

Number: ML0201  
Date: 06.11.2020

## OPINION

ACCORDING TO THE ANALYSIS REPORT ID: ML0201 DATED 06.11.2020

Received sample of the product (ID: MD290101)

### Aqualor H 500

§Active substance: Active chlorine, obtained from sodium chloride by electrolysis in device Hlorogen®, concentration 0,05% in product

was tested according to Low on biocidal product (Official Gazette RS, no. 36/09, 88/10, 92/11, 25/11) Article 14, Item 5 and according to Guidelines for evaluation of biocidal product based on technical dosie (Official Gazette of RS, no. 28/11) Item 3.6.2, and based on results of the tests:

- **bactericidal activity for hygienic handrub, surgical handrub, instrument disinfection and surface disinfection**, under clean conditions, according to SRPS EN 13727:2017, have tested concentrations of product 80 % (v/v) and 40% (v/v), under obligatory test conditions: test organisms *Pseudomonas aeruginosa* ATCC 15442, *Escherichia coli* K12 NCTC 10538, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 and additional test organism *Proteus hauseri* ATCC 13315, test temperature 20 °C, interfering substance 0,3 g/l albumin bovine fraction V, and required 5 log reduction, for tested contact time 1 minute,
- **yeastcidal activity for hygienic handrub, surgical handrub, surface disinfection and instrument disinfection**, under clean condition, according to SRPS EN 13624:2014, have tested concentrations of product 80% (v/v) and 40 % (v/v), under obligatory test conditions: test organism *Candida albicans* ATCC 10231, test temperature 20 °C, interfering substance 0,3 g/l albumin bovine fraction V, and required 4 log reduction, for tested contact time 1 minute,
- **fungicidal activity for surface disinfection and instrument disinfection**, under clean condition, according to SRPS EN 13624:2014, has tested concentration of product 80% (v/v), under obligatory test conditions: test organisms *Candida albicans* ATCC 10231, *Aspergillus brasiliensis* ATCC 16404, test temperature 20 °C, interfering substance 0,3 g/l albumin bovine fraction V, and required 4 log reduction, for tested contact time 1 minute.

- §submitted information for which MP Lab - Laboratory for analysis does not take responsibility: active substances and concentrations of active substances
- concentration of product 80% (v/v) is equivalent to content of 0,04% active chlorine in product
- concentration of product 40% (v/v) is equivalent to content of 0,02% active chlorine in product
- strain *Proteus vulgaris* ATCC 13315 cited in Guidance on the BPR: volume II Parts B+C, Version 3.0. april 2018. p. 262, has now name: *Proteus hauseri* O'Hara et al. (ATCC® 13315™)
- SRPS EN 13727:2017, Hemijski dezinficijensi i antiseptici – Kvantitativni suspenzioni test za vrednovanje baktericidnog dejstva u oblasti medicine – Metode ispitivanja i zahtevi (faza 2, korak 1), identical to EN 13727:2012+A2:2015, Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)
- SRPS EN 13624:2014, Hemijska dezinfekciona sredstva i antiseptici — Kvantitativno ispitivanje suspenzije za vrednovanje fungicidnog dejstva ili dejstva na kvasce u oblasti medicine — Metoda ispitivanja i zahtevi (faza 2, korak 1), identical to EN 13624:2013, Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal or yeastcidal activity in the medical area. Test method and requirements (phase 2, step 1)

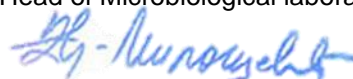
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Submitted to:  
1. Applicant 2x  
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