

FILE NO. 26-03/2023-CIR-I

भारत सरकार/Government of India

कृषि एवं किसान कल्याण मंत्रालय/Ministry of Agriculture & Farmers Welfare
कृषि एवं किसान कल्याण विभाग/Department of Agriculture & Farmers Welfare
वनस्पति संरक्षण, संगरोध एवं संग्रह निदेशालय

DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE

केंद्रीय कीटनाशी बोर्ड एवम पंजीकरण समिति

Central Insecticides Board and Registration Committee

एन. एच. 4, फरीदाबाद (हरियाणा)-121001

N.H. IV, FARIDABAD (HARYANA)-121001

Dated: May, 2023

PUBLIC NOTICE

Subject: Public notice regarding formulation guidelines for formulation under import/indigenous manufacturing with registration of technical (first time registration of a molecule) -reg.

The Registration Committee in its 445th meeting held on 03.03.2023 at Agenda Item No. 10.36 has deliberated the guidelines and modalities for formulation under import/indigenous manufacturing with registration of technical (first time registration of a molecule) and decided to upload a public notice on the website for seeking comments of the stakeholders.

The proposed requirements in the guidelines as mentioned in **Annexure-I** and the proposed modalities of its implementations are as under-

1. The guidelines once approved shall be applicable for the insecticide/pesticides for which RTT permits will be issued by the RC till the approval of said guidelines.
2. All such applicants required to submit the Form-I, NJSP, shelf life and packaging data of technical for its registration.
3. After the approval of the guidelines the RTT permits shall be issued accordingly.
4. Post approval of guidelines at (**Annexure-I**) the application for technical and formulation registration with prescribed requirements of the approved guidelines shall be submitted simultaneously.

2. In view of above, stakeholders are requested to submit their views/comments in the matter through email at cibsecy@nic.in within 7 days of uploading of the public notice on the official website of this Secretariat.

Signed by Sanjay Arya

Date: 22-05-2023 11:04:20

(Sanjay Arya)
Reason: Approved
Secretary (CIB&RC)

Copy to:

1. All Registered Pesticide Associations
2. Chairman, Registration Committee
3. PS to JS (PP), DA&FW, Krishi Bhawan, New Delhi
4. PPA, Dte. of PPQ&S, NH-IV, Faridabad
5. PPS to Secretary (CIB&RC), NH-IV, Faridabad
6. IT Cell, HQ, Faridabad for uploading the same on the web

Guidelines for Formulation under import/indigenous manufacturing with registration of technical (first time registration of a molecule). The data requirement for first time registration of technical (These data requirement has to be fulfilled by the applicant in case of Formulation Import/Indigenous Manufacturing-With Registration of Technical)

Abbreviations :

R : Required
 TIM : Indigenous Manufacture
 NR : Not Required
 TI : Technical Import

Note:

- (i) Data requirements of chemical pesticides are also applicable for registration of chemical plant growth regulators (PCR).
- (ii) The data requirement for Formulation under import and Formulation Indigenous Manufacturing (New molecule) remains same as prescribed by the RC in its 284th RC meeting.

| S. No. | Parameter | 9(3B) | | 9(3) | |
|--------|--|-------|-----|------|-----|
| | | TI | TIM | TI | TIM |
| A. | Chemistry | | | | |
| 1. | Source of Supply of Technical | R | NR | R | NR |
| 2. | Chemical Composition | R | R | R | R |
| 3. | Documents such as registration certificate containing registered CC in the country of Import | R | NR | R | NR |
| 4. | Certificate of DNA | R | NR | R | NR |
| 5. | Chemical Identity of technical | R | R | R | R |
| 6. | Physico - Chemical Properties of adjuvant | R | R | R | R |
| 7. | Technical Bulletin | R | NR | R | NR |
| 8. | Product Specification & Method of analysis for AI and its impurities | R | R | R | R |
| 9. | Analytical Test Report | R | R | R | R |

| | | | | | |
|-----|---|----|----|----|----|
| 10. | Identification & Quantification of identifiable Impurities | R | R | R | R |
| 11. | Shelf-life claim | R | R | R | R |
| 12. | Shelf-life Data | NR | NR | R | R |
| 13. | Establishment of Chemical Equivalence | NR | NR | NR | NR |
| 14. | Process of Manufacture in detail from 1 st step | R | R | R | R |
| 15. | Information about Raw Materials Used and their formula | R | R | R | R |
| 16. | Their Source of Supply. | R | R | R | R |
| 17. | Step-wise Manufacturing Process with condition. | R | R | R | R |
| 18. | Chemical Equation and Formula | R | R | R | R |
| 19. | Flow sheet diagram of process of manufacture | R | R | R | R |
| 20. | Effluent Treatment method | NR | R | NR | R |
| 21. | Certificate of manufacturing license if issued or any other approval under any Govt. regulation to support that applicant is a manufacturer. | R | NR | R | NR |
| 22. | Certificate from manufacturer that the dealer/ trader is an authorized dealer/ trader of the manufacturer. | R | NR | R | NR |
| 23. | A test report about the quality of the product from a laboratory as per GLP scheme. This requirement will be provided along with first consignment. Thereafter, | R | NR | R | NR |

