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Acute Pulmonary Toxicity/ Pathogenicity (APP)

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About the author

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Dr. Vishvesh Dalal is working as Assistant Director and leading the *in-vivo* and *in-vitro* acute study toxicity and repeated dose inhalation toxicity study teams. He is also leading the team which carried out the testing of microbial products (pathogenicity study) in JRF. He has very vast experience in conducting the acute, in-vitro eye irritation and repeated dose inhalation studies and has been actively involved in validation of in-vitro inhalation studies. He was also worked as Quality Assurance Officer in JRF. He is having professional experience of more than 18 years in CRO industry.

01. Overview

Conversely, with the past, chemical manures and pesticides are being traded by bio-composts and bio-pesticides, separately, because of their solace of purpose, harmless to the ecosystem nature, cost-viability, and nontoxicity.

Bacillus thuringiensis (Bt) is very poisonous to a broad assortment of fundamental farming and wellbeing related bothers alongside different spineless creatures so practically 90% of the microbial bio-pesticides are gotten from this.

The bio-pesticide market is characterized into bio-herbicides, bio-insecticides, and bio-fungicides based on the product type. Concerning fixings, it is again partitioned into:

A. Microbial pesticides

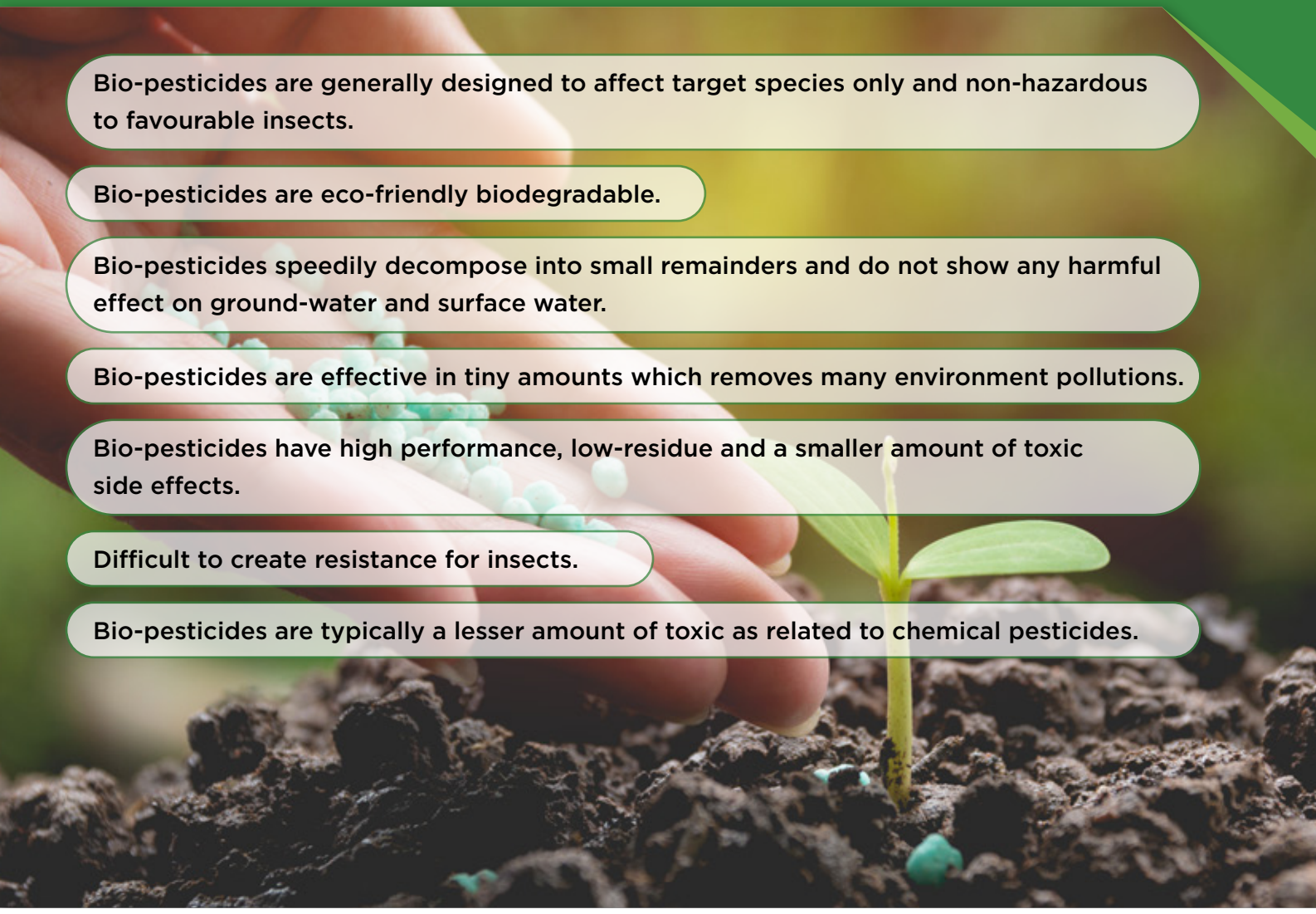
i. Bacteria - *e.g., Bacillus sp*
ii. Fungi - *e.g., Beauveria sp, Metarhizium sp, Trichoderma sp*
iii. Viruses – *e.g., granulosis virus, entomopox virus, cytoplasmic polyhedrosis virus*
iv. Protozoans - *e.g., Schizogregrine*
v. Algae - *e.g., Enteromorpha flexuosa, Sargassum wightii*

