NSF Protocol P423

Electrochemically Activated Water Cleaning and Sanitizing Devices in Commercial Food Operations

The Public Health and Safety Company.™

NSF International, an independent, not-for-profit organization, is dedicated to public health safety and protection of the environment by developing standards, by providing education and by providing superior third-party conformity assessment services while representing the interest of all stakeholders.

This Protocol is subject to revision.
Contact NSF to confirm this revision is current.

Users of this Protocol may request clarifications and interpretations, or propose revisions by contacting:

NSF International
789 Dixboro Road
Ann Arbor, MI 48105
Phone: (734) 769-8010 FAX: (734)769-0109
E-mail: info@nsf.org
Web: http://www.nsf.org

NSF Protocol P423
Electrochemically Activated Water Cleaning and Sanitizing Devices in Commercial Food Operations

NSF International
Engineering & Research Services

Prepared by NSF Engineering & Research Services staff with assistance from NSF Protocol Development Panel members shown below:

- Robert Powitz, Ph.D., MPH
- Syd Williams, GenEon Technologies, Inc.
- Michael Kohler, NSF International
- Elizabeth Nutt, Tulsa Health Department
- Daniel Okenu, Ph.D., MPH, Chick-fil-A, Inc.
- Dr. Yen-Con Hung, Professor, University of Georgia, Department of Food Science and Technology
- Cameron Wiggins. Georgia Department of Health
- Roger Carlson, Senior Engineer, ACP Solutions

Originated October 2012

Published by
NSF International, 789 N. Dixboro Road, Ann Arbor, Michigan 48105, USA

Disclaimers

NSF International (NSF), in performing its functions in accordance with its objectives, does not assume or undertake to discharge any responsibility of the manufacturer of any other party. The opinions and findings of NSF represent its professional judgment. NSF shall not be responsible to anyone for the use of or reliance upon this protocol by anyone. NSF shall not incur any obligations or liability for damages, including consequential damages, arising out of or in connection with the use, interpretation of, or reliance upon this protocol.

Participation in NSF's protocol development activities by a representative of a regulatory agency (Federal, state, local) shall not be construed as the agency's endorsement of NSF, its policies, or any of its protocols.

NSF Protocols provide basic criteria to promote and protect public health and the environment. Provisions for safety have not been included in this protocol because governmental agencies or other national standards-setting organizations provide safety requirements.

Unless otherwise referenced as normative, the appendices are not considered an integral part of NSF protocols. They are provided as general guidelines to the manufacturer, regulatory agency, user, or certifying organization.

NSF Protocol P423
Electrochemically Activated Water Cleaning and Sanitizing Devices in Commercial Food Operations

1 General

Engineered electrochemically activated water systems are a class of products, typically including a specially designed reactor and a collection and dispensing vessel, that produces cleaning and sanitizing products through electrically activating tap water or water and salt into ionic compounds containing oxidizers such as oxygen, chlorine, bromine or iodine, as well as weak (or dilute) ionic reducing agents used for cleaning of oily soils. The systems are intended to create cleaning/sanitizing solutions on-site, eliminating the need to purchase, transport and store cleaning products.

1.1 Purpose

This protocol describes the requirements for the safety and effectiveness of engineered electrochemically activated sanitizer devices and their applicability to produce a cleaner and sanitizer that could be used as a substitute for chemical sanitizers to be used on food contact surfaces in commercial food operations.

For the purposes of this protocol, it is assumed that the product manufacturer would specify that a batch of sanitizing solution would be created and consumed in the same 24-hour period. If a portion of a solution would remain unused after a 24-hour period, that solution would be discarded in accordance with the manufacturer's recommendations and applicable regulations and a fresh solution would be made.

1.2 Scope

The methods described in this protocol are intended to provide safety and testing requirements and acceptance criteria to certify that the sanitizer created through the electrochemical activation process is safe and effective for use as a sanitizer for food contact surfaces in commercial food operations. This protocol will set forth regulatory and safety requirements and laboratory testing criteria to demonstrate that the sanitizer meets testing requirements consistent with sanitizers in commercial food service operations, and the apparatus is suitable for use on non-porous food contact surfaces.

