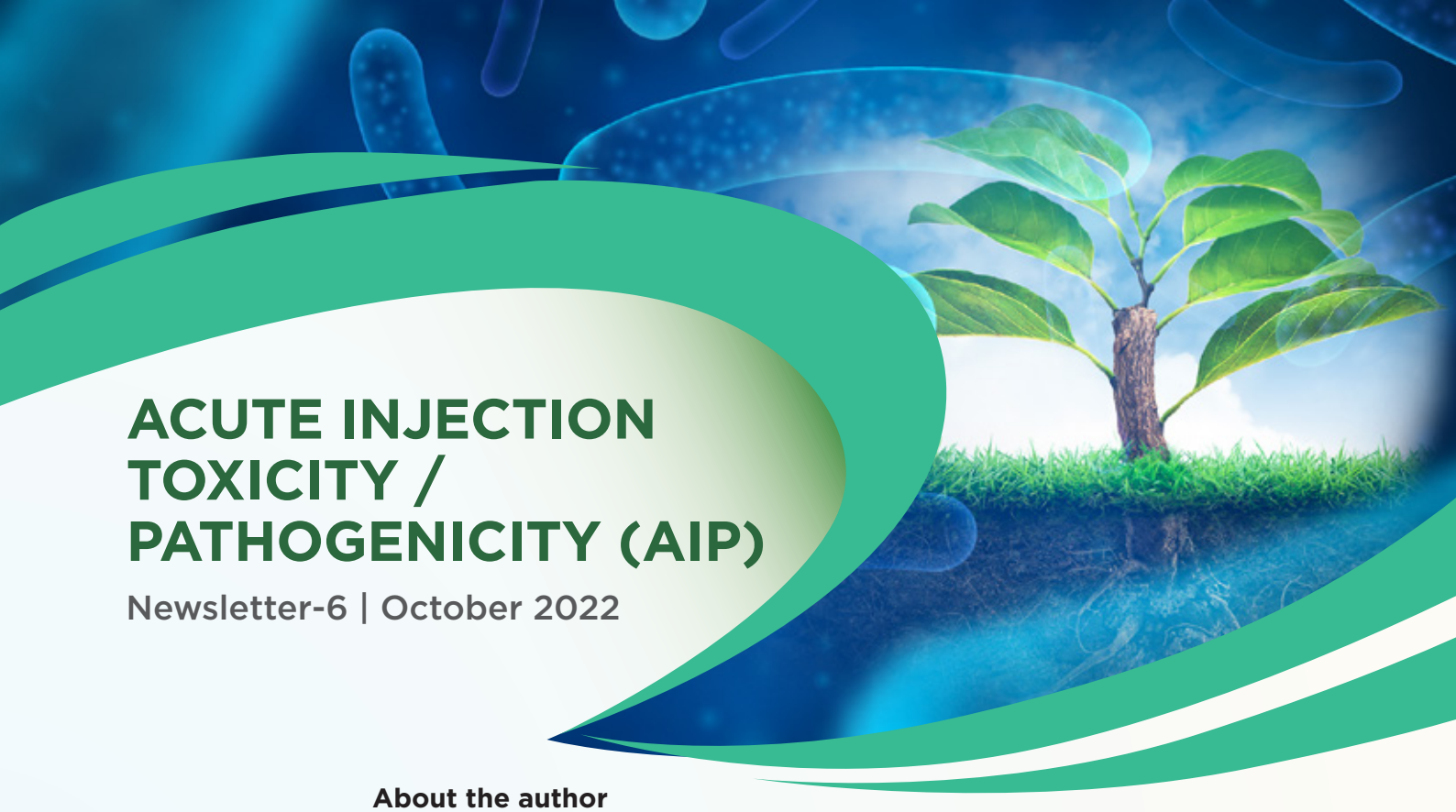


ACUTE INJECTION TOXICITY / PATHOGENICITY (AIP)

Newsletter-6 | October 2022

About the author

Rahul Badgha

Research Officer

Mr. Rahul Badgha is experienced in the Industrial Microbiology, and he is study director for all type of acute pathogenicity studies. He is actively involved in microbial method validation and Acute Pathogenicity studies for various microbial based products. Apart from this, He is instrumental in maintaining the GLP and AAALAC approved Animal Breeding Facility for different species of laboratory animals for toxicology studies. He is also involved in the breeding and health monitoring of laboratory animals. He has professional experience of more than 6 years in CRO industry.

