

The document is subdivided in two main sections and must contains all information necessary for registration of laboratory chemicals.

2.1. Arrangement of required documentation for easy assessment format

The registration application dossiers must be arranged as the following to make the document to be effectively assessed.

Section 1: Administrative information and product information requirements

Section 2: Technical data requirements

Note: All sections and subsections of this document must be presented on the CD as directed in the guideline. Due to the form of the product, there are information which cannot be completed, and the "**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 completed 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 section 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/registrant shall prepare and present the product dossier information in the following format.

2.1.1 Administrative information and product information requirement

2.1.1.1 Table of contents

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

2.1.1.2 Cover letter

The applicant should include an official cover letter for each laboratory chemical product dossier. A copy of the letter should be placed at the forefront of Administrative Data. The cover letter template is availed in the annexes to the guidelines for registration of laboratory chemical products. For product registration, it shall be dated and signed as stipulated in these guidelines.

2.1.1.3 Application form

An application to register a laboratory chemical product must be accompanied by a completed product application form downloadable from Rwanda FDA website. The application form should

be duly filled with relevant information and attachments, dated, signed, and stamped by the applicant/appointed LTR.

2.1.1.4. Proof of payment of non-refundable registration application fee

A scanned original copy of the proof of appropriate payment must appear on the CD-ROM or any other used external driver containing laboratory chemical product dossier.

2.1.1.5 Manufacturing license or Operation license

The applicant should also submit a valid certificate of laboratory chemical product manufacturing license granted by the competent authorities in the country of manufacturing.

2.1.1.6 Contract Manufacturing Agreement (if Applicable)

Once a laboratory chemical product is manufactured under the manufacturing contract, evidence of the updated contract shall be produced in the submitted documentation. And this shall be clearly stated on the product label/artwork.

2.1.1.7 Valid GMP Certificate

For all local and foreign laboratory chemical product, all key manufacturing and/or processing steps in the production of the finished chemical product must be performed in plants that comply with Rwanda FDA good manufacturing practice guidelines. Therefore, to the submission, a valid GMP certificate provided by Rwanda FDA must be enclosed in the application dossier. Otherwise, the applicant has to apply for GMP inspection to Rwanda FDA referring to Rwanda FDA regulation.

2.1.1.8 Local technical representative names and address supported by the appointment letter and power of attorney.

Any applicant who is not resident in Rwanda shall appoint a registered chemical wholesale or retail company or an accredited manufacturer's technical representative in Rwanda to deal with their laboratory chemical 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 notarized in country of origin. According to the local laboratory chemical product manufacturers, they must specify the detailed information of the qualified person in charge of the laboratory chemical product safety monitoring as well as post-marketing surveillance.

2.1.1.9 Two Commercial samples

Two commercial samples of laboratory chemical product accompanied with its coloured label artwork must be submitted with the application. However additional samples might be required during the course of the assessment where applicable.

2.1.1.10 Commitment letters (if applicable)

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

2.1.1.11 Market Authorization or Registration Certificate/ status in other countries (If applicable)

2.1.1.12 Statement on rejection or withdrawal application where applicable.

2.2 Technical data requirements

2.2.1 Identification of the laboratory chemicals/substances

2.2.1.1 Table of content

2.2.1.2 Name or other identifier of each substance

a) Name(s) in the IUPAC nomenclature or other international chemical name(s)

b) Other names (Usual name, trade name, abbreviation)

c) CAS number

d) EC number (if applicable)

e) Other identity code (if available)

2.2.1.3. Information related to molecular and structural formula of each substance:

a) Molecular structure
b) Molecular weight
c) Information on optical activity and typical ratio of stereo- isomers (if applicable and appropriate)

2.2.1.4 Composition of each substance

a) Degree of purity

b) Nature of impurity (%), including isomers and by-products (if applicable)

c) Percentage of (significant) main impurities

d) Spectral data (ultra-violet: if applicable, infra-red, nuclear magnetic resonance, or mass spectrum: if applicable)

e) HPL chromatograph, Gas chromatogram (volatile compound): if applicable

f) Description of the analytical methods for the identification of impurities and determination of purity. This information shall be sufficient to allow the reproducibility of the used analytical methods.

