

#### **Introduction to Selecting an EPA-Labeled Sanitizer**

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The use of properly labeled sanitizers (i.e., antimicrobial pesticides) in water that comes in contact with fruits and vegetables at or after harvest is highly encouraged to reduce the risk of crosscontamination by human pathogens. The use of sanitizers that have a United States Environmental Protection Agency (EPA) label are encouraged since these products have been evaluated by the EPA to limit the product's impact on the environment and human health. Sanitizers are employed as a water treatment to prevent the spread of contamination in harvest and postharvest systems, such as dump tanks (or high volume tanks) and flumes. Sanitizers also can be used as part of a multi-step cleaning and sanitizing routine to reduce the level of pathogens on food contact surfaces to acceptable levels (see 'sanitizer' in Produce Safety Alliance glossary)1. Once growers realize the significant role that sanitizers play, they often ask how to find and select an EPA-labeled sanitizer. This document has been developed for educators to help growers understand the importance of selecting a labeled sanitizer and using the right sanitizer for their operation.

### Why should growers use an EPA-labeled sanitizers?

Sanitizers fall under the <u>EPA definition of an</u> <u>antimicrobial pesticide</u> because they are "substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms such as bacteria, viruses, or fungi..."<sup>2</sup>. All pesticides distributed in the U.S. are regulated by the EPA Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA ensures that using a product correctly will help to limit the product's risk to humans, wildlife, and the environment. All pesticides sold in the U.S. must be registered and list an EPA registration

number. Additionally, EPA must review any statements made on the product's label; this information may include efficacy statements describing the organism(s) that the sanitizer will control if used according to label instructions, and directions for use, storage, and disposal. More information can be found in the EPA FIFRA summary document<sup>3</sup>. Though the FSMA PSR does not expressly require growers to use an EPA-labeled sanitizer, it is one way to determine if a sanitizer will be effective. If a grower uses a sanitizer that does not have an EPA label, the grower should be able to prove that the product is suitable for the intended use (such as washing fresh produce) and for reducing contamination risks.

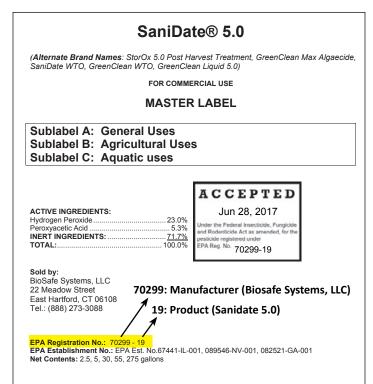
#### What should a grower look for in a sanitizer label?

Here are key elements of a sanitizer label that should be reviewed by growers. They are each addressed in detail below:

- EPA registration number to identify the product
- Labeled use(s) for the sanitizer, such as sanitizing nonporous food contact surfaces
- Instructions to guide the use of the sanitizer
- Efficacy statement listing organisms the product is labeled to treat

When selecting a sanitizer to incorporate into food contact surface sanitation activities or postharvest water treatment, growers should first determine whether the sanitizer has an EPA registration number; this unique identifier demonstrates that the product is registered with EPA. The EPA number may be listed in several places including on the label on the outside of the product bottle, on the EPA label that may or

may not be on the bottle, and/or with paperwork accompanying the product. EPA registration numbers include two or three fields, separated by hyphens. The first set of numbers references the manufacturer, the second set designates the specific product, and if present, the third field identifies the vendor's private label. The EPA registration number for Sanidate 5.0 can be used as an example, see Figure 1. Understanding the parts of an EPA registration number can be helpful when searching through sanitizer labels.



**Figure 1**: Sanidate 5.0 is a commonly used sanitizer with the EPA registration number 70299-19. The first field, 70299, is specific to the manufacturer (Biosafe Systems, LLC), and the second field, 19, identifies the Sanidate 5.0 product itself. In this example, there is no third number because the company does not have a private label.

When reviewing a sanitizer label, notice that the label includes a statement indicating labeled uses. Growers need to use a sanitizer that is labeled for a specific purpose; relevant examples of labeled uses may include sanitizing nonporous food contact surfaces or treating fruit and vegetable washwater. Once an appropriately labeled sanitizer is selected, growers must follow the usage directions on the EPA label. Each sanitizer label contains instructions for using

the product according to its labeled use, including information such as dilution rates, minimum contact time, storage, and disposal. These directions must be followed exactly as written.

Sanitizer labels should also list the types of microorganisms that the product is able to control. Many sanitizers used on farms and packinghouses are labeled to control postharvest spoilage and decaycausing organisms or public health organisms (e.g., Escherichia coli or Listeria monocytogenes). Sanitizers with an EPA label to control public health organisms must have an efficacy statement describing the organism(s) the product is effective at controlling and the demonstrated level of control. The claims must be supported by data demonstrating that the product is effective at controlling the target microorganism(s). More information on sanitizer efficacy claims can be found in the EPA Product Performance Test Guidelines for Antimicrobial Agents<sup>4</sup>. Although the FDA has not yet (as of October 2018) issued guidance to clarify whether sanitizers used by growers to meet requirements of the FSMA Produce Safety Rule must be specifically labeled to control public health organisms, some third party auditors may look for this labeled use when conducting Good Agricultural Practices (GAPs) audits.