In the United States, sanitizing chemicals are regulated as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) by the U.S. Environmental Protection Agency (EPA). FIFRA defines a pesticide as, "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest…." In order to comply with FIFRA, chemical manufacturers must register their product and conduct studies to demonstrate the product's pesticidal performance claims. Sanitizers generated on-site through means such as electrochemical activation fall outside this definition, so the sanitizer generated by an electrochemically activated disinfectant device cannot be registered with the EPA under FIFRA. In general, electrochemically activated disinfectant devices are considered to be "Pesticidal Devices" and pesticidal device manufacturers are required to file the production establishment address, report annual production, and label their device in accordance with FIFRA reporting requirements.

The U.S. Food and Drug Administration (FDA) 2009 Food Code recognizes various categories of FIFRA-regulated sanitizers as being suitable for use in food establishments. Specifically, the 2009 Food Code specifies conditions under which FIFRA-registered sanitizers whose active ingredients contain free available chlorine, iodine, or quaternary ammonium compounds may be safely used in food establishments. Sanitizers generated on-site through means such as electrochemical activation falls outside the scope of FIFRA, but it is within the scope of the Food Code.

The FDA and USDA may give a "Generally Recognized as Safe" (GRAS) designation to food additives recognized as being adequately shown to be safe under the conditions of intended use. Electrochemically activated sanitizers may be classified as GRAS.

NSF Protocol P423 is intended to certify electrochemically activated sanitizer devices that produce sanitizers that meet the requirements of the 2009 Food Code, even though those sanitizers are not registered under FIFRA. The protocol sets forth the following key elements:

1. Materials requirements, indicating that the electrochemically activated sanitizer device is made of substances suitable for use in food establishments, and designed to promote cleanability;
2. Labeling and product information requirements, to ensure that operating instructions are clear and legible; that the instructions and device yield a suitable sanitizer; and that the product labels meet the FIFRA labeling requirements for pesticides;
3. Testing criteria that demonstrate that the concentrations of active ingredients in the electrochemically activated sanitizer achieve the active ingredient requirements in the Food Code, and that the sanitizer kill microorganisms at rates established by EPA and in the Food Code.

1.3 Limitations

The requirements of this protocol are limited to addressing the suitability, safety and effectiveness of electrochemically activated sanitizers and associated devices for use on food contact surfaces in commercial food service establishments.

Certification to this protocol does not supersede the jurisdictional authority of regulatory agencies. It shall be the applicant's responsibility to determine their compliance with applicable local, State and Federal regulations.

2 Normative References

The following documents contain provisions that, through reference in this text, constitute provisions of this protocol. At the time of publication, the indicated revisions were valid. All standards are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

- 40 CFR 156 – Labeling requirements for pesticides and devices.

- 40 CFR 180.940 – Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

- American Public Health Association - Standard Methods for the Examination of Water and Wastewater, 21st Edition, January 2005.
- AOAC 955.16 Chlorine (Available) in Disinfectants
- AOAC 960.09 Germicidal and Detergent Sanitizing Action of Disinfectants
- California Health and Safety Code Part 7 – California Retail Food Code
- Codex Alimentarius Standard 150-1985, "Codex Standard for Food Grade Salt," Amendment 3-2006.
- EPA DIS/TSS 4- Sanitizing Rinses (for previously cleaned food-contact surfaces)
- NSF/ANSI 170, Glossary of Food Equipment Terminology.
- NSF/ANSI 51, Food Equipment Materials.
- NSF/ANSI 53, Drinking Water Treatment Units – Health Effects.
- Underwriters Laboratories (E23357970JJ)
- U. S. Food and Drug Administration – FDA Food Code 2009.
- U. S. Food and Drug Administration - Bacterial Analytical Manual, March 2012. Available online at: http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm.

3 Definitions

Terms used in this protocol that have a specific technical meaning are defined here.

3.1 Electrochemically Activated Sanitizer: A sanitizer created through an electrochemical reaction including water or water and salt.

