

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	<p>Name(s) and complete physical address(es) of the manufacturer(s)</p> <p>Company name:</p> <p>Physical address:</p> <p>Postal address:</p> <p>Country:</p> <p>Telephone:</p> <p>Telefax:</p> <p>E-mail:</p>
1.2	<p>Particulars of Applicant/ Registrant</p> <p>Name:</p> <p>Physical Address:</p> <p>Postal Address:</p> <p>Country:</p>

Doc. No.: DAR/GDL/068	Revision Date: 13/01/2022	Review Due Date: 14/03/2025
Revision No.: 0	Effective Date: 14/03/2022	

	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):

Rwanda Food and Drugs Authority

Doc. No.: DAR/GDL/068	Revision Date: 13/01/2022	Review Due Date: 14/03/2025
Revision No.: 0	Effective Date: 14/03/2022	

	<p>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</p> <p>If yes state:</p> <p>Product name (s):</p> <p>strength (s):</p> <p>product form (s):</p> <p>Indication(s):</p> <p>Short description of difference.....</p> <p>.....</p> <p>.....</p>
	<p>1.4.3 Product Marketing Authorisation in the country of manufacture of the same product.</p> <p>Product name:</p> <p>Authorised Country:</p> <p>Date of authorisation (dd-mm-yyyy):</p> <p>Authorisation number:</p> <p>If not registered/licensed state reasons:</p> <p>Date of refusal (dd-mm-yyyy):</p> <p>Reason for Refusal:</p>
	<p>1.4.4 Product Marketing Authorisation in the country of manufacture of the same product. (Withdrawn by applicant after authorisation)</p> <p>Withdrawn Country:</p> <p>Date of withdrawal: (dd-mm-yyyy):</p>

Doc. No.: DAR/GDL/068	Revision Date: 13/01/2022	Review Due Date: 14/03/2025
Revision No.: 0	Effective Date: 14/03/2022	



	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 <input type="checkbox"/> Hand washing detergent products <input type="checkbox"/> Dishwasher detergent products <input type="checkbox"/> Laundry detergents <input type="checkbox"/> All-purpose <input type="checkbox"/> Glass cleaners <input type="checkbox"/> liquid laundry detergents <input type="checkbox"/> car washing <input type="checkbox"/> Other(specify)..... 2 Soap <input type="checkbox"/> toilet soaps <input type="checkbox"/> laundry soaps <input type="checkbox"/> Other(specify)..... 3. Acid cleaners <input type="checkbox"/>

Doc. No.: DAR/GDL/068	Revision Date: 13/01/2022	Review Due Date: 14/03/2025
Revision No.: 0	Effective Date: 14/03/2022	



	<p>4. Solvent cleaners/Degreaser <input type="checkbox"/></p> <p>5. Alkaline cleaners <input type="checkbox"/></p> <p>6. Abrasive products</p> <p><input type="checkbox"/> Powdered (Scouring powder) Cleansers <input type="checkbox"/> Liquid Cleansers,</p> <p><input type="checkbox"/> Other(specify).....</p>
2.4	<p>Hazard class (If any):</p> <p><input type="checkbox"/> Class Ia ("DANGER-POISON") <input type="checkbox"/> Class Ib ("DANGER - POISON")</p> <p><input type="checkbox"/> Class II ("WARNING") <input type="checkbox"/> Class III ("CAUTION")</p>
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	<p>Distribution category: <input type="checkbox"/> Institutional <input type="checkbox"/> Industrial <input type="checkbox"/> General public.</p> <p><input type="checkbox"/> Other.....</p>
1.14	Country of (origin) manufacture:

Doc. No.: DAR/GDL/068	Revision Date: 13/01/2022	Review Due Date: 14/03/2025
Revision No.: 0	Effective Date: 14/03/2022	

Cary

JM *AP*

1.15 Qualitative and Quantitative composition (active substance (s) and excipient(s))					
No	Name of ingredient	Quantity/unit (ml, g)/ batch	Reasons of inclusion	of	Manufacturer and/or Supplier's full address
1					
2					
3					
4					
	etc				
<p>Note If the formula is considered to be confidential seal in an envelope and mark confidential and then attach.</p>					
<p>3. Type of Formulation</p> <p>3.1 Solids</p> <p><input type="checkbox"/> Powder <input type="checkbox"/> Wettable Powder <input type="checkbox"/> Soluble Powder <input type="checkbox"/> tablet</p> <p><input type="checkbox"/> Pellet <input type="checkbox"/> Cake <input type="checkbox"/> Other (specify)</p> <p>3.2 Liquids</p> <p><input type="checkbox"/> Emulsifiable Concentrate <input type="checkbox"/> Flowable Concentrate</p> <p>3.3 Other</p> <p><input type="checkbox"/> Suspension <input type="checkbox"/> Gel <input type="checkbox"/> Aerosol <input type="checkbox"/> Emulsion <input type="checkbox"/> Gaseous</p> <p><input type="checkbox"/> Powder: <input type="checkbox"/> Paste <input type="checkbox"/> Others (Specify).....</p>					
<p>4. LABELLING</p> <p>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.</p> <p>.....</p> <p>.....</p>					

Doc. No.: DAR/GDL/068	Revision Date: 13/01/2022	Review Due Date: 14/03/2025
Revision No.: 0	Effective Date: 14/03/2022	

Car

JM

AP

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



Doc. No.: DAR/GDL/068	Revision Date: 13/01/2022	Review Due Date: 14/03/2025
Revision No.: 0	Effective Date: 14/03/2022	

Car

JM P