2.2.2 Information on manufacture and use (s) of the laboratory chemical/substance(s)

2.2.2.1 Flow chart and narrative description of the manufacturing process including raw material quantities, used in manufacture or production of chemical substance.

2.2.2.2. Physical properties (Form, colour, physical state, odour, density, etc).

2.2.2.3 Intended use (s)

2.2.3.1 The hazard classification of the substance (s

Note: For each entry, the reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification

2.2.3 Labelling

2.2.3.1 Product information content

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

a) Name, address of the manufacturer, or responsible party.

b) Product name

c) Manufacturing date and Expiry date

d) Net content (weight/volume)

e) Purity/concentration

f) Density (if applicable)

g) Lot or batch number

h) List of ingredients used

i) Instructions for use

j) Storage conditions

k) Country of origin

2.2.3.2 Hazard and safety information

a) Product identifier

b) Signal word and hazard symbol;

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 chemical product or mixture. In case your laboratory chemical PRODUCT 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) GHS pictogram(s)

2.2.4 Safety data sheet(SDS)

The applicant of registration of laboratory chemical substances shall submit to the national regulatory authority a safety data sheet compiled according to the Global harmonization system.
The SDS to be submitted should contain the detailed information as required by Global harmonization system for hazard communication standard. Specifically, the SDS containing the following sections is recommended:

Section 1. Product Identification: Brand name and chemical name

Section 2. Hazards identification and analysis

Section 3. Composition and information on ingredients

Section 4. First Aid Measure

Section 5. Firefighting measures

Section 6. Accidental release measures

Section 7. Handling and storage

Section 8. Exposure control/Personal protection

Section 9. Physical and chemical properties

Section 10. Stability and reactivity

Section 11. Toxicological information

Section 12. Ecological information

Section 13. Disposal information

Section 14. Transport information

Section 15. Regulatory information

Section 16. Other information

2.2.5 Certificate of analysis

The duly signed and dated certificate of analysis bearing its unique identification number, batch number, date of manufacturing and expiry date, tested parameters, specifications, methods and test results should be submitted.

ENDORSEMENT OF THE GUIDELINES

	Author	Checked by		Approved by
Title	**Division manager**	**Head of Department**	**Quality Assurance Analyst**	**Director General**
Names	Dr. Janvier MUKIZA	Dr. Védaste HABYALIMANA	Mr. Théogène NDAYAMBAJE	Prof. Emile BIENVENU
Signature				
Date	24/11/2022	24/11/2022	29/11/2022	23/11/2022

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ANNEXES

ANNEX I: COVER LETTER

Letter header of the applicant/manufacturer/LTR

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

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

Dear Sir/Madam,

Subject: Submission of application for registration of laboratory 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 laboratory chemical product that details are as follows:

Name of the laboratory chemical product as follow:

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

You will find enclosed the submission dossier as specified hereafter:

☐ The relevant fees for this application have been paid.
☐ Two 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 LABORATORY CHEMICAL PRODUCTS

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20/06/2022	Department/Division/ Office/ Unit	**Cosmetics and Household Chemicals Assessment and Registration Division**
Document Type: **Form, Checklist**		Doc. No : DFAR/CHCAR/FOM/005
RWANDA FDA	Title:	Revision Number: 0
		Revision Date: : …/…/2022
		Effective Date : …/…/2022
		Review Due Date: …/…/2022
		Ref Doc. : DFAR/CHCAR/GDL/005