3.2 Electrochemically Activated Sanitizer Apparatus: The physical device used to create electrochemically activated sanitizer. The electrochemically activated sanitizer apparatus generally includes a liquid storage container and a base with electric probes designed to initiate the electrochemical reaction.

3.3 General Test Water: A public water supply utilized for tests that meets the specific characteristics outlined in NSF/ANSI 53, Drinking Water Treatment Units – Health Effects:

pH	7.5 ± 0.5
temperature	20 ± 2.5 °C (68 ± 5 °F)
total dissolved solids (TDS)	200 – 500 mg/L
total organic carbon (TOC)	> 1.0 mg/L
turbidity	< 1 NTU

3.4 GRAS: An acronym for the phrase Generally Recognized as Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

3.5 parts per million (ppm): A unit of concentration. 1 part per million = 1 milligram per liter.

3.6 Sanitization: The application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance (Source: U. S. Food and Drug Administration – FDA Food Code 2009).

3.7 Sanitizer: For food service applications, a chemical substance that reduces bacterial concentrations by 99.999%.

3.8 Protocol: A written reference document that clearly states the objectives, goals, scope, and procedures for a study.

4 Materials

The requirements contained in this section are intended to protect food from contamination and ensure that the materials used in the manufacture of food handling and processing equipment resist wear; penetration by vermin; and the effects of foods, heat, cleaning compounds, sanitizers, and other substances that may contact the materials in the intended use environment. Materials used in unexposed non-food zone areas shall be exempt from all requirements in 4.

4.1 Conformance with NSF/ANSI 51

Materials shall conform to the requirements in NSF/ANSI 51 applicable to the zone in which the material is used.

4.2 Solder

Solder containing lead as an intentional ingredient shall not be used in a food zone or splash zone.

4.3 Corrosion Resistance

Materials shall be corrosion resistant in the intended end-use environment.

4.4 Salt

Salts used in the generation of electrochemically activated sanitizer must meet the requirements set forth in the “Codex Standard for Food Grade Salt (CODEX STAN 150-1985)” or provide alternate demonstration that the salt meets food grade requirements.

5 Design and Construction

This section contains design and construction requirements for equipment covered within the scope of this Protocol.

5.1 General Sanitation

5.1.1 Equipment shall be designed and manufactured to prevent the harborage of vermin and the accumulation of dirt and debris, and to permit the inspection, maintenance, servicing, and cleaning of the equipment and its components.

5.1.2 Splash zone surfaces shall be accessible and cleanable.

5.2 Electrical Safety

Equipment shall be certified to the applicable electrical safety standards.

6 Labeling and Product Information Requirements

The product packaging must include the following information, consistent with the Establishment labeling requirements established in 40 CFR 156.10:

6.1 Label Contents

At a minimum, the product label must include the following information:

1. Product name, brand, or trademark;
2. Manufacturer name, and phone number or Internet address;
3. Net contents;
4. EPA Establishment Number or Registration Number;
5. Ingredient statement;
6. Solution preparation instructions;
7. Use instructions;
8. Hazard and precautionary statements;
9. First aid instructions;
10. Product performance claim;
11. NSF Mark or reference to NSF certification (see Annex A).

6.2 Operation and Instruction Manual

The product must include an Operation and Instruction Manual that includes the following information:

1. Product Name;
2. Manufacturer name, address, phone number and Internet address;
3. Contents List (to include catalyst);
4. Information on ordering replacement parts or electrolyte;
5. Solution preparation instructions;
6. Use instructions;
7. First aid instructions;
8. Disposal/recycling information for solutions or products;
9. EPA Establishment Number or Registration Number;
10. Water quality requirements, if certain water quality parameters need to be achieved;
11. Warranty information;
12. Troubleshooting information; and
13. NSF Mark and reference to NSF certification (see Annex A).

6.3 Legibility

All words, statements, graphic representations, designs, or other required information must be clearly legible, easy to understand, and conspicuous.

1. All required label text must be set in 6-point or larger type, appear on a clear contrasting background, and not be obscured or crowded.
2. All required label text must be in a language suitable for the country where the product is to be used.