B. Biochemical pesticides
Plant extracts or sex pheromones

C. Plant-Incorporated-Protectants
Insecticidal transgenic crops

02. Advantages of Bio-pesticide

In the field of agronomy, there are numerous complications of pests like insects, fungi, and weeds from the ancient period resulting in a decrease in yield as well as the efficiency of crops.



- **Bio-pesticides are generally designed to affect target species only and non-hazardous to favourable insects.**
- **Bio-pesticides are eco-friendly biodegradable.**
- **Bio-pesticides speedily decompose into small remainders and do not show any harmful effect on ground-water and surface water.**
- **Bio-pesticides are effective in tiny amounts which removes many environment pollutions.**
- **Bio-pesticides have high performance, low-residue and a smaller amount of toxic side effects.**
- **Difficult to create resistance for insects.**
- **Bio-pesticides are typically a lesser amount of toxic as related to chemical pesticides.**

03. Data Requirements for Registration of Bio-Pesticides

For registration of Bio-pesticides, every dominion has requirements for the data package submitted.

Data requirements for the formulated product:

- Identity and composition of the formulation
- Physical and chemical properties
- Application, labelling, and packaging
- Supplementary information
- Analytical methods
- Efficacy data
- Toxicology and exposure
- Residues
- Fate and behaviour in the environment
- Effects on non-target organisms

04. Objective of the study

This study was performed to provide initial information on the pulmonary toxicity, infectivity and pathogenicity of a microbial pest control agents (MPCA), MPCA in rats following a single high dose exposure.

05. Principle of test method

The Microbial Pest Control Agent (MPCA) is administered intranasal instillation (day 0) using a micropipette in a single high dose to experimental animals. Subsequent observations of effects and deaths are made and rate of clearance of the MPCA is estimated. Animals those die during the study period will be necropsied, and at the end of the test, the surviving animals will be sacrificed and necropsied. Infectivity of the test item (MPCA) is evaluated periodically during the test, and at the end of the study.

06. Regulatory testing for MPCA as per OCSPP guidelines 885.3150

6.1 Test System

Rat (Wistar) or Mice (CD1)

6.2 Method Validation

Before starting any Study of MPCA, we perform Microbiological Method validation for better clarity of the behaviour of the active ingredient. Method validation part contains,

Limit of Detection (LOD) → Limit of Quantification (LOQ)

After Method validation, the Main study is to be initiated.

Test	Necropsy & Interim Sacrifice / Terminal Sacrifice	Biometrics collection for MPCA clearance & enumeration
Acute Pulmonary Toxicity / Pathogenicity (OCSPP 885.3150)	On Day 0, 3,7,14 & 21	Microbiological enumeration of MPCA done from major tissue like Blood, Lung, brain, liver, kidney, stomach, whole intestine, caecum, mesenteric lymph node, and spleen was also examined.

6.3 Tier Progression

If MPCA noticed as Pathogenic/ Toxic than higher tier testing may be performed.

JRF has extensive involvement in MPCA regulatory studies with GLP compliances for different microbial strains.

References:

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