



**APPLICATION FORM FOR THE REGISTRATION OF A
HOUSEHOLD CHEMICAL SUBSTANCE**

**APPLICANTS
CHECKLIST**

**FDB DOUBLE
CHECKLIST**

Signed Declaration

Covering Letter

Certificate of Analysis of Finished products

Real/ Accelerated Stability Data

Manufacturing License

Free Sale Certificate

Documents relating to Appendix IV

**APPLICATION FORM FOR THE REGISTRATION OF A
HOUSEHOLD CHEMICAL SUBSTANCE**

(To be submitted in duplicate)

ADDRESSED TO: **THE CHIEF EXECUTIVE
FOOD AND DRUGS BOARD
P. O. BOX CT 2783
CANTONMENTS – ACCRA
GHANA**

Samples and printed matter to be forwarded by post or by other means and carriages; customs duty and clearance to be effected by the applicant in all instances.

Proprietary Name (if any).....

Dosage Form.....Strength.....Colour.....

Commercial Presentation(s).....Country of Origin.....

Name of Applicant:.....

Business Address:.....

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Phone:.....Fax.....

E. mail.....

Name and Address of Manufacturer.....

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Business Address:.....

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Phone:.....Fax.....

E.mail.....

Name and Address of Local Agent:.....

Phone.....Fax.....

E.mail.....

Application Fee

Date.....

Declaration

I/We the undersigned, hereby declare that all information contained herein and in the appendices is correct and true.

Date:.....

Name:.....

Position:.....

Signature:.....

Official Stamp:.....

APPENDIX 1

General Product Specifications

Name of Chemical:.....

Name of Applicant:.....

Application Number:.....

Dosage Form.....Strength.....Size.....Colour.....

The following is a table of the: adopt formula for cosmetics application form

- a. Active ingredients, giving their approved names, chemical names, specification and quantity in a dosage unit of the household chemical:
- b. Other ingredients giving specifications and quantity and reasons for inclusion e.g. preservative, fragrance, antioxidant, etc.

Approved Name	Chemical Name	Quantity Per Dosage Unit	Active or Non-Active	Specification	Reason for Inclusion of Ingredient

Specifications of additional raw materials (if any) used in the manufacturing process and not in the final product.....

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Page 4 of 12 pages

Specifications of packaging materials

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Where no specifications for raw materials and packaging materials exist, this must be mentioned

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Does product contain a skin lightening cream Yes

No

If Yes, provide details

NOTE:

1. The Chemical name must, where possible, be given in terms of the published list of an appropriate international body
2. Reference to the following publications will, where applicable, be accepted.
 - a. British Pharmacopoeia
 - b. European Pharmacopoeia
 - c. Pharmacopoeia of the United States of America
 - d. British Pharmaceutical Codex
 - e. International Pharmacopoeia
 - f. Extra Pharmacopoeia
 - g. Such other works of reference as may be approved by the Board

APPENDIX II

Manufacturing Procedures and Related Controls

Name of Chemical:.....

Name of Applicant:.....

Dosage Form:.....Strength:.....Size:.....Colour:.....

a. Give a brief summary of the manufacturing procedure.....
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b. Name and address of the manufacturer and certificate(s) of analysis of the raw materials used.....
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c. Certificates of Quality Control Tests performed on the raw materials
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d. Attach a final analytical report and authorization for release and any other appropriate records.....

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e. Proposed shelf-life of chemical

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f. Stability data and justification on which shelf life has been predicted

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Attach names, address, qualification of authorized person(s) in charge of product and the person(s) in charge of quality control, packaging and release of product

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APPENDIX III

Administrative Status of the Product

Name of Chemical:.....

Name of Applicant:.....

Dosage Form:.....Strength:.....Size:.....Colour:.....

- 1a. Has the household chemical substance been registered in the country of origin?
YES NO

IF YES a valid certificate of registration in respect of such a chemical issued by the appropriate authority established for the registration of chemical substances in the country must accompany this application.

If NO, state the reason(s)

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- b. Has an application for the registration of the household chemical substance been made in any other country? YES/NO.

If YES, list countries and attach copies of certificates:

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- c. Has the registration of the household chemical substance been rejected, refused, deferred or cancelled in any country? YES NO

If YES, state details

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2. Is the household chemical substance manufactured in other countries? YES/NO

If YES, state details and list manufacturing plants from which imports can be made to Ghana

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3. Attach text of labels and other written material which would be made available with the products in accordance with Appendices IV and V

4. How do you envisage distributing the household chemical substance?

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APPENDIX IV

Toxicological Information

Name of Chemical Substance:.....

Name of Applicant:.....

Dosage Form:.....Strength:.....Size:.....Colour:.....

1. List documents attached on any toxicological trials undertaken

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2. List documents attached on any adverse effects of the substance on humans or animals

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3. State details of residue of the substance in plant and animal species intended for human consumption (if applicable)

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4. Provide information on antidotes and management in cases of accidental poisoning

APPENDIX V

List of Attached Documents and Materials

Name of Household Chemical Substance:.....

Name of Applicant:.....

Dosage Form:.....Strength.....Size.....Colour.....

- a. Attach four (4) copies of labels, package inserts and packaging materials proposed for marketing in Ghana

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The text of labels and written material shall conform to labelling regulations in force in Ghana (Refer to Food and Drugs Board Guidelines on Labelling of Products).