7 Performance

7.1 Ability to Produce Sanitizer

This test is designed to evaluate whether the Electrochemically Activated Sanitizer apparatus can produce a sanitizer based on an evaluation of the active ingredient in the electrochemically activated sanitizer.

Based on Section 4-501.114 of the 2009 FDA Food Code, a chemical sanitizer used in a sanitizing solution for manual of mechanical operation must have the characteristics expressed in Table 1. An Electrochemically Activated Sanitizer apparatus must therefore demonstrate the ability to produce sanitizing solution that repeatedly meets these characteristics.

Table 1: Chlorine Sanitizer Characteristics (Based on 2009 FDA Food Code)

Active Ingredient[1]	Concentration Range (mg/L)	Minimum Temperature (°C)	pH Range (S.U.)
Chlorine Solution (as free available chlorine)	≥100	13	10 or less

Notes:

1. Solutions other than chlorine must demonstrate through microbiological testing that the solution achieves sanitization and comply with applicable requirements of the Food Code.
2. Concentration range chosen to comply with requirements of the California Retail Food Code.

7.1.1 Test Procedure

This test shall be conducted with five (5) replicates. The manufacturer shall submit five apparatuses for simultaneous testing.

1. Produce general test water that meets the specifications outlined in NSF/ANSI 53.

2. Produce electrochemically activated sanitizer in accordance with the manufacturer's instructions.

    a. The test shall be conducted indoors at a room temperature of (23°C ± 5°C). Record the room temperature on a bench sheet.
    b. The units shall be plugged in to an electrical outlet that meets the manufacturer's electrical requirements. The voltage on each outlet used must be within ± 5V of the manufacturer's recommendation. Record the voltage on a bench sheet.
    c. The units shall be filled with general test water meeting the requirements of ANSI NSF 53. The container shall be filled with a volume of water specified in the manufacturer's instructions, measured to within ± 5 mL. Record the water volume for each replicate on a bench sheet.
    d. If salt or additional additive(s) are required to make the solution, the additives shall be placed into the container in accordance with the manufacturer's instructions, measured to within ± 0.1 g. Record the additive weight for each replicate on a bench sheet.
    e. Activate the electrochemically activated water device in accordance with the manufacturer's instructions. The operating cycle for each replicate must be within a time range of ± 10%. Specify the operating cycle for each replicate on a bench sheet.

3. Within 30 sec of completion of the activation cycle, remove the activated solution from the power source and store in the apparatus container at room temperature.

4. Within 60 min of the completion of the activation cycle, analyze a sample of the electrochemically activated water for the presence of the active ingredient. Also measure pH of the solution. Each replicate shall meet the requirements outlined in Table 3.

Table 3. Active Ingredient Analysis

Analyte	Allowable Concentration	Allowable Concentration Range
Free available chlorine	≥100 mg/L	±20% of average
pH	≤10 S.U.	±20% of geometric mean

7.2 Active Ingredient Stability

This test is designed to ensure that once produced, the electrochemically activated water remains in a condition where the active ingredient(s) remain in a state suitable for chemical disinfection.

This test shall be conducted with five (5) replicates. The manufacturer shall submit five apparatuses for simultaneous testing.

7.2.1 Test Procedure

1. Produce the electrochemically activated sanitizer in accordance with Section 7.1.1.
2. Remove the apparatus from the power source and remove 50% ± 5% of the solution from the apparatus container. Seal the apparatus container using the equipment associated with the device.
3. Place the half-full container in a cabinet or storage area at room temperature (23°C ± 5°C) for a period of 24 ± 2 hours.
4. At the end of the storage period, analyze the remaining solution for the active ingredient and pH. Each replicate shall meet the requirements outlined in Table 3.

7.3 Sanitizer Effectiveness

This test is designed to ensure that the product generated in Section 7.1.1 is effective as a sanitizer.

7.3.1 Devices Producing Chlorine

Devices producing chlorine are exempt from microbiological testing.