APPLICATION FORM FOR NEW REGISTRATION OF LABORATORY 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	**Is the applicant/registrant different from the manufacturer? Yes ☐ No ☐** **Note**: if **No**, the information **1.2** is **NOT** mandatory **Particulars of Applicant/ Registrant** Name: …… Physical Address: …… Postal Address: …… Country: …… Phone: …….. Fax: …… Email: …… Status of applicant (tick where appropriate): Manufacturer: 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 laboratory chemical product containing the same chemical substance (s) in the Rwanda FDA? **Yes ☐ No ☐** If **Yes** state: ..... Product name (s): ..... **CAS** number..... **EC** number: ..... **Other reference number** (EINES, ELINCS/ NLP): ..... Strength/percentage purity: ..... product form (s): ..... Use(s): .....
	1.4.2 Have you applied for Marketing Authorization of laboratory chemical product containing the same formulation with different excipients/composition/mixture (s) in the Rwanda FDA? Yes ☐ No ☐ If **Yes** state: ..... Product name (s): ..... **CAS** number..... **EC** number: ..... **Other reference number** (EINES, ELINCS/ NLP): ..... Strength/percentage purity: ..... product form (s): ..... Use(s): ..... Short description of difference..... ....
	1.4.3 Product Marketing Authorisation in the country of manufacture of the same laboratory chemical product. Product name: ..... **CAS** number..... **EC** number: ..... **Other reference number** (EINES, ELINCS/ NLP): ..... 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 laboratory chemical product. (Withdrawn by applicant after authorisation) Withdrawn Country: ..... Date of withdrawal: (dd-mm-yyyy): ..... Product name: ..... **CAS** number..... **EC** number: ..... **Other reference number** (EINES, ELINCS/ NLP): ..... Reason for withdrawal: .....
	1.4.5 Product Marketing Authorisation in the country of manufacture of the same laboratory chemical product. (Suspended/revoked/banned by competent authority) Suspended/revoked/banned Country: ..... Date of suspension/revocation/ban (dd-mm-yyyy): ..... Product name: ..... **CAS** number..... **EC** number: ..... **Other reference number** (EINES, ELINCS/ NLP): ..... Reason for suspension/revocation/ban: .....
	2. Product information
2.1	**Proprietary name of the product and Brand name (exactly as shown on label):** .....
2.2	**Name and strength/purity of chemical substance(s)**..... **CAS** number..... **EC** number: ..... **Other reference number** (EINES, ELINCS/ NLP): .....
2.3	**a. Class of laboratory chemical product**

Hazard Class and category	**Specify**
Acute toxicity, category 1,2, and 3	
Acute toxicity, category 4	
Skin corrosion/irritation, category 1, sub-categories: 1A, 1B, 1C and Category 2	
category 1: Sub-category: 1A…., 1B…..., 1C….	
Category 2	
Serious damage to eyes/eye irritation, category 1 and 2	
Category 1	
Category 2	
Respiratory/skin sensitization	
Germ cell mutagenicity category 1A and	

	1B		
	category 1A		
	category 1B		
	Germ cell mutagenicity category 2		
	Carcinogenicity category 1A, 1B and 2		
	category 1A		
	category 1B		
	category 2		
	Reproductive toxicity, category 1A, 1B, 2 and effects on or via lactation		
	category 1A		
	category 1B		
	category 2		
	Specific target organ toxicity (STOT)-Single exposure, category 1 and 2		
	category 1		
	category 2		
	Specific target organ toxicity (STOT)-Repeated exposure, category 1 and 2		
	category 1		
	category 2		
	Aspiration Hazard		
	Hazardous to the aquatic environment-Acute, category 1		
	Hazardous to the aquatic environment-Chronic, category 1		
	Hazardous to the aquatic environment-Chronic, category 1, 2,3 and 4		
	category 1		
	category 2		
	category 3		
	category 4		
	Hazardous for the ozone layer		
2.4	Packing type:		
2.5	Intended use:		
2.6	Pack size:		
2.7	Visual description:		
2.8	Proposed shelf life:		
2.9	Proposed shelf life (dilution if any):		
2.10	Proposed shelf life (after first opening container):		
1.11	Proposed storage conditions:		
1.12	Proposed storage conditions after first opening:		
1.13	Other sister products registered or applied for registration		

1.14	Distribution category: ☐ Institutional ☐ Industrial ☐ General public. ☐ Other.....
1.15	Country of (origin) manufacture:

1.16 Qualitative and Quantitative composition (chemical 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			

1.17 Submitted Spectral data (if applicable):

Ultra-violet: **Yes** ☐ **No** ☐

Infra-red: **Yes** ☐ **No** ☐

Nuclear magnetic resonance: **Yes** ☐ **No** ☐

Mass spectrum: **Yes** ☐ **No** ☐

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 SAFETY DATA SHEET (SDS) TEMPLATE

SDS must be generated in accordance with Globally Harmonized System (GHS) compliant requirements before shipping or transporting the chemical away from the supplier. Use the SDS template to make a GHS compliant SDS.

