

REPORT

Report No.: 682271/1

Sample number: 2250685

Customer name/address:	Clean System Global Ipari, Kereskedelmi és Szolgáltató Kft 2131 Göd Dózsa György út 31.
Project:	Microbiological analysis (2021/E/06885)
Description of sample:	HIGÉN+99
Sample ID:	ECO-KF 50 /2021 12.02., Active substance: Active chlorine released from hypochlorous acid (CAS: 7790-92-3) 500 ppm
Producer:	C.S.G Kft. 2131 Göd, Dózsa György utca 37.
Sample type:	Chemical disinfectants and antiseptics
Sampling by:	C.S.G. Kft.
Sampling date / Sampling place:	04. 06. 2021. / 2131 Göd Dózsa Gy. u. 37.
Packaging / Quantity:	Plastic bottle / 1000 ml
Time of shipment:	11:00 13. 07. 2021.
Beginning of analysis / end:	13. 07. 2021. - 30. 07. 2021.
Comments:	

Microbiological parameters

Storage conditions:	Room temperature.
Appearance of the product:	Colourless liquid.
Test concentration:	80,0%
Active substance:	Active chlorine released from hypochlorous acid (CAS: 7790-92-3) 500 ppm
Test method:	MSZ EN 1276:2010 (withdrawn standard) and MSZ EN 1650:2008+A1:2013 (withdrawn standard) Dilution neutralization method
Test circumstances	
<i>Test microbes:</i>	<i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Staphylococcus aureus</i> ATCC 6538 <i>Escherichia coli</i> ATCC 10536 <i>Enterococcus hirae</i> ATCC 10541 <i>Candida albicans</i> ATCC 10231 <i>Aspergillus brasiliensis</i> ATCC 16404
<i>Test temperature:</i>	20°C
<i>Contact time:</i>	Bacteria and <i>Candida albicans</i> : 1 minute <i>Aspergillus brasiliensis</i> : 5 minutes
<i>Interfering substance:</i>	3,0 g/l bovine albumin (dirty)
<i>Temperature of incubation:</i>	37 °C± 1°C bacteria 30 °C± 1°C fungi
<i>Neutralizer:</i>	2% Sodium thiosulfate, 0,3% Lecithine, 0,1% L-Histidine, 3% Polysorbate 80



Certificate validity check.

 The laboratory is accredited under Reg.
 No: NAH-1-1009/2019 by NAH

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Validation and controls
In case the contact time is 1 minute:

Test microbes	CFU/ml				
	Test suspension (N)	Validation suspension (N_{v0})	Experimental conditions control (A)	Neutralizer control (B)	Method validation (C)
<i>Pseudomonas aeruginosa</i>	$4,9 \times 10^8$	$1,2 \times 10^2$	$1,0 \times 10^2$	$1,1 \times 10^2$	$1,1 \times 10^2$
<i>Staphylococcus aureus</i>	$4,9 \times 10^8$	$1,3 \times 10^2$	$1,1 \times 10^2$	$1,2 \times 10^2$	$1,2 \times 10^2$
<i>Escherichia coli</i>	$4,6 \times 10^8$	$1,2 \times 10^2$	$1,0 \times 10^2$	$1,1 \times 10^2$	$1,0 \times 10^2$
<i>Enterococcus hirae</i>	$4,6 \times 10^8$	$1,1 \times 10^2$	$9,4 \times 10^1$	$1,0 \times 10^2$	$1,0 \times 10^2$
<i>Candida albicans</i>	$4,8 \times 10^7$	$1,3 \times 10^2$	$1,2 \times 10^2$	$1,2 \times 10^2$	$1,3 \times 10^2$
Control:	$1,5 \times 10^8 \leq N \leq 5,0 \times 10^8$, $3,0 \times 10^1 \leq N_{v0} \leq 1,6 \times 10^2$ (bacteria) $1,5 \cdot 10^7 \leq N \leq 5,0 \times 10^7$, $3,0 \times 10^1 \leq N_{v0} \leq 1,6 \times 10^2$ (fungi) $A \geq 0,5 \times N_{v0}$ $B \geq 0,5 \times N_{v0}$ $C \geq 0,5 \times N_{v0}$				
All controls and validation were within the basic limits.					

In case the contact time is 5 minutes:

Test microbes	CFU/ml				
	Test suspension (N)	Validation suspension (N_{v0})	Experimental conditions control (A)	Neutralizer control (B)	Method validation (C)
<i>Aspergillus brasiliensis</i>	$3,3 \times 10^7$	$7,1 \times 10^1$	$6,6 \times 10^1$	$6,5 \times 10^1$	$6,9 \times 10^1$
Control:	$1,5 \cdot 10^7 \leq N \leq 5,0 \times 10^7$, $3,0 \times 10^1 \leq N_{v0} \leq 1,6 \times 10^2$ (fungi) $A \geq 0,5 \times N_{v0}$ $B \geq 0,5 \times N_{v0}$ $C \geq 0,5 \times N_{v0}$				
All controls and validation were within the basic limits.					

TEST RESULTS:
Surviving microbial count (N_a) (cfu/ml)

Test microbes	1 minute	5 minutes
<i>Pseudomonas aeruginosa</i>	$<1,4 \times 10^2$	-
<i>Staphylococcus aureus</i>	$<1,4 \times 10^2$	-
<i>Escherichia coli</i>	$<1,4 \times 10^2$	-
<i>Enterococcus hirae</i>	$<1,4 \times 10^2$	-
<i>Candida albicans</i>	$<1,4 \times 10^2$	-
<i>Aspergillus brasiliensis</i>	-	$<1,4 \times 10^2$

Reduction of viability at test concentration (R)

Test microbes	1 minute	5 minutes
<i>Pseudomonas aeruginosa</i>	$>5,5$	-
<i>Staphylococcus aureus</i>	$>5,5$	-
<i>Escherichia coli</i>	$>5,5$	-
<i>Enterococcus hirae</i>	$>5,5$	-
<i>Candida albicans</i>	$>4,5$	-
<i>Aspergillus brasiliensis</i>	-	$>4,4$

$$N_0 = N/10$$

$$R = (\lg R = \lg N_0 - \lg N_a)$$



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Terms of disinfecting effect: R \geq 5 (bacteria)
R \geq 4 (fungi)

SUMMARY:

According to MSZ EN 1276:2010 (withdrawn standard) and MSZ EN 1650:2008+A1:2013 (withdrawn standard) the **HIGÉN+99** at **80,0%** concentration, at **20°C** temperature, under dirty conditions, in the contact time **1 minute** by the dilution neutralization method decreased the number of alive microbes *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 10536, *Enterococcus hirae* ATCC 10541 by at least 5 (lg) orders, the number of alive microbes *Candida albicans* ATCC 10231 by at least 4 (lg) orders, and in the contact time **5 minutes** it decreased the number of spores *Aspergillus brasiliensis* ATCC 16404 by at least 4 (lg) orders.

The product **HIGÉN+99** under defined conditions in the contact time **1 minute** possesses **bactericidal and yeasticidal activity**, and in the contact time **5 minutes** it possesses **fungicidal activity**.

Judit dr. Reichardt Gasparikné
Deputy Head of Laboratory

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