



EPA Classifies “Green” Antimicrobial as Pesticide — Do Regulations Need a Refresh?

By Mike Krall

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PURE Bioscience, a San Diego-based biotechnology company, has spent years navigating the EPA regulatory process for its patented silver-based formula, silver dihydrogen Citrate (SDC), a molecule that kills dangerous viruses and bacteria without the use of toxic chemicals.

In 2001, we finally secured EPA registration for SDC—as a pesticide. All antimicrobials are processed as pesticides; however, SDC, with its unique multiple modes of action, is not toxic yet is still evaluated under antiquated standards that were very useful to protect the public from misleading marketing claims by companies selling poisonous and hazardous chemicals. In fact, the EPA itself has classified our technology as a category IV toxicity level – the safest rating a formulation can receive and still make a claim to kill *anything*.

The danger of the pesticide classification and a regulation process that evaluates new technologies based on old ones, is that the EPA is muddling the market, stifling business innovation and confusing consumers. This not only makes it hard for consumers to understand how newer formulations work, but also makes it more difficult for companies to bring new innovations to light, which could be especially damaging as the “green” movement continues to accelerate, requiring entirely new formulations.

For example, the majority of mainstream household and consumer products with “green” marketing campaigns do nothing more than dilute the toxic chemical that companies have relied on for years. Although this results in slightly less toxic and slightly more environmentally friendly formulations for consumers, its efficacy is often compromised. The concept is uninspired and hardly groundbreaking, but the EPA tends to evaluate new product formulations based on old methodologies. And the EPA expressly prohibits disinfectants from making claims regarding toxicity or environmental friendliness, because – until now – all disinfectants were toxic and environmentally damaging. Ironically, it’s not intuitive for an antimicrobial

technology like SDC to be classified as a pesticide, given its safety profile and the markets it serves: healthcare; agriculture; water purification; food contact sanitization, etc.

From a marketing standpoint, the EPA also places a number of restrictions on how distributors can describe our product and make claims for what it does. For example, most consumers do not grasp the difference between a sanitizer and a disinfectant. In short, a sanitizer kills 99.99 percent of bacteria while a disinfectant calls for a total elimination of a broad spectrum of pathogens, including viruses and fungi, not just bacteria. The restrictions on marketing a disinfectant are much more stringent than those for marketing a sanitizer. The EPA will not allow products to promote a “100 percent” kill rate or similar term, making it easier to market a sanitizer rather than a disinfectant, even though in EPA language, a sanitizer signifies a lower efficacy.

As the “green” movement continues to pick up steam, consumers are becoming “label readers” and will demand products that are both good for the environment, yet just as effective as harsh chemicals at confronting a number of emerging global health threats. This is especially alarming given the threat of Staph (including MRSA), which continues to plague schools, hospitals and locker rooms across the country, and most recently H1N1, as the Obama administration and other worldwide officials continue preparing for another wave of the virus in the fall.

There are a number of innovative technologies on the market today that offer highly effective alternatives to traditional chemicals, proving that products don’t need to be toxic to be effective. However, these new formulations are typically “disruptive” technologies that require the EPA, consumers and industry to come up the steep learning curve and understand how they work compared with the incumbent technologies on the market. We face this issue constantly.

As the movement toward green technologies continues, it is critical that consumers become educated on the innovative technologies available today that do more than simply dilute harsh chemicals. It is equally important that the EPA and regulatory bodies prioritize and revise the evaluation approval and labeling claims of new, greener technologies to bring to market more effective and environmentally friendly formulations.

Michael L. Krall is Founder and Chief Executive Officer of PURE Bioscience, creator of the patented SDC molecule. In addition to its distribution network for SDC-based disinfectant formulations, the Company has partnered with a drug development Company to pursue dermatological applications for SDC as an active pharmaceutical ingredient. The Company also has a partnership with specialty chemical manufacturer Ciba (now BASF) to market SDC in a variety of personal care products. In addition, SDC has industrial applications, including food processing, rural water treatment and agriculture.