

Federal Service for Surveillance on Consumer Rights Protection and Wellbeing
Federal Budget Institution of Science «State Research Center for Applied
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SCIENTIFIC REPORT

On the results of the expertise of medical-preventive disinfecting agent
“SCORPIUS” for state registration in the Russian Federation and The Customs
Union

The subject of the Report: “The study of the bactericidal and disinfecting
activity of the disinfecting agent “SCORPIUS” produced by “IPLASMA
SCORPIUS” installation (“IPLASMA”, LLC).

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MAIN PART

Unit 1. MATERIALS AND METHODS

1.1. Information on the studied agent

Disinfecting agent “SCORPIUS”, produced by “IPLASMA SCORPIUS” installation (“IPLASMA”, LLC) by means of cold plasma discharge on distilled water, is a fine-disperse aerosol of plasma-activated water (PAW). The scent can be sensed when aerosol particles get into the nasal cavity.

The active agent (AA) of the “SCORPIUS” disinfectant is peroxyxynitrite/peroxyxynitrous acid (ONOOH/ONOO⁻). The constant of dissociation of the acid is pK_a = 6.8. A certain type of chemical compound is determined by pH.

During the treatment of water, a complex is formed that does not exert chemical activity and degrades within 48 hours into peroxyxynitrite/peroxyxynitrous acid.

In an acid solution, the compound is present as peroxyxynitrous acid. Peroxyxynitrous acid dissociates into nitrous acid, which degrades when the solution dries out because nitrous acid exists only in a diluted solution. The redox potential of the acid depends on the channel of dissociation of peroxyxynitrous acid and varied from 1.6 V to 2 V. For comparison, the redox potential of Chlorum in water (ClO⁻) is E=0.4 V and hydrogen peroxide E = 0.88 V and 1.5 V depending on the reaction channel.

The concentration of oxidants is determined by the outcome of the oxidation of Fe²⁺ in Mohr’s salt (Fe²⁺ → Fe³⁺). The concentration of oxidants in the water right after the treatment is 5 ± 2 μmol/L. On the day after the treatment, the concentration of oxidants decreases to 1 ± 0.1 mmol/L. The concentration decreases to the level of measurement errors after 48 hours. The activity of the formed oxidants is much higher than in Chlorum and hydrogen peroxide, so there is no point in comparing their concentrations.

After the application, the disinfecting agent “SCORPIUS” completely degrades to initial substances (water and oxygen), does not accumulate in the environment, does not create a film on the treated surface, and does not require washing away from the treated surface or deactivation.

1.1.2. Disinfecting agent “SCORPIUS” is intended for:

- Disinfection of the air and surfaces in transport (including during the transportation of food, passengers);
- Disinfection of indoor surfaces, disinfection of the air, and pieces of decor.

1.1.3 The evaluation of the effectiveness of the disinfecting agent “SCORPIUS” was conducted for the state registration in Russia and the Eurasian Economic Union.

1.2 Material and Methods

1.2.1. The studies were conducted in accordance with the Guidelines P 4.2.2643-10 “Methods of laboratory studies and trials on medical-preventive disinfecting agents for the evaluation of their effectiveness and safety” with the consideration of the Unified Sanitary, Epidemiological, and Hygienic Requirements for Goods Subject to Sanitary and Epidemiological Supervision, (Section 20 “The main requirements to disinfecting, disinsecting, and deratizing agents), and “Normative parameters of safety and effectiveness of disinfecting agents that are subject to obligatory certification” №01-12/75-97.

1.2.2. The object of the study was a sample of a disinfecting agent “SCORPIUS” (batch №001 dd 11.01.2021). The compliance of the agent to the requirements of TU 20.20.14-019-28662441-2020 is confirmed by the respective report on the evaluation of physical-chemical properties.

1.2.3. The study included the following strains of microorganisms: *Escherichia coli* (strain 1257), *Staphylococcus aureus* (strain 906), *Pseudomonas aeruginosa* (strain ATCC), *Salmonella typhimurium* (strain 5725).

Note: the strain with number code is obtained by FBIS SRCAMB, ATCC - American typical culture collection.

To exclude the bacteriostatic effect of the agent, a universal neutralizer was used (Tween-80 - 3%, saponin – 3%, histidine – 0.1%, hydrochloric cysteine – 0.1%).

Reference cultures were grown on nutrient media: Endo, egg yolk high salt agar culture medium, casein agar, GRM agar, meat-and-peptone broth, staphylococcus-agar, SS-agar, within 24 hours at +37°C.

