



North Carolina Department of Health and Human Services  
Division of Public Health

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April 27, 2015

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MAY 04 2015  
BY: \_\_\_\_\_

Rebecca Lei, Quality Assurance manager  
Aquaiox, Inc.  
16155 Sierra Lakes Parkway – Suite 160-714  
Fontana, CA 92336

Dear Ms. Lei,

Thank you for sharing the test data and documentation regarding regulatory listings of Aquaiox Disinfectant 275 and Aquaiox Disinfectant 525 with the U.S. Environmental Protection Agency (EPA). The reason this department has requested the data is the process equipment used to generate electrolyzed water disinfectants for use on site are not subjected to the same data review for efficacy that the EPA requires for EPA-registered disinfectants that enter commerce. That has resulted in manufacturers of disinfection process equipment making disinfectant claims for processes that were not fully tested in the past.

Current North Carolina Rules Governing the Sanitation of Hospitals, Nursing Homes, Adult Care Homes and Other Institutions (15A NCAC 18A .1300) require patient contact surfaces in health care settings to be disinfected with an EPA-registered hospital disinfectant. The EPA registration number on the label of all disinfectant products that enter commerce provides assurance that EPA has completed a data review to assure the efficacy of the product.

Under the Federal Insecticide, Fungicide and Rodenticide Act, Manufacturers are not permitted to make label claims for antimicrobial pesticides for use as disinfectants unless there is data to support those claims, but since products generated for use on site never enter commerce, EPA does not require the data review and provide a registration number for the on-site products. For this department to accept an unregistered disinfectant product generated on site as equivalent to an EPA Registered product, we need to know the product has been subjected to the same efficacy testing as the registered products.

Based on the information you provided, Aquaiox Disinfectant 275 has been tested and registered by EPA under Pesticide Producing Establishment Number 85021-CA-001, Registration Number 85021-4, and Aquaiox Disinfectant 525 is registered under Pesticide Producing Establishment Number 85021-CA-001, Registration Number 85021-5. You have indicated identical equipment to that used to prepare the EPA-registered products is being placed in health care facilities in North Carolina to generate disinfectant products identical to the EPA-registered products on site.

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Tel 919-707-5000 • Fax 919-870-4829

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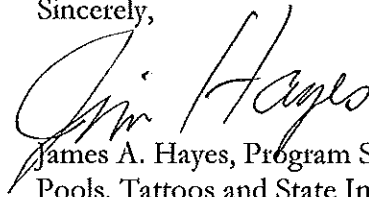
After reviewing the test data and documentation of EPA registration of the products, this department has determined that Aquaox Disinfectant 275 and Aquaox Disinfectant 525 generated on site using an Aquaox Pesticide Producing Establishment Number 85021-CA-001 electrolyzed water generator are the same as the EPA-registered Aquaox Disinfectant 275 and Aquaox 525 products produced and shipped commercially. Both the products shipped and those prepared on site are compliant with the requirement for use of EPA-registered hospital disinfectants.

The North Carolina Rules Governing the Sanitation of Hospitals, Nursing Homes, Adult Care Homes and Other Institutions further require disinfectant products mixed or prepared on site to be either measured or tested for quality control. Based on the descriptions and documents you provided, the process equipment monitors pH and oxidation-reduction potential of the product and will cease production if the product strength varies from acceptable concentrations. Further chemical field testing to verify the free available chlorine content of the products is done at least daily and a log of the test results is kept with the equipment. The quality control methods recommended by Aquaox do meet the requirement for measuring or testing the product.

I understand Aquaox, LLC, CA has received a separate pesticide producing establishment number 85021-CA-002 and Aquaox, LLC has applied in EPA Region 4 for a North Carolina establishment number likely to be 85021-NC-00X. I am not sure different establishment numbers are needed, but it is understood that identical Aquaox electrolyzed water generators may be labeled with one of the three establishment numbers. Please verify how the equipment will be labelled so I can update this letter to indicate the appropriate establishment number.

Thank you for your assistance in providing complete information for us to review.

Sincerely,

A handwritten signature in cursive script that reads "Jim Hayes".

James A. Hayes, Program Supervisor  
Pools, Tattoos and State Institutions Program