The SDS includes information such as the properties of each chemical; the physical, health, and environmental hazards; protective measures; and safety precautions for handling, storing, and transporting the chemical. The person preparing the SDS must ensure the information accurately reflects the scientific evidence used in making the hazard determination.

For solutions or mixtures of chemicals it is best practice to list 100% of the ingredients, regardless if they are hazardous or not.

Bellow SDS template is based but not limited on the Washington State Department of Labor & Industries hazard communication standard WAC 296-901-14028 Appendix D-Safety data sheets. If no relevant information is found for any given item within a section, the SDS must clearly indicate that no applicable information is available

When SDS is completed delete the instructions in **red italics**

In addition to the SDS, chemical containers must be labeled according to WAC 296-901-14026 Appendix C-Allocation of label elements.

SAFETY DATA SHEET

Section 1: Identification

(a) Product identifier used on the label
(b) Other means of identification
(c) Recommended use of the chemical and restrictions on use
(d) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible part y
(e) Emergency phone number

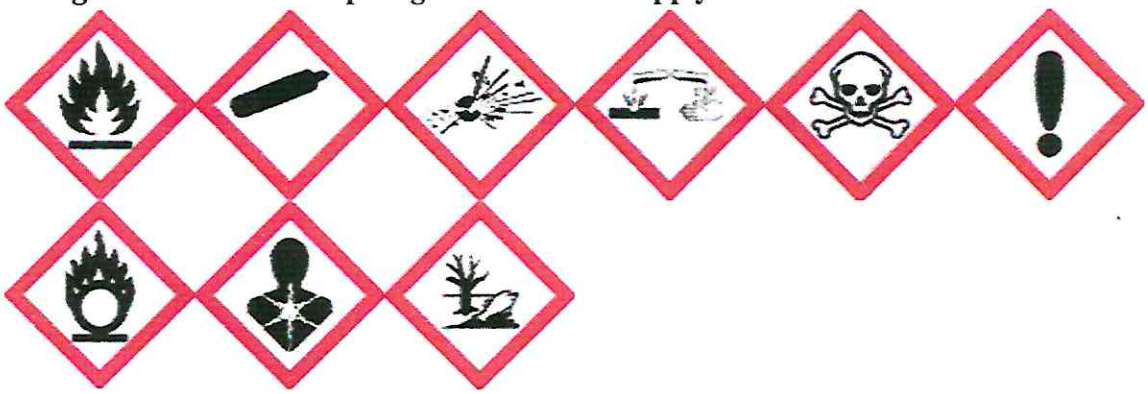
Product Name:
Chemical Name/Synonyms:
Company:

In emergency call: .....
For information about this SDS, use this contact phone#:

Section 2: Hazard(s) Identification

(a) Classification of the chemical in accordance with WAC 296-901-14008
(b) Signal word(s), hazard statement(s); symbol(s) and precautionary statement(s) in accordance with WAC 296901-14012. (Hazard symbols may be provided as graphical reprod uctions in black and white or the name of the symbol, e.g., flame, skull and crossbones)
(c) Describe any hazards not otherwise classified that have been identified during the classification process
(d) Where an ingredient with unknown acute toxicity is *used in a mixture at a concentration ≥ 1%* and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required

Hazard Classification:
Signal Word(s):
Hazard Statements:
Pictograms: **Delete pictograms that don't apply!**



Precautionary Statements:
Description of other hazards:

Section 3: Composition/ Information on Ingredients

For Substances

(a) Chemical name

(b) Common name and synonyms

(c) CAS number and other unique identifiers

(d) Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance

For Mixtures

In addition to the information required for substances:

(a) The chemical name and concentration (exact percentage) of all ingredients which are classified as health hazards in accordance with WA C 296-901-14008 and

(1) are present above their cut -off/concentration limits; or

(2) present a health risk below the cut-off/concentration limits.

(b) The concentration (exact percentage) must be specified.

Chemical Name	Synonym	CAS#	Conc.