To obtain a bacterial suspension, the culture was flushed from the surface of the nutrient media and the obtained volume was diluted by the saline solution to the concentration that corresponded to 2 billion microbial bodies in 1 ml (according to the opacity standard).

1.2.4. The treatment of indoor surfaces, solid and soft furniture, etc.

The test-objects were linoleum, painted wood, plastic, metal, ceramic tile, natural and synthetic rubbers, and leather contaminated with microorganisms. The surfaces were disinfected by the method of aerosol spraying.

1.2.5. The evaluation of the effectiveness of the active agent on the studied strains after the inactivation of aerosol test-organisms was performed on the installation model 099C A4224 (Glas-Col, USA). The air probes were taken using an impactor “PU-1B” (“Khimko”, Russia) during the operation installation.

Aerosol installation Glas-Col was used to prepare aerosol with the chosen microorganism strain at the concentration of $(5 \pm 2.5 \times 10^3)$ CFU/cm³. Further, a certain amount of aerosol was sprayed into the chamber at the application rate required per one application (1-2 sec/m³). Aerosol probes were taken at certain intervals (30 minutes) from the aerosol installation Glas-Col using a sampler PU-1B and isolated them from further effect of active agent sprayed in the testing chamber. Sterile water of the same volume as the agent was used as a control sample.

Petri dishes taken out of the sampler “PU-1B” were placed in the thermostat and incubated in the conditions typical for a given test-microorganism. After the incubation, the number of colonies grown in Petri dishes was counted. The effectiveness of the disinfection was calculated by the formula $([1 - Nd/Nk] \times 100)\%$, where Nd – CFU in the Petri dish after the treatment with the disinfecting agent; Nk – CFU in the Petri dish in the control.

1.2.6. In the control trials, contaminated test-surfaces were treated or sprayed with sterile tap Water at the same application rate.

Unit 2. STUDY RESULTS

2.1 The results of the study on the effectiveness of the disinfecting agent after the treatment of the surface (Table 1).

Table 1. The effectiveness of the disinfecting agent “SCORPIUS” after the treatment of indoor surfaces, firm and soft furniture, décor, etc.

Microorganism	Colony Forming Units (CFU)		Method of Treatment	Time of exposition, min	Effectiveness of disinfection, %
	Before the application	After the application			
<i>E. Coli</i>	$(4.1 \pm 0.4) \times 10^6$	4 ± 2	Aerosol spraying	60	99.99
<i>S. aureus</i>	$(7.6 \pm 0.4) \times 10^6$	12 ± 2			99.99
<i>P. aeruginosa</i>	$(5.3 \pm 0.5) \times 10^6$	10 ± 4			99.99
<i>S. typhimurium</i>	$(3.5 \pm 0.4) \times 10^6$	9 ± 3			99.99

The treatment of surfaces with the disinfecting agent “SCORPIUS” for 60 minutes leads to 99.99% reduction of microorganisms on the test-objects contaminated with bacteria (except tuberculosis).

2.2 The evaluation of the effectiveness of the disinfecting agent “SCORPIUS” after the air disinfection

Table 2. The effectiveness of the disinfecting agent “SCORPIUS” after the air disinfection

Object of disinfection	Microorganism	Colony Forming Units (CFU)		Method of Treatment	Application rate	Effectiveness of disinfection, %
		Before the application	After the application			
Air	<i>E. Coli</i>	$(5.8 \pm 0.5) \times 10^2$	0	Aerosol spraying	15 s/m ³	99.99
	<i>S. aureus</i>	$(5.4 \pm 0.5) \times 10^2$	0			99.99
	<i>P. aeruginosa</i>	$(4.5 \pm 0.4) \times 10^2$	0			99.99
	<i>S. typhimurium</i>	$(3.6 \pm 0.3) \times 10^2$	0			99.99

Aerosol treatment of the air with the disinfectant agent “SCORPIUS” at the application rate of 15 s/m³ with further exposition for 60 minutes results in a 99.99% reduction of bacterial contamination with such cultures as *E. Coli*, *S. aureus*, *P. aeruginosa*, *S. typhimurium*.

Conclusion

The present report contains the results of the studies on the evaluation of the antimicrobial activity of the disinfecting agent “SCORPIUS” and the conclusions that were made: disinfecting agent “SCORPIUS” produced by “IPLASMA SCORPIUS” installation exerts the required antimicrobial activity and can be used

- for the disinfection of air and surfaces in transport (including during the transportation of food, passengers);
- for the disinfection of indoor surfaces, air, décor, and furniture.