

EPA Grants Emergency Exemption to Texas Antimicrobial with 7-Day Efficacy Claim Allowed for Use by American Airline and Two Clinics

On August 24, 2020, the U.S. Environmental Protection Agency (EPA) authorized a public health emergency exemption under the provisions of Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to the Texas Department of Agriculture (TDA) for use of an unregistered product, SurfaceWise®2, on non-porous, nonfood-contact surfaces to control the novel coronavirus (Severe Acute Respiratory Syndrome Coronavirus 2 or SARS-CoV-2), for use by 27 American Airlines aircraft and airport facilities in Texas, as well as Total Orthopedics Sports and Spine, also in Texas.

According to EPA, SurfaceWise®2, manufactured by Allied BioScience, Inc., inactivates SARS-CoV-2 on surfaces for up to 7 days. After reviewing the available data and information, EPA determined that the product in question will help address the current national emergency related to the pandemic. Consequently, EPA granted to the TDA a rarely issued emergency exemption for use of an antimicrobial product related to a public health emergency. Emergency exemptions may be granted by EPA under defined conditions set forth in Section 18 of FIFRA. FIFRA governs the manufacture, sale and use of all pesticides in the U.S., including disinfectant products intended to be used on inanimate surfaces.

Efficacy Data. According to the Agency, data was submitted that demonstrated the coating's efficacy against a different human coronavirus similar to SARS-CoV-2 (COVID-19), as well as bacteria. EPA stated that it expects products that are effective against other human coronaviruses will also be effective against SARS-CoV-2. In addition, data was submitted that indicated the product remains efficacious up to 7 days after application and inactivates the virus after 2 hours of exposure on the surface. Additional data are needed in order to substantiate other claims that the product is effective for periods of time longer than 7 days. EPA is working with TDA and the manufacturer to review additional data that may support such claims.

Limitations. As an emergency exemption, the use of SurfaceWise®2 is limited in a number of ways by EPA. First, the emergency exemption granted by EPA is effective for one year. Moreover, the product is geographically restricted to use at two Texas Methodist Health Group Total Orthopedics and Spine Clinics, and American Airlines aircraft and airport facilities at specific locations in Texas, as specified in the TDA's Section 18 request.

In addition, SurfaceWise®2 is not available for sale or use by the general public; it may only be sold by Allied BioScience to American Airlines authorized users and Total Orthopedics Sport and Spine Clinics for their use in Texas. It is also important to note that EPA calls for pre-cleaning and disinfection prior to applying SurfaceWise®2. Specifically, prior to application of SurfaceWise®2, EPA states that surfaces must be pre-cleaned/disinfected using a one-step EPA registered disinfecting cleaner listed under List N: Disinfectants for use against SARS-CoV-2.

For more detail on the conditions EPA has placed on the use of SurfaceWise®2, please see EPA's correspondence to American Airlines and Total Orthopedics authorizing the public health emergency exemption:

- American Airlines: https://www.epa.gov/sites/production/files/2020-08/documents/20tx05-aa-auth_8-24-2020.pdf
- Total Orthopedics: <https://www.epa.gov/sites/production/files/2020-08/documents/20tx04-toss-auth-8-24-2020.pdf>

Background: Section 18 Emergency Exemptions. Section 18 of FIFRA authorizes EPA to exempt state and federal agencies from certain provisions of FIFRA and allow unregistered uses of pesticides, including disinfectant products, to address emergency conditions, including public health emergencies. Under such an exemption, EPA allows limited use of a pesticide in defined geographic areas for a finite time, once EPA confirms that the situation meets that statutory definition of "emergency condition."

The regulations governing Section 18 of FIFRA (found at [Title 40 of the Code of Federal Regulations, part 166 \(40 CFR 166\)](#)) define the term "Emergency Condition" as an urgent, non-routine situation that requires the use of a pesticide(s). EPA must also conduct assessments of potential risks to human health and the environment which confirm the pesticide use meets the required safety standards. The state or federal agency applying for the Section 18 exemption must submit information describing the pest emergency and request permission for a specific unregistered pesticide use. Instructions for applicants and detailed listings of required information to include in emergency exemption requests may be found at 40 CFR 166.

Section 18 emergency exemptions must be requested by a state or federal agency.

Historically, Section 18 emergency exemptions are routinely requested and granted for use in agricultural settings involving invasive pest outbreaks. EPA's August 24th announcement is the first Section 18 emergency exemption that we are aware of that authorizes the use of an antimicrobial product for a public health emergency.

To date, Texas is the only state that has petitioned EPA under Section 18 for emergency use of antimicrobial products to address the current public health crisis. Other states can submit Section 18 Emergency Exemption Requests to EPA. Typically, EPA evaluates these requests within 45 days, assessing whether the criteria for an emergency are met and the if product meets the required standards for safety and efficacy. EPA anticipates that it would process much more quickly requests involving products and claims similar to the one EPA addressed on Aug. 24.

To learn more about the Section 18 Emergency Exemptions granted by EPA under FIFRA, please visit <https://www.epa.gov/pesticide-registration/pesticide-emergency-exemptions>.

Going Forward. At the present, EPA has indicated that it does not have an established protocol that would allow manufacturers to pursue a "traditional" disinfectant registration under

Section 3 of FIFRA. However, the Agency has promised to make such information available “in the coming weeks” so that manufacturers may seek registration for similar antiviral surface coatings.

In the interim, states or federal agencies interested in pursuing a Section 18 Emergency Exemption Request for products that claim residual efficacy against viruses for up to seven days should be prepared to include efficacy data demonstrating that the product is both durable and effective against viruses in their applications. For example, according to EPA, antiviral efficacy should be assessed using methods that account for conditions expected to exist in settings where the products will be used, such as surfaces that are exposed to physical touches or abrasion and treated in combination with other cleaning products and disinfectants.

SurfaceWise2 is not yet available to the general public because Allied Biosciences has not yet submitted the necessary data to qualify for registration under section 3 of FIFRA. However, EPA’s current understanding is that the company intends to complete the necessary research and apply for registration. If the full registration process is completed, the product would become available for purchase by members of the public and may be eligible to be included as a supplement to EPA’s List N.