7.3.2 Devices Producing Halides

Iodophors, mixed halides, and chlorine bearing chemicals produced shall be tested according to AOAC 955.16 Chlorine (Available) in Disinfectants. *Salmonella enterica* ATCC 6539 shall be the test organism. Chemicals produced shall demonstrate equivalence to 100 ppm chlorine.

7.3.3 Devices Producing Other Chemicals

Quaternary ammonium compounds, chlorinated trisodium phosphate, and anionic detergent-acid formulations produced shall be tested according to AOAC 960.09 Germicidal and Detergent Sanitizing Action of Disinfectants. *Escherichia coli* ATCC 11229 and *Staphylococcus*

aureus ATCC 6538 shall be the test organisms. Chemicals produced shall demonstrate 99.999% reduction of each organism within 30 seconds.

8 Acceptance Criteria

An Electrochemically Activated Sanitizer in Commercial Food Operations device is considered to have met the requirements of NSF Protocol P423 when all of the following conditions have been met:

8.1 Materials

Materials used in the construction of the Electrochemically Activated Sanitizer in Commercial Food Operations device conform to the requirements outlined in Sections 4.1 through 4.3 of this protocol.

8.2 Salt

If salt is used in making Electrochemically Activated Sanitizer solution, it meets the requirements outlined in Section 4.4 of this protocol.

8.3 Design and Construction

The design and construction of the Electrochemically Activated Sanitizer in Commercial Food Operations device conform to the requirements outlined in Section 5 of this protocol.

8.4 Labeling and Product Information

The labeling and product information for the Electrochemically Activated Sanitizer in Commercial Food Operations device conform to the requirements outlined in Section 6 of this protocol.

8.5 Ability to Produce Sanitizer

When the Electrochemically Activated Sanitizer apparatus is operated in accordance with Section 7.1 of this protocol, it is able to able to produce sanitizer that meets the following specifications:

8.5.1 Chlorine Solution

1. Each test replicate produces an Electrochemically Activated Sanitizer that achieves a minimum of 100 mg/L free available chlorine;
2. The chlorine concentration from each replicate does not vary more than the average concentration of all replicates by more than ±20%;
3. Each test replicate produces an Electrochemically Activated Sanitizer with a pH of 10 or lower;
4. The pH from each replicate does not vary more than the geometric mean concentration of all replicates by more than ±20%.

8.6 Sanitizer Stability

When the Electrochemically Activated Sanitizer apparatus is operated in accordance with Section 7.2 of this protocol, it is able to able to produce sanitizer that meets the following specifications:

8.6.1 Chlorine Solution

1. Each test replicate produces an Electrochemically Activated Sanitizer that achieves a minimum of 100 mg/L free available chlorine;
2. The chlorine concentration from each replicate does not vary more than the average concentration of all replicates by more than ±20%;
3. Each test replicate produces an Electrochemically Activated Sanitizer with a pH of 10 or lower;
4. The pH from each replicate does not vary more than the geometric mean concentration of all replicates by more than ±20%.

8.7 Sanitizer Effectiveness

When the Electrochemically Activated Sanitizer solution is tested in accordance with Section 7.3 of this protocol, it shall achieve the following:

- Iodophors, mixed halides, and chlorine bearing chemicals shall demonstrate equivalence to 100 ppm chlorine.
- Quaternary ammonium compounds, chlorinated trisodium phosphate, and anionic detergent-acid formulations produced shall demonstrate 99.999% reduction of each organism within 30 seconds.

Annex A

Program Specific Policies

A.1 Marking

In addition to the requirements outlined in the NSF Certification Policies for NSF Protocols and Non-NSF Standards, certified individual products, packaging materials, or promotional information should bear the following information:

NSF Protocol P423
Electrochemically Activated Sanitizers in
Food Service Operations

A.2 Audits / Re-testing

NSF shall conduct audits of all production locations at least annually. Audits will cover the following basic items, at a minimum:

- No process or product changes have been made that could affect the performance of the certified product.
- Labeling shall be consistent with the requirements described in this protocol.
- Product data and records, along with nonconformance records, are maintained at the facility and are available for inspection. Records shall be maintained for a minimum of the preceding three year period.