## How can growers select an appropriate sanitizer for their operation?

In addition to ensuring that a sanitizer has the federal EPA registration number, many states restrict the use of pesticides sold and used within the state and may require additional state registration<sup>5,6</sup>. Not all federally registered sanitizers are approved for use in all states. A sanitizer product registered for use in Maryland, for example, may not be registered for use in California. How can growers navigate the EPA and state registration systems to select a sanitizer that is approved for use in a particular state? The public National Pesticide Information Retrieval System (NPIRS), hosted by Purdue University, is a searchable database of EPA-labeled products<sup>7</sup>. The federal NPIRS list can be used in conjunction with the public state NPIRS directory to find sanitizers approved in certain states8.

A chemical that is registered by one company, with a single EPA registration number, may also be sold by other companies under different brand names and vendor labels. This situation is similar to over-the-counter medication, where the same drug is marketed under a variety of different names. It is important for growers to check that these types of third-party sanitizers are registered for use in their state and also labeled for the intended use (e.g., sanitizing food contact surfaces or produce wash water). Just as all federally registered sanitizers are not approved for use in all states, not all third-party sanitizers are approved in each state.

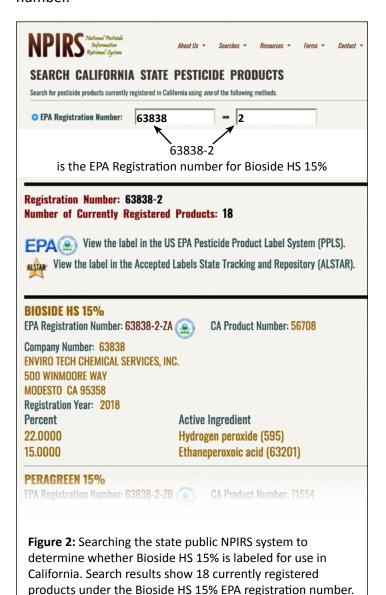
When advised to use a sanitizer that is 'EPA-labeled', growers are asked to check for multiple components: the sanitizer must have a federal and state registration; it must be labeled for its intended use, such as nonporous food contact surfaces or fruit and vegetable washwater; and if it is labeled to control public health organisms it should be appropriately labeled for specific target microorganisms, such as Salmonella enterica or Listeria monocytogenes (instead of human pathogens less relevant to produce safety, such as the respiratory pathogen Klebsiella pneumoniae).

# What resources are available to assist growers in finding the right sanitizer for their operation?

Navigating these requirements may make selecting an appropriate sanitizer difficult for growers, however resources are available to help growers select a sanitizer suitable for their operation. The Produce Safety Alliance (PSA) has developed a 'Labeled Sanitizers for Produce' Excel tool describing EPA-labeled products, as well as a corresponding video tutorial 9,10. The list of EPA-labeled sanitizers in the PSA tool can be used in conjunction with the public state NPIRS list to develop a state-specific list of approved sanitizers8.

In order to determine if a sanitizer has state approval using the public state NPIRS tool, begin with a sanitizer that has a federal EPA label; only sanitizers with a federal EPA label can be found through the

NPIRS system. The list of sanitizers in the PSA Excel tool may be a useful starting point. Type the EPA registration number of the individual product into the state-specific NPIRS tool to determine if the sanitizer is approved for use in the state. Figure 2 demonstrates the public state NPIRS directory being used to check whether Bioside HS 15%, a peroxyacetic acid sanitizer, is labeled for use in California (EPA registration number: 63838-2). Users will find that the search results for specific states will often include privately labeled names. For example, the state search for Bioside HS 15% shows that it is approved for use in California, with 18 privately labeled sanitizers (as of October 2018) listed under the single EPA registration number.



Before assuming the 18 privately labeled products are suitable, the marketing label should be checked to make sure the private label retained the same uses as in the product-specific marketing label. While a comprehensive state-by-state resource is not currently available, educators working in this field should consider creating a state-specific list of approved sanitizers to supplement PSA Grower Training courses and distribute as outreach material.

In summary, growers are being increasingly encouraged to incorporate a sanitizer into their postharvest practices and cleaning/sanitation programs due to the documentation of foodborne illness outbreaks that have been associated with postharvest activities. <sup>11</sup> The process of selecting an EPA-labeled sanitizer can be a source of confusion, and this fact sheet is intended to be a resource to help growers select effective, labeled sanitizers for their operation. If there are questions or additional information that may impact that contents of this factsheet, please contact Donna Pahl of the PSA team. The PSA team's contact information may be found on the PSA website.

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