

Confidential Business Information Regulations, 2018

1. Interpretation

In these Regulations, unless the context otherwise requires—

“Confidential Business information” (CBI) means the following:

- information that discloses manufacturing or quality control processes and 5-batch analysis
 - information that discloses methods for testing and measuring the quantity of deliberately added inert ingredients and impurities
 - information that discloses the identity or percentage quantity of deliberately added inert ingredients in the technical grade or formulated product
1. The Authority, the registrant/ applicant and local agents shall put measures to protect confidential business information (CBI).
 2. All applications for registration of a pest control product shall be accompanied with detailed CBI as stipulated in Form G in the schedule.
 3. The applicant shall ensure that all CBI is submitted to the Authority in a secure manner and by a responsible person, authorized by the Registrant.
 4. The applicant shall package and submit CBI in a sealed envelop or file separated from the other regulatory data clearly marked “Confidential Business Information”
 5. The local agent submitting the CBI shall sign confidential declaration, Form H at the time of dossier submission.
 6. An Officer of the authority receiving the CBI shall record the list of CBI data submitted in Form G in the first schedule.
 7. The authority shall store the CBI in a secure place and only allow access to authorized persons.
 8. On occasions it may be necessary to reveal to the Authority or its committees or in court proceeding, tribunal/ hearings or in findings of fact issued by the Authority, formulas of products, even if confidential, to carry out other provisions of the Authority, e.g., in cancellation or suspension hearings.
 9. Information received that is marked “confidential business information” must not be copied unless authorized by the Authority.
 10. The authorization to make copies must contain the following information:
 - 1) The name of the recipient of the copy.
 - 2) The intended purpose for which the copy is to be used.
 - 3) The manner in which the copy is to be disposed of after use.

First Schedule

Form G.

CONFIDENTIAL BUSINESS INFORMATION SUBMISSION/RECEIPT FORM

| | | Provided | | Remarks |
|---|---|----------|----|---------|
| | | Yes | No | |
| 1 | Method of manufacture (e.g. synthesis pathway) | | | |
| 2 | Specifications of the technical grade (active ingredient) | | | |
| 3 | Composition of the formulation | | | |
| 4 | Method of analysis for impurities | | | |
| 5 | '5-batch' analysis; including chromatographs | | | |
| 6 | Any other information | | | |

| | |
|--------------------------------------|--|
| Date received | |
| Trade name of the Product | |
| Active ingredient(s) | |
| Registrant | |
| Manufacturer(s) of active ingredient | |
| Formulator | |
| Exporter | |
| Local agent | |

| | |
|--|--|
| Submitted by (Full Name and signature)* | |
| Received by: Officer's name and signature | |
| Handed over to the Head of department. Signature: | |

** Confidential business information received as it is subject to technical evaluation.*

Second Schedule

Form H

CONFIDENTIALITY DECLARATION

I.....from(*company of local agent, representative*) declare that I shall maintain confidentiality of all Confidential Business information (CBI) as provided for under the Pest Control Products Act and Regulations made thereunder.

Signature.....

Name of agent/representative

Designation

Date.....