Section 4: First-Aid Measures

(a) Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion

(b) Most important symptoms/effects, acute and delayed

(c) Indication of immediate medical attention and special treatment needed, if necessary

After skin contact:

After eye contact:

After inhalation:

After swallowing:

Section 5: Fire-Fighting Measures

(a) Suitable (and unsuitable) extinguishing media

(b) Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products)

(c) Special protective equipment and precautions for fire-fighters

Suitable extinguishing agents:

Special protective equipment for firefighters:

Section 6: Accidental Release Measures

(a) Personal precautions, protective equipment, and emergency procedures
(b) Methods and materials for containment and cleaning up

Personal precautions:
Measures for environmental protection:
Measures for cleaning/collecting:

Section 7: Handling and Storage

(a) Precautions for safe handling
(b) Conditions for safe storage, including any incompatibilities

Handling:
Storage:

Section 8: Exposure Controls/Personal Protection

(a) DOSH permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available
(b) Appropriate engineering controls
(c) Individual protection measures, such as personal protective equipment

Chemical Name	OSHA PEL	OSHA PEL (ceiling)	ACGIH OEL (TWA)	ACGIH OEL (STEL)

General protective and hygienic measures:
Breathing equipment:
Protection of hands:
Eye protection:

Section 9: Physical and Chemical Properties

(a) Appearance (physical state, color, etc.)
(b) Odor
(c) Odor threshold
(d) pH
(e) Melting point/freezing point
(f) Initial boiling point and boiling range
(g) Flash point
(h) Evaporation rate
(i) Flammability (solid, gas)
(j) Upper/lower flammability or explosive limits

(k) Vapor pressure
(l) Vapor density
(m) Relative density
(n) Solubility(ies)
(o) Partition coefficient: n-octanol/water
(p) Auto-ignition temperature
(q) Decomposition temperature
(r) Viscosity

Form:
Odor:
Odor threshold:
pH:
Melting point/melting range:
Boiling point/boiling range:
Flash point:
Evaporation rate:
Flammability:
Upper/lower flammability or explosive limits:
Auto ignition temperature:
Danger of explosion:
Vapor pressure:
Vapor density:
Relative density:
Solubility in/Miscibility with water:

Section 10: Stability and Reactivity

(a) Reactivity
(b) Chemical stability
(c) Possibility of hazardous reactions
(d) Conditions to avoid (e.g., static discharge, shock, or vibration)
(e) Incompatible materials
(f) Hazardous decomposition products

Reactivity:
Chemical stability:
Conditions to avoid:
Incompatible materials:
Hazardous decomposition products:

Section 11: Toxicological Information

Description of the various toxicological (health) effects and the available data used to identify those effects, including:
(a) Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact)

(b) Symptoms related to the physical, chemical and toxicological Characteristics
(c) Delayed and immediate effects and also chronic effects from short and long-term exposure
(d) Numerical measures of toxicity (such as acute toxicity estimates)
(e) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agen cy for Research on Cancer (IARC) Monographs (latest edition), or by DOSH

Acute toxicity:
Potential routes of exposure/potential health effects
Skin:
Eye:
Inhalation:
Ingestion:
Carcinogenic effects:
Mutagenic effects:
Reproductive toxicity:
Sensitization:
Target organs:

Section 12: Ecological Information (non-mandatory)

(a) Ecotoxicity (aquatic and terrestrial, where available)
(b) Persistence and degradability
(c) Bioaccumulative potential
(d) Mobility in soil
(e) Other adverse effects (such as hazardous to the ozone layer)

Ecotoxicity:
Mobility:
Biodegradation:
Bioaccumulation:

Section 13: Disposal Considerations (non-mandatory)

Description of waste residues and information on their safe handl ing and methods of disposal, including the disposal of any contaminated packaging

Section 14: Transport Information (non-mandatory)

(a) UN number
(b) UN proper shipping name

(c) Transport hazard class(es)
(d) Packing group, if applicable
(e) Environmental hazards (e.g., Marine pollutant (Yes/No));
(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)
(g) Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises

DOT regulations:

- **Hazard class:**
- **Land transport ADR/RID (cross-border):**
- **ADR/RID class:**
- **Maritime transport IMDG:**

Air transport ICAO-TI and IATA-DGR:

- **ICAO/IATA Class:**

Section 15: Regulatory Information (non-mandatory)

Safety, health and environmental regulations specific for the product in question

US Federal Regulations
SARA Section 355 (extremely hazardous substances):
SARA Section 313 (specific toxic chemical listings):
Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs):
TSCA (Toxic Substances Control Act):
Etc.

Section 16: Other Information

The date of preparation of the SDS or the last change to it

SDS date of preparation/update: