VAYLERA

Independent Laboratory Efficacy Summary

AOAC Use Dilution Test against *Aspergillus niger*

450 PPM HOCl | 5 + 10 MINUTES | PROJECT 1168-104

REPORTED OUTCOME

Number of subculture tubes exhibiting growth / total tubes

5-MINUTE CONTACT	10-MINUTE CONTACT
0 / 10 PASS	0 / 10 PASS

Executive finding

The Microbac final report states that ready-to-use hypochlorous acid at 450 ppm passed the AOAC Use Dilution Test against *Aspergillus niger* ATCC 6275 at both evaluated contact times. No visible growth was observed in any of the 10 test tubes at 5 minutes or the 10 test tubes at 10 minutes, and all controls met the criteria for a valid test.

Prepared from Microbac Project No. 1168-104, final report dated July 17, 2025.

The signed laboratory report is reproduced unchanged in Appendix A.

Study design at a glance

Reported study conditions from Microbac Project No. 1168-104

TEST METHOD

AOAC Use Dilution Test

CHALLENGE ORGANISM

Aspergillus niger, ATCC 6275

TEST SUBSTANCE

Hypochlorous Acid - 450 ppm

ACTIVE INGREDIENT

Hypochlorous acid 0.045%

TEST LOT

POH250619T450570

DILUTION

Ready to use

CONTACT TIMES

5 minutes and 10 minutes

TEMPERATURE

Ambient; actual 20 C

ORGANIC LOAD

5.0% heat-inactivated fetal bovine serum

STUDY START

June 24, 2025 at 3:22 p.m.

Primary test result

Challenge organism	Test substance	Contact time	Growth / total tubes	Outcome
Aspergillus niger	HOCl - 450 ppm	5 minutes	0 / 10	PASS
Aspergillus niger	HOCl - 450 ppm	10 minutes	0 / 10	PASS

WHY THE TEST WAS VALID

Sterility controls showed no growth; viability controls showed growth; neutralizer-effectiveness controls met protocol requirements; and the challenge organism was confirmed by morphology and wet mount.

Using the findings responsibly

The clearest, most defensible statement is that the reported 450 ppm HOCl test substance passed the specified AOAC method against *Aspergillus niger* under the exact conditions evaluated.

SUPPORTED BY THE REPORT

- Pass at both 5-minute and 10-minute contact times.
- No visible growth in any of 10 test tubes at either contact time.
- Controls met the report's criteria for a valid test.

KEEP CLAIMS TIED TO THE TEST

- Do not extend the result to other concentrations, organisms, surfaces or contact times without supporting data.
- Product-specific claims should match the applicable label, registration and formulation documentation.
- Maintain evidence linking the tested lot to any VAYLERA product represented by this study.

Document provenance

Laboratory	Sponsor	Study identification	Final report
Microbac	Sani-TEST LLC	Project 1168-104 Protocol 1168.M.25.002	Signed July 17, 2025 Alexis N. Jackson

VAYLERA technical and commercial inquiries

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ORIGINAL REPORT FOLLOWS

This VAYLERA summary is not an independent laboratory report and does not replace the signed source document. If any wording differs, the original Microbac report controls. The original four pages are reproduced unchanged in Appendix A.

MICROBAC

CONFIDENTIAL ABBREVIATED FINAL REPORT

SPONSOR: Sani-TEST LLC

SPONSOR'S REPRESENTATIVE: Trevor Anderson

STUDY TITLE: AOAC Use Dilution Test *Aspergillus niger*

STUDY IDENTIFICATION: Project No. 1168-104 (refer to signed protocol 1168.M.25.002)

TEST SUBSTANCE(S):	LOT NO.:	DATE RECEIVED:	DS NO.:
Hypochlorous Acid – 450ppm	POH250619T450570	06/20/25	Q173

CHALLENGE ORGANISM: *Aspergillus niger*, ATCC 6275

ACTIVE INGREDIENTS: Hypochlorous Acid: 0.045%

NEUTRALIZERS USED: Sabouraud Dextrose Neutralizing Broth containing 0.3% Sodium Thiosulfate

EXPOSURE TIME: 5 minutes, 10 minutes

EXPOSURE TEMPERATURE: Ambient Room Temperature (Actual 20°C)

DILUTION(S): Ready to Use

DILUENT(S): Not Applicable

ORGANIC LOAD: 5.0% Heat-Inactivated Fetal Bovine Serum (HIFBS)

STUDY START TIME: 3:22 pm on 06/24/25

RESULTS:

Results are presented in Tables 1-7. The sterility controls exhibited no growth. The neutralizer effectiveness controls exhibited growth within the protocol requirements. The challenge microorganism was consistent with *Aspergillus niger* based on conidial morphology and wet mount results of streaks from tubes exhibiting growth as well as purity and carrier count controls.

Table 1
Test Results
Results Expressed as Number of Tubes Exhibiting Growth / Total Number of Tubes

Challenge Microorganism	Test Substance	Contact Time	Results
Aspergillus niger	Hypochlorous Acid – 450ppm	5 minutes	0/10
		10 minutes	0/10

Table 2
Sterility Control
Results Expressed as Tubes Exhibiting (+) or No Growth (0)

Media	Result
Neutralizer + Carrier	0
Neutralizer + Organic Soil Load	0

Table 3
Viability Control
Results Expressed as Tubes Exhibiting Growth (+) or No Growth (0)

Microorganism	Replicate	Result
Aspergillus niger	1	+
	2	+

Results (continued)

Table 4
Carrier Counts

Results Expressed as CFU/Carrier, Log_{10} Density (LD), Average CFU/Carrier and Average LD

Challenge microorganism	Phase	Replicate	CFU/Carrier	LD	Average CFU/Carrier	Average LD
Aspergillus niger	Pre-Test	1	6.89×10^4	4.84	5.0×10^4	4.7
		2	6.94×10^4	4.84		
		3	5.27×10^4	4.72		
	Post-Test	1	4.28×10^4	4.63		
		2	4.19×10^4	4.62		
		3	3.33×10^4	4.52		

Table 5
Purity Control

Microorganism	Source	Conidial Morphology on SDA	Wet Mount
Aspergillus niger	Carrier Count Replicate	Black/woolly; reverse is yellow	Septate hyphae; unbranched conidiophores
	Purity Control Plate	Black/woolly; reverse is yellow	Septate hyphae; unbranched conidiophores

Table 6
Neutralizer Effectiveness Controls

Results Expressed as Tubes Exhibiting Growth (+) or No Growth (0)

Challenge microorganism	Test Substance	Contact Time	Tube Result		Average Count Per Tube
			Rep 1	Rep 2	
Aspergillus niger	Hypochlorous Acid – 450ppm	10 minutes	+	+	16

Results (continued)

Table 7
Challenge Microorganism Confirmation

Organism	Source	Replicate	Microscopic Morphology	Conidial Morphology on SDA
Aspergillus niger	Viability	1	Black/woolly; reverse is yellow	Septate hyphae; unbranched conidiophores
		2	Black/woolly; reverse is yellow	Septate hyphae; unbranched conidiophores

CONCLUSIONS:

According to the regulatory agency, the test substance passes the "AOAC Use Dilution Test" if no visible growth is observed in any of the subculture tubes for each lot and the controls meet their stipulated criteria.

When tested as described, Hypochlorous Acid – 450ppm, Lot POH250619T450570 passed the AOAC Use Dilution Test when *Aspergillus niger* containing 5.0% Heat-Inactivated Fetal Bovine Serum was exposed to the test substance for 5 minutes at 20°C.

When tested as described, Hypochlorous Acid – 450ppm, Lot POH250619T450570 passed the AOAC Use Dilution Test when *Aspergillus niger* containing 5.0% Heat-Inactivated Fetal Bovine Serum was exposed to the test substance for 10 minutes at 20°C.

All the controls met the criteria established for a valid test. Conclusions are based on observed data.

Study Director Signature: _____ 07/17/25
Alexis N. Jackson Date