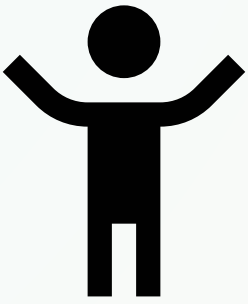
1. Overview

Microbial pesticides are bio pesticides that are created to kill pests, weeds, and diseases without harming the environment. They can be used in many ways such as soil treatments, foliar sprays, and seed treatments.

PROS

Microbial pesticides have several benefits over traditional chemical pesticides.

They are environmentally friendly and safe for humans and animals to be around.



CONS

There is still a lot we don't know about microbial pesticides so we need more research on them before they can become a viable alternative to chemical pesticides.

The bio-pesticide market is characterized into,

- Bio-Herbicides
- Bio-Insecticides
- Bio-Fungicides

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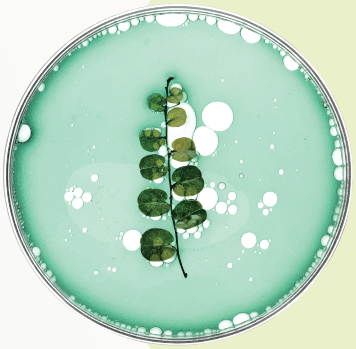
Based on the product type and ingredients, it is again partitioned into:

Microbial Pesticides
Bacteria, Fungi, Viruses, Protozoans, Algae

Biochemical Pesticides
Plant extracts or sex pheromones

Plant-Incorporated Protectants
Insecticidal transgenic crops

2. Operational Attributes Of Biofertilizers and Biopesticides



- ✓ Solubilize phosphates of Fe, Ca, and Al to available forms
- ✓ Enhance nutrient proximity to soil and crop yield
- ✓ Fix atmospheric N in soil for plant utilization
- ✓ Take effect as phosphate scavengers of soil
- ✓ Stimulate growth by producing phytohormones and plant metabolites
- ✓ Enhance soil fertility by organic decomposition
- ✓ Improve resistance to pests & pathogens on plants

3. Data Requirements for Registration of Bio-Pesticides (formulated product)

- ✓ For registration of Bio-pesticides, every region has requirementsfor the data package submitted.
- ✓ 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

4. 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), in rats following a single high dose exposure.

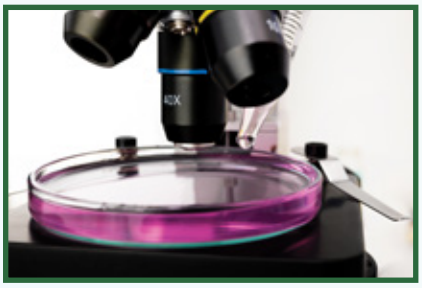
5. Principle of Test Method

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.

6. Regulatory Testing for MPCA as per OCSPP guidelines 885.3200

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

- **Purity of Test Item(MPCA)**
- **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 Injection Toxicity / Pathogenicity (OCSPP 885.3200)	On Day 0, 3,7,14 & 21	Microbiological enumeration of MPCA done from major biological matrices like Blood, Lung, brain, liver, kidney, heart, stomach, whole intestine, caecum, mesenteric lymph node, and spleen was also examined.

6.3 Tier Progression

If MPCA spotted as pathogenic/ toxic than higher tier testing may be performed.

7. JRF Qualities

JRF has huge contribution in MPCA regulatory studies with GLP compliances for different microbial varieties.

8. References

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