aragen.com

Case-study-

Designing an optimal and scalable protocol for formulating a 40% emulsifiable concentrate for a systemic insecticide.

An emulsifiable concentrate formulation combines an active ingredient in a water-immiscible solvent with emulsifiers. ECs remain a widely used formulation for crop protection globally. When diluted with water in the spray tank, they spontaneously form emulsions with droplets ranging from 0.1 to 1.0 µm. By selecting surfactants compatible with the solvent system, including the active ingredient, the emulsion is achieved. When sprayed, the diluted emulsion ensures a uniform and precise application of the active ingredient on the crop, crucial for effective pest control.

Developing emulsifiable concentrates (ECs) poses multifaceted challenges in regards to crop protection. Ensuring the solubility of active ingredients in water-immiscible solvents while maintaining compatibility with emulsifiers is a critical hurdle. Achieving stable emulsions with controlled droplet sizes (0.1 to 1.0 µm) demands precise formulation. Selecting surfactants that stabilize the emulsion and complement with both the solvent and active ingredient is complex. Environmental concerns regarding solvent and emulsifier impact, residue persistence, and regulatory compliance further complicate the development process.

In this case-study, we showcase one of the projects executed by Aragen's expert agro-formulation scientists for an EU based agriscience company. Aragen successfully engineered a robust and scalable emulsifiable concentrate formulation for a systemic insecticide. The clients received and subsequently endorsed all the formulation development parameters, which were then approved by global regulatory agencies.

The Project:

To develop a new 40% w/w EC formulation for a systemic insecticide as an alternative to the one developed by the client. This formulation must replicate the physicochemical properties of the client's original 40% EC formulation. However, it should be developed using environmentally safe excipients approved by regulatory agencies, including the US EPA.

Key Challenges:

The key challenge was to replicate the physiological properties of the original formulation developed by the client. The essential physicochemical properties to be duplicated encompass precipitation behavior, crystal growth at low temperatures, emulsion stability, pH fluctuations during prolonged storage, and the consistency of emulsion upon dilution.

Additionally, the formulation needs to be developed using excipients (co-formulants, emulsifiers, and surfactants) along with solvents that are environmentally safe and pose no threat to the relevant crops.

About the client:

A prominent agriscience company headquartered in the European Union is entirely committed to the field of agriculture. Leveraging state-of-the-art technologies, they integrate modern agricultural techniques with AI and ML methodologies to create formulations for crop protection. Additionally, they stand out as a leading organization in the development of crop protection agents, genetically modified seeds, and biologicals.

Aragen's Approach:

The team comprehensively gripped the influence of surfactant types. Equipped with this understanding, they chose suitable non-ionic and anionic surfactants to tackle concerns regarding crystal growth and pH fluctuations. In the revised formulation, a co-solvent was additionally incorporated to address other physicochemical parameters.

Different steps for developing the optimal 40% emulsifiable concentrate formulation:

Identification of appropriate surfactants: Different blends of surfactants, encompassing non-ionic and anionic types, were formulated along with the active pharmaceutical ingredient (API) at varying concentrations to create an optimal emulsion.

Identification of appropriate co-solvents: Various environmentally friendly solvents were evaluated for their compatibility with the aqueous phase and for formulating the ideal emulsion with the required droplet size.

Lab scale stable formulation development: A laboratory-scale formulation was created using identified excipients. Parameters such as solvent volume, API concentration, RPM, temperature, and pH were optimised during the process.

Scale-up, parameter and physiochemical optimization: The laboratory-scale formulation was upscaled, and the parameters were fine-tuned to attain the optimal formulation. Comprehensive physiochemical characterization was conducted, covering aspects such as precipitation behavior, crystal growth at low temperatures, emulsion stability, pH variations during extended storage, and the uniformity of emulsion upon dilution.

Project outcomes (Achievements):

- The newly formulated product physicochemical parameters matched those of the original formulation.
- The GLP physicochemical data of developed protocol was submitted to regulatory agencies (US EPA) and approval was granted.
- Stability data for an extended duration was generated across diverse agro-climatic conditions, demonstrating the formulation's remarkable stability.
- With assistance from Aragen's specialists, the client effectively conducted the in-house technology transfer and introduced the product to the US market.

To know more about Aragen's formulation development capabilities write to us at bd@aragen.com.