

food contact world

Owner declares its contact biocide to be safe

By Food Contact World

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Pure Bioscience declared its patented silver dihydrogen citrate (SDC) antimicrobial to be 'generally recognised as safe' (Gras). The self-affirmation is for the aqueous product used on food processing equipment, machinery and utensils.

Companies are free to make the determination of a substance as Gras without seeking pre-market approval from the US *Food and Drug Administration* (FDA). The decision must be based on generally available and accepted scientific data.

Sanford Bigelow of *Vanguard Global Associates* prepared the Gras documentation, which was independently reviewed. The experts are Wayne Bidlack, Gras consultant and professor at *California State Polytechnic University*, and Robert Deibel of *Deibel Laboratories*.

Tom Myers, executive vice president of sales and marketing for the publicly traded company, notes: 'Having Gras designation puts Pure Hard Surface in a league of its own as we move into the food processing market.'

Pure is not required to seek a concurrence letter from the agency, and the company did not petition for one. The FDA keeps an *inventory* of Gras notices it does receive, however.

In response to an inquiry from Food Contact World, the company says: 'When contacted by Vanguard Global Associates, the FDA agreed that a food contact notification was not appropriate for the use patterns outlined in the Gras determination, based upon the US EPA's jurisdiction for regulatory oversight.'

The uses outlined for food contact applications are primarily regulated by the US *Environmental Protection Agency* (EPA) under the Federal Insecticide, Fungicide and Rodenticide *Act*, and the amending Food Quality Protection *Act* of 1996.

The EPA granted registration for the SDC as a food contact surface sanitiser, on the basis of an exemption from the requirement for a pesticide tolerance (see Food Contact World 5.10).

Because the FDA shares jurisdiction with the EPA in enforcing the EPA-established exemption from the requirement for a pesticide tolerance, the uses outlined in the Gras determination are eligible for Gras status.

Pure intends to file Gras declarations directly related to food contact notification eligible uses with the FDA.

Myers says: 'Gras resonates strongly in the industry,



pure Hard surface eliminates food pathogens and is registered with the epA for use on food contact surfaces and eases the challenge of introducing a completely new technology by providing customers with assurance that, in spite of its powerful antimicrobial activity, the SDC is safe.

‘In addition, customers are assured that the SDC will not negatively impact their food products or processes.

‘Looking ahead, this Gras designation also lays the groundwork for expansion of the SDC applications as a food additive.’