| | | | | | |
|-----------------------|---|----------------|----------------|----------------|-----------------|
| | each consignment should have proper analytical test report of the manufacturer. | | | | |
| 24. | In process sample to be drawn of technical u/s 9(3) TIM. In case of technical grade pesticides u/s 9(3), along with drawl of samples, std. of impurities are also to be provided for chemical verification. | R | R | R | R |
| 25. | Methodology for residue estimation as per BIS format. | R | R | R | R |
| B. BIOEFFICACY | | | | | |
| 1. | Bio-effectiveness | R [§] | R [§] | R [§] | R ^{**} |
| 2. | Phyto toxicity | R [§] | R [§] | R [§] | R ^{**} |
| 3. | Effect on parasites & predators | R [§] | R [§] | R [§] | R ^{**} |
| 4. | Translocation in plants | R | R | R | R |
| 5. | Metabolism in soil | R | R | R | R |
| 6. | Metabolism in water | R | R | R | R |
| 7. | Metabolism in plant | R | R | R | R |
| 8. | Persistence in soil | R | R | R | R |
| 9. | Persistence in water | R | R | R | R |
| 10. | Persistence in plant | R | R | R | R |
| 11. | Compatibility with other chemicals | NR | NR | R | R |
| 12. | Residues in plant | NR | NR | R | R |

| | | | | | |
|-----|---|----|----|---|----|
| 13. | Residues in soil | NR | NR | R | R |
| 14. | Residue tolerance limits fixed by foreign countries | NR | NR | R | R |
| 15. | Cost benefit ratio | NR | NR | R | R |
| 16. | Registration status in foreign countries | R | NR | R | NR |

R*: Two seasons/years data generated at minimum two agro climatic conditions/locations+

R**: Two seasons/years data generated at minimum three agro climatic conditions/locations+

Locations+ : Locations shall be applicable for the crops for which required agro-climatic conditions are not available.

R #: Data on compatibility is required, if the product is proposed to mix with other chemicals.

Notes:

(i) In case of herbicides data on effect on soil physico-chemical and biological properties, and effect on normally cultivated three succeeding crops is required along with residue studies in the same plots of the field.

Example: For a herbicide intended to be registered for use in wheat crop, data on effect on succeeding crops of maize at location 1, green gram at location 2, sesamum at location 3, may be generated along with residue studies. However, this is only an example and data on any other normally cultivated succeeding crop may be generated.)

For the requirement of data on translocation in plants, international data from any authentic source shall be accepted.

C. TOXICITY

| | | | | | |
|----|--------------------------|---|---|---|---|
| 1. | Acute oral in rat & mice | R | R | R | R |
| 2. | Acute dermal | R | R | R | R |
| 3. | Acute inhalation | R | R | R | R |

| | | | | | |
|-----|--|----|----|----|----|
| 4. | Primary skin irritation | R | R | R | R |
| 5. | Irritation to mucous membrane | R | R | R | R |
| 6. | Sub-acute oral rat | R | R | R | R |
| 7. | Sub-acute oral dog | R* | R* | R* | R* |
| 8. | Sub-acute dermal | R | R | R | R |
| 9. | Sub-acute inhalation | R | R | R | R |
| 10. | Neuro-toxicity | NR | NR | R | R |
| 11. | Synergism & potentiation | NR | NR | R | R |
| 12. | Teratogenicity | NR | NR | R | R |
| 13. | Effect on reproduction | NR | NR | R | R |
| 14. | Carcinogenicity | NR | NR | R | R |
| 15. | Metabolism | NR | NR | R | R |
| 16. | Mutagenicity | NR | NR | R | R |
| 17. | Toxicity to birds (two) | R | R | R | R |
| 18. | Toxicity to fish (fresh water) | R | R | R | R |
| 19. | Toxicity to honeybees | R | R | R | R |
| 20. | Toxicity to live stock | R | R | R | R |
| 21. | Medical data | R | R | R | R |
| 22. | Human toxicity information from foreign countries | R | R | R | NR |
| 23. | Observation in man (Health records of spray operators) | NR | NR | NR | NR |

| | | | | | |
|---|---|----|----|------|------|
| 24. | Health records of industrial workers. | NR | NR | R | NR |
| 25. | Toxicity to live stock (Field trial & observation) | NR | NR | NR | NR |
| 26. | International report on carcinogenicity & genotoxicity status | NR | NR | R/NR | R/NR |
| <p>NR^{AAA}: Not required as per decision of 318th RC held on 27-04-2011 NF^{**} : In case of wettable powder, if toxicological data is generated for EC formulation applicable as per guidelines, then there is no need to generate data on wettable powder containing the same a.i. R*: Any peer reviewed published data/information shall be acceptable (approved in 343rd and 344th RC Meeting)</p> | | | | | |

D. PACKAGING

| | | | | | |
|----|---|---|---|---|---|
| 1. | Labels and leaflets as per IR-1971, all fields (as applicable) and as amended from time to time | R | R | R | R |
| 2. | Manner of Labelling and leaflets | R | R | R | R |
| 3. | Types of packaging (Ultra, Small or Big whichever is applicable) | R | R | R | R |
| 4. | Manner of packaging | R | R | R | R |
| 5. | Specification of primary, secondary and transport packages (whichever is applicable) | R | R | R | R |
| 6. | Details of packaging materials and its compatibility with content | R | R | R | R |
| 7. | Performance of container during storage stability test (Shelf-life study) | R | R | R | R |
| 8. | Transport worthiness test | R | R | R | R |