



## About Battelle

Battelle is the world's largest nonprofit independent research and development organization, providing innovative solutions to the world's most pressing needs through its four global businesses: Laboratory Management, National Security, Energy Technology, and Health and Life Sciences. It advances scientific discovery and application by conducting \$5 billion in global R&D annually through contract research, laboratory management, and technology commercialization.

# Developing a New Fungicide Co-Formulation and Generating GLP Registration Data

## Challenge

Battelle was challenged to develop a stable liquid combination formulation of two fungicides without using polar solvents. To do this, Battelle needed to solve known problems of the formulations' physical instability when diluted in cold water after 24 hours. Constant attention to regulatory concerns was also required for the project to be considered a success.

## Battelle Solution

Battelle developed an experimental formulation without using troublesome polar solvents. The two fungicides are usually dissolved in water-miscible polar solvents. These allow the dissolved active ingredients to crystallize out when the dilution in water is prepared for spraying. This is especially problematic when left for any time in the cold water likely to be used at normal application times in the spring. Battelle tested a range of toxicologically and environmentally acceptable solvents and identified a mixture that provides good solubility for the fungicides, a formulation that was very effective in protecting crops against fungi and did not have tox or eco-tox issues that would cause problems with registration or require the product to identify additional hazard warnings on the label. Optimization work improved the

dilution properties, with no crystals or oil separation after 24 hours at 5°C. Battelle also validated a method of analysis, provided a certified sample for field trials, and conducted GLP stability studies to generate data required for registration.

## Benefits

- **Improved Formulation:** The new formulation contains readily available and less expensive solvents than the previous standard.
- **Proficient Stability:** The product demonstrates proficient stability in both the concentrated and diluted states.
- **Registration Application:** Battelle developed and validated methods of analysis for the formulation and carried out GLP storage stability tests, generating the data needed to support a registration application.
- **Renewable Feedstocks:** The new formulation uses solvents made in part from renewable feedstock.
- **No Hazard Classification:** The best polar solvent for the two fungicides is now coming under regulatory pressure, causing the product to have an unwelcome hazard classification on the label and is unacceptable in modern formulations. Battelle's solution does not have this problem.