

Efficacy of the ECA technology of Nera-Tec GmbH

DHI
Agern Alle 5
DK-2970 Hørsholm

+45 4516 9200 Telephone
+45 4516 9292 Telefax

dhi@dhigroup.com
www.dhigroup.com
Created by Michael Fink
mif@dhigroup.com
For the ECA Europe Group

1. Broad spectrum antimicrobial effect

2. Mode of action

3. Test results of representative biocidal products

DHI has submitted a complete dossier to the European Chemicals Agency (ECHA) on behalf of the ECA Europe Group. The dossier was compiled according to the requirements of the EU Biocidal Products Regulation 528/2012 for the purpose of getting ECA Europe group members listed on the article 95 list. The dossier was assessed to be complete by ECHA. The below specified tests were used in the dossier documentation.

1. Broad spectrum antimicrobial effect

Active chlorine generated in situ in aqueous solution referred to as "electrochemically activated solutions (ECAS)" have been shown to have broad-spectrum antimicrobial activity. Numerous studies have found ECAS to be efficacious against gram positive bacteria like *Staphylococcus* spp, *Listeria monocytogenes*, sporeforming *Bacillus* spp., *Clostridium difficile* and gram negative bacteria like *Legionella pneumophila*, *Pseudomonas aeruginosa*, *Enterococcus* spp., *Escherichia coli*, *Campylobacter jejuni*, the fungus *Aspergillus* spp and the yeast *Candida* spp.

2. Mode of action

Solutions with active chlorine characteristically have an ORP of +800 mV to +1,200 mV, creating an environment outside the working range of important microbial processes, including energy-generating mechanisms. If immersed in these solutions, microorganisms will be exposed to powerful oxidants which will sequester electrons with high efficiency from microbial structural compounds, causing the rupturing of biochemical bonds and subsequent loss of function. Moreover, the high ORP environment creates an unbalanced osmolarity between the ion concentrations in the solution and that within unicellular organisms, further damaging membrane structures. This causes increased membrane porosity, enabling oxidising moieties (present in excess in active chlorine solutions) to penetrate (via diffusion) into the cell cytoplasm, ultimately leading to the inactivation of intracellular protein, lipids and nucleic acids, rendering the cell non-functional.

3. Test results of representative biocidal products

Test solutions of active chlorine have been tested for their bactericidal, sporicidal, fungicidal and virucidal efficacy. The tests are either according to EN standards or national standards for testing efficacy of disinfectants. The tests have been performed on human skin, on non-porous surfaces and in aqueous suspensions in order to cover the full range of product types 1-5 defined in the BPR. The tests performed are phase 1 or phase 2 types of tests. No field trials (phase 3 tests) have been performed. The golden standard so far accepted by European authorities is that disinfectants have to

pass either phase 1 suspension tests or phase 2 semi-field tests. The results are presented in the following.

3.1 Efficacy against bacteria on skin

EN 1499 Chemical disinfectants and antiseptics: Hygienic handwash - Test methods and requirements: The test solution with active chlorine showed significantly more bactericidal activity than the positive control and more than log 4 reduction after 1 min. The test solution passed the efficacy criteria for hygienic handwashing products.

EN 1500 Chemical disinfectants and antiseptics: Hygienic handrub - Test methods and requirements: The test solution with active chlorine showed equally bactericidal activity as the positive control and more than log 4 reduction after 1 min. It passed the efficacy criteria for hygienic handrub products.

3.2 Efficacy against bacteria, fungi and yeast on non-porous surfaces

EN 13697 Chemical disinfectants and antiseptics - quantitative surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (Phase 2, Step 2): The test solution with active chlorine achieved a 4 log reduction in viable counts for bacteria under the required test conditions with a minimum exposure time of 5 min. The test solution with active chlorine sufficiently inactivated the fungi *Aspergillus brasiliensis* with a log reduction >3, under clean conditions after 15 minutes exposure. For the yeast *Candida albicans* a 3 log reduction in viable counts under the required test conditions was achieved with after a contact time of 15 min.

3.3 Efficacy against sporeforming bacteria in suspension

The sporocidal effect test, quantitative suspension trial with *Bacillus subtilis* according to **VLB-method** was performed. The test solution with active chlorine achieved a reduction of *Bacillus subtilis*-spores. The reduction was between log 2,7 and log 3,5.

3.4 Efficacy against bacteria in suspension

EN 1656 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics for use in the veterinary field - Test method and requirements (Phase 2, Step 1) was performed. The test solution with active chlorine showed bactericidal activity under organic load of 1% skimmed milk after 5 minutes exposure time.

EN 13623 Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity against Legionella of chemical disinfectants for aqueous systems- Test method and requirements (phase 2, step 1) was performed. The test solution with active chlorine showed bactericidal activity with 0,0005% yeast extract under conditions for hard water for general purposes after 60 min. exposure.

3.5 Efficacy tests against enveloped and non-enveloped virus

EN 14476 + German guideline was performed. Test solutions with active chlorine effectively inactivated adenovirus and murine norovirus after 1 min under clean and dirty conditions, poliovirus after 1 min under clean conditions and after 30 min. under dirty conditions. The solution also effectively inactivated vaccinia virus after 1 min. and bovine viral diarrhea virus after 5 min. exposure.

For more information on this matter please contact project manager at DHI Michael Fink-mif@dhigroup.com