FILE NO. 26-01/2022-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

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Dated the 11th February, 2022

PUBLIC NOTICE

Subject: Public notice for inviting comments of stakeholders on the draft guidelines for post harvest use of Ethephon -reg.

Reference is invited to Agenda No. 10.6 of the 436th RC meeting held on 28.01.2022 wherein the Registration Committee discussed a request regarding exemption of registration of Ethylene releasing sachet used for the post harvest ripening of fruits under IA, 1968.

RC noted that Ethylene gas is released from Ethephon (PGR) which is listed in schedule of the Insecticide Act 1968 thus it is mandatory to get registration and decided that draft guideline/protocol for post harvest use of Ethephon (fruit ripening) should be uploaded on the website seeking comments of the stake holders.

Accordingly, as per the decision taken by the RC, the draft guidelines for post harvest use of Ethephon are uploaded herewith for inviting comments of the stake holders within a period of 15 days from the date of uploading of this public notice. The comments may also be sent through email at cibsecy@nic.in .

Encl: Draft guidelines for post harvest use of Ethephon.

A Kumar
11/2/22

(Ajay Kumar)
Sr. Administrative Officer

Copy to:

1. All Registered Pesticide Associations
2. Chairman, Registration Committee
3. PPS to JS(PP)/ PA to PPA
4. IT Cell Hqrs., Faridabad for uploading the same on the official website.

Annexure

Draft guidelines/data Requirement proposed for Registration of new Formulation indigenous Manufacture for post-Harvest (Fruit Ripening only) of already registered molecule U/s 9(3):

A. Legal Requirements:

I. Form - I duly signed
II. Copy of BOD Resolution/Affidavit/partnership deed (Notarized)
III. Affidavit for Chemical composition on NJSP (Notarized)
IV. (iv) Certificate as per category of industry/ Manufacturing license (Notarized)
V. PAN No. (Notarized)
VI. Incorporation Certificate Notarized
VII. Proof of Source of Technical to be used in formulation is duly registered.(ln case of indigenous manufacture / import - Reference of RC meeting in which it was approved). {Only deemed registration status without issuance of Certificate of registration shall not be considered].
VIII. Letter of consent, duly legalized from Indian Embassy/High Commission/ Consulate in the Country of origin (Applicable in case of 9(4) TI/Fl Applications).
IX. Copy of 9(38) Registration certificate, if relevant.

B. Chemistry:

I. Chemical composition of formulation.
II. Chemical identity of technical and adjuvants.
III. Physico-chemical properties of technical and adjuvants.
IV. Specification of the product and Method of analysis
V. Analytical Test report
VI. Data on rate of release/application
VII. Shelf life claim & data
VIII. Process of manufacture, Step-wise manufacturing process and Flow sheet diagram of process of manufacture
IX. Information about raw material used and their source of supply
X. The applicant should provide sample along with ref./analytical standard for pre-registration verification along with Specification, Method of analysis, Chromatograms etc.
XI. Methodology for residue estimation as per BIS format.
XII. Source of supply of technical: The technical should be registered in India for use in country and proof of supply that the formulated product has ' been manufactured using the particular technical only for consent provided.
XIII. Form-1, Labels/Leaflets and copy of RTT permit, if relevant.
XIV. ETP certificate, if applicable

C. Bio efficacy and Residues:

1. Data on bio-effectiveness. 2. Adverse effect on post-harvest crop produce, if any (phytotoxicity, change in appearance and flavor etc.)	For label claim of controlled atmospheric conditions data on 1. And 2. To be submitted for three repeated trials (same temperature and relative humidity). Or For label claim of ambient atmospheric condition data to be submitted for min. three repeated trials of different locations.
3. Residue and persistence at different interval (immediately after treatment start from 0 hours till BDL or acceptable level) in post-harvest crop produce.	For label claim of controlled atmospheric conditions (same temperature and relative humidity) data to be submitted for three repeated trails. Or For label claim of ambient atmospheric condition data to be submitted for min. three repeated trials of different locations.
4. Registration status of formulation in other countries	Required
5. MRL Performa and label leaflets	Required
6. Label claims as per product Bio-efficacy : Information as per latest Gazette Notification issued by the Government of India.	

D. Toxicity:

I. Acute oral in rat and mice
II. Acute dermal
III. Acute In halation
IV. Primary skin irritation.
V. Irritation to mucous membrane.
VI. Observation in man- If the concentration is lower and type of formulation is such i.e. WC in place of EC etc., data may not be required.(NR as per decision of 318th RC held on 27 -O4-2O11.
VII. Sub-acute oral rate: NR/R
VIII. Sub-acute Oral dog: NR/R
IX. Sub-acute dermal: NR/R
X. Sub-acute in halation: NR/R
XI. Neuro toxicity: N R/R

XII. Synergism & potentiation: N R/R
XIII. Toxicity to birds (two): NR/R
XIV. Toxicity to fish (fresh water): NR/R
XV. Toxicity to honeybees: NR/R
XVI. Medical Data: R

Note: R: In case of formulation is more toxic than the technical in the acute Studies.

E. Packaging and Labeling:

I. Labels and leaflets as per-1971 existing norms
   a. For size 25O ml/gm& below
   b. For 5OO ml/gm& above.

II. Label to contents
   a. Detailed Chemical composition
   b. Purpose for import/manufacture
   c. Antidote
   d. Toxicity triangle
   e. Cautionary statement
   f. Brief direction concerning usages
   g. Restriction if any

III. **Leaflets to contain:**
   a. Detailed Chemical composition leaflets accompanying small labels(up to 25O mg/ml size container)
   b. Introductory para about the pesticide
   c. Detailed directions concerning usages
   d. Time of application
   e. Application equipment
   f. Waiting period
   g. Symptoms of Poisoning
   h. First-aid measures
   i. Antidote and treatment
   j. Restriction, if any
   k. Instruction for storage
   l. Information regarding disposal of used packages

IV. Type of packaging (packing material + compatibility with content)

V. Manner of packing
   a. Specification for primary package
   b. Specification for secondary packaging
   c. Specification for transport packaging
   d. Manner of labeling
   e. Performance of container during storage stability test
   f. Transport worthiness Test