

**FOOD AND DRUGS AUTHORITY**

**APPLICATION FORM FOR THE REGISTRATION OF**

**HOUSEHOLD CHEMICAL SUSBTANCE**

**Document No.:** FDA/MCH/CHC/AP-RHC/2016/02

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**Version No.:** HC02

**APPLICATION FORM FOR THE REGISTRATION OF**

**HOUSEHOLD CHEMICAL SUBSTANCE**

**APPLICANTS**  **FDA DOUBLE**

**CHECKLIST CHECKLIST**

Signed Declaration

 Covering Letter

 Certificate of Analysis of Finished Product

 Manufacturing License

 Material Safety Data Sheet

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* **Any relevant documentation or reference material which will aid in the registration process should be attached**

**APPLICATION FORM FOR THE REGISTRATION OF**

**HOUSEHOLD CHEMICAL SUSBTANCE**

**A. COVER LETTER**

ADDRESSED TO: **THE CHIEF EXECUTIVE OFFICER**

 **FOOD AND DRUGS AUTHORITY**

 **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.**

**B. PRODUCT INFORMATION**

Name of Household Chemical Substance: …………………………………………………………..

…………………………………………………………………………………..……………………..…

Formulation Type: ………………………………………………………………………………………

Physical Description of Household Chemical: ……………………………………………………………………….………………………………………

……………………………………………………………………………………………….

Intended Use: ……………………………………………………………………………………………

Sizes: ………………………………………………………………………………………………….

Variants of the Household Chemical: ………………………………………………………………….

**C. DETAILS OF APPLICANT**

Name of Applying Company/ License Holder: ………………………………………………………………………..……………………………

…………………………………………………………………………………………………………..

Postal/Business Address: …………………………………………………………………………………………………….…………

…………………………………………………………………………..……………………….…………

…………………………………………………………………………………………………………….

Tel No: ………………………………………………………………………………………………………

Fax: …………………………………………………………………………………………………….

Email: ……………………………………………………………………………………………………

Website: ……………………………………………………………………………………………………

**D. DETAILS OF MANUFACTURER**

Name of Manufacturing Company: ……………………………………………………………………..

…………………………………………………………………………………………………………….

Postal/Business Address: ………………………………………………………………………………

………………………………………………………………………………………………………………

……………………………………………………………………………………….……………………..

Manufacturing Site/Location Address: …………………………………………………………………………………………………..

………………………………………………………………………………………………………………

……………………..

Tel No: ………………………………………………………………………………………………………

Fax: ………………………………………………………………………………………………………

Email: ………………………………………………………………………………………………………

Website: ………………………………………………………………………………………………

**E. DETAILS OF LOCAL AGENT**

Name of Company: ……………………………………………………………………………………….

Postal/Business Address: ………………………………………………………………………………

Tel No: ………………………………………………………………………………………………….

Email: ……………………………………………………………………………………………

Website: ……………………………………………………………………………………

Contact Person: ..............................................................................................................

Tel. No: ........................................................................................................................

**F. DECLARATION**

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

Name: ……………………………………………………………………………………………………………………………

Position in Company: ………………………………………………………………………………………………………

Signature: ………………………………………………………………………………………………………………………

Date: ………………………………………………………………………………………………………………………………

Official Stamp of Company:

…………………………………………………………………………………………………………………………………………

***(Declaration should be signed, stamped & dated by the Applicant)***

**G. GENERAL PRODUCT SPECIFICATIONS**

The following is a table of the ingredient list:

1. Active ingredients, giving their approved names, chemical names, quantity of ingredient in the formulation and specification of the household chemical substance.
2. Other ingredients giving specifications, quantity and reasons for inclusion

 e.g preservative, fragrance, antioxidant etc

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **APPROVED NAME OF INGREDIENT** | **CHEMICAL NAME** | **QUANTITY****IN THE FORMULATION** | **ACTIVE OR INACTIVE** | **SPECIFICATION** | **REASON FOR INCLUSION OF INGREDIENT** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. Proposed Shelf-Life of Household Chemical Substance

………………………………………………………………………………………………………………………………

**H. NOTE:**

1. The Chemical name must, where possible, be given in terms of the published list of an appropriate international body (e.g. INCI Name).
2. REFERENCE to the following publications will, where applicable, be accepted.
3. British Pharmacopoeia
4. European Pharmacopoeia
5. Pharmacopoeia Of The United States Of America
6. British Pharmaceutical Codex
7. International Pharmacopoeia
8. Extra Pharmacopoeia
9. Such other works of reference as may be approved by the Authority.

**I. ADMINISTRATIVE STATUS OF THE HOUSEHOLD CHEMICAL SUBSTANCE**

1. 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 household chemical issued

 by the appropriate authority established for the registration of cosmetic products in the

 country must accompany this application.

1. 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:

 ……………………………………………………………………………………………………………………………

1. Has the registration of the household chemical substance been rejected, refused, deferred or cancelled in any country?

 Yes ( ) No ( )

 If Yes, state details

 ………………………………………………………………………………………………………………………..

1. 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:

 ………………………………………………………………………………………………

1. 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.

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

**J. TOXICOLOGICAL INFORMATION**

1. List documents attached on any toxicological trials undertaken

………………………………………………………………………………………………………………..........

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

…………………………………………………………………………………………………………………………

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

…………………………………………………………………………………………………………………………