

Nanosilver Conditionally Registered as New Active Ingredient

By

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The U.S. Environmental Protection Agency (EPA) on December 1, 2011, issued a conditional registration for a pesticide product containing nanosilver as a new active ingredient. This article provides background on this regulatory achievement.

The Product

HeiQ AGS-20 is a nanosilver-silica composite where the nanosilver is sintered onto amorphous silicon-dioxide having typical particle diameters of one micrometer (1,000 nanometers). The textiles will be incorporated into the starting materials or treated by application of HeiQ AGS-20 as a surface coating (textile finishing).

EPA's risk assessment relied on the existing reregistration decision for silver and concluded that the human health or ecological risk from exposure to silver ions derived from HeiQ AGS-20 treated textiles is not of concern. For purposes of risk from exposure to HeiQ AGS-20, HeiQ submitted results from short-term acute animal-toxicity tests completed using high-level doses of HeiQ AGS-20. No major issues were identified. According to EPA's Decision Document, HeiQ AGS-20 caused moderate to no irritation to the skin and eyes of test animals, but was not a skin sensitizer. Based on these results, EPA will require shipping containers filled with HeiQ AGS-20 "to carry a label stating 'CAUTION' where contact with

items treated with AGS-20 is restricted for 12 hours after application and AGS-20 does not require child-resistant packaging.”

EPA used conservative assumptions that overestimate the dose of nanosilver that could potentially be derived from HeiQ AGS-20 along with maximum values for risk uncertainty factors. It determined that for the period of conditional registration, there is a low probability of adverse risk to children and the environment. Thus, EPA concluded that use of HeiQ AGS-20 will not cause unreasonable adverse effects on the environment during the period when newly required data are being developed. EPA notes that it does have a risk concern for occupational exposure when handling HeiQ AGS-20 powder during mixing and loading operations.

As a condition of registration, EPA is requiring HeiQ to conduct many studies during the period of conditional registration. The required tests include route-specific toxicity studies for occupational exposure scenarios, as well as product characterization and stability tests to determine if nanosilver breaks away from HeiQ AGS-20. EPA states that, if nanosilver is found to break away from HeiQ AGS-20 or textiles treated with HeiQ AGS-20, then additional testing will be triggered to determine the effect of HeiQ AGS-20 derived nanosilver on humans and the environment. These studies must be completed within four years, which EPA chose to allow time for protocol reviews prior to initiation of the studies, completion of the studies, and its review of the study results. The data requirements are set forth in Appendix A of the Decision Document. The studies listed in Table 1A are considered Tier I because their need is not based on the results of any other studies. Tier II studies may or may not be required based on the

results of the Tier I studies. Tier I studies are required to be submitted according to the schedule set forth in the registration.

EPA intends to evaluate these data as they are submitted to confirm that the use of HeiQ AGS-20 will not cause unreasonable adverse effects to human health and the environment. If HeiQ fails to take appropriate steps to initiate the required studies, or if HeiQ fails to submit the protocols or data, EPA will issue a notice of intent to cancel HeiQ's registration under FIFRA Section 6(e).

Discussion

EPA's approval of the HeiQ nanopesticide product is a big deal. EPA's determination that the use of HeiQ AGS-20 is in the public interest is very promising. EPA states that it may lead to less environmental loading of silver as compared to currently registered products with the same use patterns. Importantly, EPA notes HeiQ AGS-20 appears to offer prolonged ability to suppress the growth of odor causing bacteria through the slow release of silver ions as compared to the rapid release of silver ions from registered products containing silver salts. This representation may offer HeiQ an important commercial advantage as this kind of validation of HeiQ's product efficacy is valuable. EPA's Decision Document is available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-1012-0064>.

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