



Application Form for New Registration of Cosmetics

1. ADMINISTRATIVE INFORMATION

1.1. Name(s) and complete physical address(es) of the manufacturer(s):

Company name:
 Physical address:
 Postal address:
 Country:
 Telephone:
 Fax:
 Email:

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 Technical Representative/Distributor (if applicable)

Physical Address:
 Postal Address:
 Country:
 Phone:
 Fax:
 Email:

2. PRODUCT DETAILS

2.1	Brand name of the product	
2.2	Proprietary name of the product/Generic name	
2.3	Name and strength of active ingredient (s)	
2.4	Form of the product: (Powder, Liquid, Gel, Cream, Lotion, Spray, Aerosol, Gaseous, Emulsion, Cream, ointment, Solution, ...)	

2.5	Intended use	Anti-Acnes Anti-Wrinkles, Anti-Eczema Sensitive Skin, Skin repair, Anti-pimple, Anti-Aging Mattifying, Skin lightening, Spot Corrector, Spot removals, Sunscreens, Anti-irritant, Anti-inflammatory, Hair conditioners, Hair Dye, Anti-itching, Anti-redness, Exfoliators, Moisturizer, Anti-crack, toothpastes, Mouth wash, anti-dandruff, antiperspirants, Hair growth, hair removal, hair relaxer, Hair Waiving, Hair Dyes, Hair Conditioner, Hair Removal, Antidandruff, Hair strengthener, Pain Relief, Aromatherapy oil, Hair Inhibitor, Scars Removal Other (Specify).....
2.6	Area of application of cosmetic (Oral cavity, hair system, Face, Body, External genital, nails, eyes. ...)	
2.7	Contraindication (where applicable)	

2.8	Do you hold Marketing Authorization (s) of this product from other regulatory authorities? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes state; Market Authorization Number: Market Authorization issuance date: Name of Regulatory Authority issued the Market Authorization: Country:																						
2.9	Application method																						
2.10	Physical description																						
2.11	Packing Material/pack size:																						
2.12	Description of container closure																						
2.13	Proposed shelf life (in months):																						
2.14	Proposed shelf life after reconstitution or dilution (if applicable)																						
2.15	Proposed shelf life (after first opening container):																						
2.16	Proposed storage conditions:																						
2.17	Proposed storage conditions after first opening (where applicable):																						
2.18	LABELLING 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.																						
2.19	List the qualitative and quantitative composition per unit pack (Please, add or delete as many rows and columns as needed. <table border="1" data-bbox="261 1535 1414 1864"> <thead> <tr> <th data-bbox="261 1535 550 1589">Name of ingredients</th> <th data-bbox="550 1535 1019 1589">Chemical Abstract service number</th> <th data-bbox="1019 1535 1187 1589">Purpose</th> <th data-bbox="1187 1535 1414 1589">Amount (%)</th> </tr> </thead> <tbody> <tr> <td data-bbox="261 1589 550 1654"></td> <td data-bbox="550 1589 1019 1654"></td> <td data-bbox="1019 1589 1187 1654"></td> <td data-bbox="1187 1589 1414 1654"></td> </tr> <tr> <td data-bbox="261 1654 550 1722"></td> <td data-bbox="550 1654 1019 1722"></td> <td data-bbox="1019 1654 1187 1722"></td> <td data-bbox="1187 1654 1414 1722"></td> </tr> <tr> <td data-bbox="261 1722 550 1789"></td> <td data-bbox="550 1722 1019 1789"></td> <td data-bbox="1019 1722 1187 1789"></td> <td data-bbox="1187 1722 1414 1789"></td> </tr> <tr> <td data-bbox="261 1789 550 1864"></td> <td data-bbox="550 1789 1019 1864"></td> <td data-bbox="1019 1789 1187 1864"></td> <td data-bbox="1187 1789 1414 1864"></td> </tr> </tbody> </table>			Name of ingredients	Chemical Abstract service number	Purpose	Amount (%)																
Name of ingredients	Chemical Abstract service number	Purpose	Amount (%)																				

3. Details on administrative & Technical documents submitted with the application	
Technical documents	Annex, Page number, etc.
Quantitative and qualitative composition of the formulation (Introduction of active ingredients and their functions)	
Manufacturing Process	
Certificate of analysis	
Product specifications and test methods	
Toxicity data	
Antimicrobial efficacy data	

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 Food and Drugs Authority.

It is hereby confirmed that fees have been paid according to the Rwanda Food and Drugs Authority fees and regulations.

I understand that if any information given here above is found false or incorrect, I will be liable for appropriate action under the provisions of the Rwanda Food and Drugs Authority regulations.

Name:

Position in the company:

Signature:

Official stamp:

Date: